Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

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Abstract	This deliverable documents the procedure for the attainment of the initial requirements of the REACTION platform and its results. This document is input to the technical WPs for the work related to all prototypes.
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2.0	A. Kouroubali, D. Manousos, F. Chiarugi, I. Karatzanis, Y. Petrakis	2010-07-14	Second version, after internal review, after the completion of the requirements analysis in JIRA and after first comments from Lukas Schaupp and Peter Rosengren
3.0	"	2010-07-16	Third version which addresses Peter's comments
4.0	A. Kouroubali, D. Manousos, F. Chiarugi, I. Karatzanis, Y. Petrakis	2010-07-30	Final version, addressing comments from Lukas, Thomas and Stephan submitted to the European Commission

Internal review history

Reviewed by	Date	Comments made
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Malcolm Clarke, UBRUN		

1. Executive Summary

The aim of this document is to present the methodology, process and results of the initial requirement analysis and engineering phase of WP2 related to the user centric requirements engineering and validation. More specifically, this deliverable is the outcome of task T2.2 initial requirements specification, as described in the description of work.

The REACTION project aims to develop a technological platform and pilot applications to improve long term diabetes management in inpatient and outpatient environments. Features of the technology include continuous glucose monitoring, monitoring of significant events, monitoring and predicting risks and/or related disease indicators, decision on therapy and treatments, education on life style factors such as obesity and exercise and, ultimately, automated closed-loop delivery of insulin.

The background and context of the work performed and described in this deliverable follow deliverable D2.1 which identified the current and future workflows in the clinical environments of REACTION and the possible future scenarios of healthcare trends foreseen to influence in the long term the REACTION platform.

The current document presents the initial requirements that define platform functionalities and pilot applications features, derived through a user-centered methodology. The approach used for the elicitation of the REACTION initial requirements is described in detail and the full set of initial functional and non-functional requirements for the REACTION platform of services is presented from different point of views. Furthermore, procedures for requirements management and tracking have been introduced in order to provide the audience with indications on how the requirements will be managed during the lifecycle of the project especially through the use of the selected tool for the requirement management. The deliverable aims to drive architectural and technical decisions and be used in the definition of the validation procedures of the various sub-systems and the entire architecture.

The target audience of this deliverable is all REACTION partners and particularly the technical partners responsible for designing REACTION technical solutions.

The document structure includes: a) a presentation of the methodology used during the initial requirement elicitation phase. The selected approach is described including the steps towards elicitation of initial requirements and the structure and modeling used for each requirement; b) a survey of existing tools for requirement management and the rationale for choosing the selected approach; c) lists of initial requirements by WP and component; d) conclusions and future steps; and e) the complete set of initial requirements.

The process of initial requirement elicitation involved all WP leaders who contributed also in the engineering phase, identifying and resolving conflicts, overlaps, errors and in general issues that needed clarifications and modifications. The consolidated list of initial requirements is documented in this deliverable, D2.5.

2. Terms and Definitions

For the purposes of this deliverable, the following abbreviations and acronyms apply.

2.1 Abbreviations and Acronyms

AGC	automatic glucose control
BAN	body area network
BM	bio measurement
BMI	body mass index
CGM	continuous glucose monitoring
COTS	commercial off the shelf
DoW	description of work
EC	European Commission
EHR	electronic health record
EPR	electronic patient record
eDSS	electronic Decision Support System
ePatch	electronic patch
HIS	health information system
HL7	Health Level 7
HbA1c	glycated haemoglobin
ICMP	Internet control messaging protocol
ICT	Information and Communication Technologies
IEEE	institute of electrical and electronics engineers
IHE-PCD01	integrating the healthcare enterprise-patient care devices technical framework version1
IP	Internet protocol
IPR	intellectual property rights
IR	infra red
ISO	International Organization for Standardisation
IT	information technology
IV	intra-venous
MDD	medical device directive
NFC	near field communication
NIR	near infra-red
NLP	natural language processing
OAD	oral anti-diabetic drug
PAN	personal area network
PEG tube	percutaneous endoscopic gastrostomy tube
PoC	point of care
POCT	point of care technology
QoS	Quality of Service
RAID	redundant array of independent disks

RFID	radio frequency identification
RM	requirements management
ROC	receiver operating curve
RPM	remote patient monitoring
SC	sub-cutaneous
SGC	safe glycaemic control
SMS	short message service
SNR	Signal to Noise Ratio
SNMP	simple network management protocol
SoA	service oriented architecture
SOAP	simple object access protocol (xml protocol)
SVN	source versioning number
TGC	tight glycaemic control
W3C	word wide web consortium
WAN	wireless area network
WAN-IF	wireless area network interface
WAR	web application archive
WP	workpackage

3. Introduction

3.1 Overview of the REACTION Project

The REACTION project aims to develop an integrated approach to improved long term management of diabetes through continuous glucose monitoring, monitoring of significant events, monitoring and predicting risks and/or related disease indicators, decision on therapy and treatments, education on life style factors such as obesity and exercise and, ultimately, automated closed-loop delivery of insulin.

The REACTION project seeks to use the great potential of new technologies to cope with the increasing number of citizens suffering from insulin-dependant diabetes. A user centred approach will be used focused on the involvement of all stakeholders (i.e. patients, relatives and professional carers as well as healthcare commissioners, business stakeholders, and regulatory authorities) in an iterative cycle with the intention of maximizing the probabilities of success of the new technological platform of services.

Technically, the REACTION platform will be structured as an interoperable peer-to-peer communication platform based on service oriented architecture (SoA) where all functionalities, including the measurement acquisition performed by sensors and/or devices, are represented as services and applications consist of a series of services properly orchestrated in order to perform a desired workflow. The REACTION platform also will make extensive use of dynamic ontologies and advanced data management capabilities offering algorithms for clinical assessment and evaluation.

A range of REACTION services will be developed targeted to the management of insulin-dependent diabetic patients in different clinical environments. The services aim to improve continuous glucose monitoring (CGM) and insulin therapy by contextualised glycaemic control based on patient activity, nutrition, interfering drugs, stress level, etc. for a proper evaluation and adjustments of basal and bolus doses. Decision support will assist healthcare professionals, patients and informal carers to make correct choices about glucose control, nutrition, exercise and insulin dosage, and thus to reach a better management of diabetes therapy.

REACTION will further develop complementary services targeted at the long term management of all diabetic patients, Type I and Type II. Integrated monitoring, education, and risk evaluation will ensure all patients remain at healthy and safe blood glucose levels, with early detection of onset of complications.

Security and safety of the proposed services will be studied and necessary solutions to minimise risks and preserve privacy will be implemented. Legal framework for patient safety and liability as well as privacy and ethical concerns will be analysed and an outline of a policy framework will be defined. Moreover, impacts on health care organizations and structures will be analysed and health-economics and business models will be developed.

3.2 Purpose, Context and Scope of this Deliverable

In this section we discuss the background and context of this deliverable. We also describe the target audience and the purpose and scope of this document.

3.2.1 Background and Context

The background and context of the work performed and described in this deliverable follow deliverable D2.1 which identified the current and future workflows in the clinical environments of REACTION and the possible future scenarios of healthcare trends foreseen to influence the REACTION platform.

The initial requirement elicitation phase started immediately after the identification of workflows. Each workpackage (WP) leader/partner was responsible for extracting the detailed requirements related to their WP and had to evaluate the architectural influence of these requirements. The completion of the visionary scenarios allows further execution of the requirement analysis phase and the finalization of the full set of initial requirements.

3.2.2 Target Audience

The target audience of this deliverable is all REACTION partners and particularly the technical partners that will have to design appropriate technical solutions to address the requirements elicited. Subsequently, all partners (clinical, technical and with legal or business expertise) will have to design and implement specific verification criteria in order to check the fulfilment of the requirements.

3.2.3 Purpose

The purpose of this deliverable is to describe the approach used for the elicitation of the REACTION initial requirements and to present the full set of initial functional and non-functional requirements for the REACTION platform of services. In the appropriate sections in this document, the adopted procedure is described in detail and the set of initial requirements is presented from different point of views.

3.2.4 Scope

The scope of this deliverable is restricted to the initial requirement gathering. This document will also present the full iterative approach for the yearly refinement of the requirements in the context of a user centred design approach whose results will be reported in future deliverables and fully managed using appropriate requirement management tools. The aim of this deliverable is to capture the initial requirements in such a way that they can drive architectural and technical decisions and be used to validate the various sub-systems and the entire architecture.

It has to be noticed that the requirements and all the project are organized in an evolutionary design with production of a prototype, validation, review of the requirements based also on the results of the validation and design of a next prototype. Thus, the requirement management is a dynamic on going process that will evolve and will be completed during the project. In this deliverable the focus is on the initial requirements.

The deliverable is not focused on the architectural design but it should aim to drive architectural and technical decisions and be used in the definition of the validation procedures of the various sub-systems and the entire architecture.

3.3 Structure of the Document

The remaining document is structured as follows:

The section “User centred design procedures” describes the methodology used during the initial requirement elicitation phase. The selected approach is described including the steps towards elicitation of initial requirements and the structure and modelling used for each requirement. The section “Tools for Supporting the Requirement Management” presents a survey of existing tools for requirement management and the rationale for choosing the selected approach. The section “Initial Requirements for the REACTION Platform” lists the initial requirements presenting them per WP and component. In the “Conclusions” section, conclusions and future steps are reported. Finally in the last chapter the complete list of initial requirements is reported with all their details.

4. User Centred Design Procedure

4.1 The Path towards the Initial Requirements

Scenarios provide coherent, comprehensive, internally consistent descriptions of plausible futures built on the imagined interaction of key trends. Creating scenarios of end-user behaviour and interaction with platform functionality is a useful instrument for identifying the key technological, security, socio-economic and business drivers for future end-user requirements.

However, during the initial discussion of the project objectives and the work plan, it was desired by the clinical partners to have a close alignment of the REACTION platform functionalities with prevailing clinical practice and medical reality. It was argued that the gap between today's practice and the potential of the REACTION platform might be too large to be realistically validated while any new clinical workflow must be rooted in the current medical and clinical reality. Thus, a more satisfactory approach from the end-user point of view was adopted which involved focusing initially on clinical workflows underpinned by a short-term look at potential improvements from the use of the REACTION platform. This approach was considered more satisfactory, instead of jumping at once in a long-term future.

On the other hand, however, it was argued that, from a technical-scientific point of view, following only a short-term approach may not lead to real breakthrough opportunities in the development of new technologies, such as SoA, semantic interoperability and dynamic ontologies. Nevertheless, the iterative method for the REACTION project allows encompassing short-term and long-term views and hence bridging the gap in the course of the project.

The short-term needs were identified through two workshops which elicited present clinical workflows in both in-hospital and outpatient settings followed by an analysis of the potential for improvement offered by using the REACTION platform. This exercise provided clear short to mid-term requirements, which would root the platform functionality solidly in clinical and medical practice and thus, ease the user acceptance and give credibility to the results in the medical domain. The short to mid-term requirements will be given high priority for the initial prototypes of the REACTION platform.

The future scenario thinking session was carried out in order to provide the long-term requirements, which should enable and support the full range of future diabetes management, where inclusion and empowerment of the patient have to be essential parts of any chronic care. This will require the re-engineering of care and the design and implementation of new care models which underpin sustainable healthcare in the future. The developed scenarios are placed in the context of sustainable patient-centric chronic care. This exercise provided long-term requirements, which are foreseen to pose great challenge to the platform architecture, interoperability and interconnectivity as well as in service composition and execution. The long-term requirements will be given priority for the later prototypes of the REACTION platform.

The slight change of scope of the requirements engineering process led to the following revised methodology for requirements elicitation:

Step 1 (task T2.1 responsible IN-JET):

The short-term view has been obtained using a user centric requirements method with a combination of interviews and focus groups. This was carried out in two workflow workshops for the Outpatient and Inpatient environments. In each workshop clinical experts and representatives of different stakeholders were interviewed about their future needs and wishes for new workflows in diabetes monitoring and management using REACTION. Selected partners were invited to pose detailed questions related to their own work packages and technologies.

The clinical partners had prepared descriptions of typical workflows. The findings from the workshops and the ensuing work were documented in D2.1 "Scenarios for usage of the REACTION platform".

The long-term visions about radically new healthcare systems and case management with a horizon of 10 years and more were elicited in a scenario workshop held at Chorleywood Healthcare Centre. The results were described in D2.1, presented through a number of storyboards.

Step 2 (task T2.2 responsible FORTH-ICS):

Using the workflow descriptions and scenarios, each WP leader/partner has been responsible for extracting the detailed technical requirements and evaluating their architectural influence. The aim has

been to create a significant number of detailed requirements, with a number of attributes being managed by a web-based requirement management tool. The WP leaders/partners have organized internal workshops/focus groups with their technical staff to discuss the workflows and scenarios, and thereby extract the relevant requirements for their area and insert them in the requirement common database.

Step 3 (task T2.3 responsible FORTH-ICS and CNET):

IN-JET, CNET and FORTH-ICS have led a final step of requirements analysis and engineering together with the WP leaders. During this phase all WP leaders have identified and resolved requirements that were conflicting, overlapping, obsolete, had errors or in other ways needed to be modified. The consolidated list of requirements is documented in this deliverable, D2.5.

As the REACTION project aims to develop 1) a technological platform and 2) pilot applications based on that platform, the requirements must contain elements that define both platform functionalities and pilot applications features. Hence, a user-centred methodology was adopted.

4.2 User-Centred Design Methodology

User centred design is a project approach that puts the stakeholders of a product or a system at the centre of its design and development. User centred design seeks to answer questions about users and their tasks and goals, such as “who are the users of this product/system/service?”, “what are user tasks and goals?”, “what functions do users need from this product/system/service?”. The answers to these questions are then used to drive development and design. That is done by involving and talking directly to key stakeholders during the course of the project, starting from its very beginning, in order to assure that the product/system/service will deliver the foreseen requirements.

The standard ISO 9241-210 “Ergonomics of human-system interaction -- Part 210: Human-centred design for interactive systems” (ISO 9241-210:2010) which is a part of the multi-part standard ISO 9241 and a revision of the withdrawn ISO 13407 "Human-centred design processes for interactive systems" (ISO13407:1999), outlines four essential activities in a user-centred design project:

1. Requirements gathering - Understanding and specifying the context of use
2. Requirements specification - Specifying the user requirements
3. Design - Producing design solutions
4. Evaluation - Carrying out user-based assessment of the product or system

The first two phases consist of the collection of requirements through end-user involvement in workshops and interviews. In these phases one of the core tasks is to negotiate and facilitate the communication across the well-known user-developer gap while acknowledging the different forms of expression and different requirements on each side. A fact also experienced in the REACTION project. Then, the next two phases involve the design and evaluation of the design against the user requirements.

Although the process outlined above looks iterative, it does not need to be. It may be converted to a sequential design and development model like the waterfall lifecycle model, by going through the process once, or follow the V-type lifecycle development. However, the true benefit of this model emerges when it is used to guide an iterative development approach. Clark, Lobsitz and Shields (Clark1989) showed that evolutionary or iterative approaches greatly reduce the large gap of understanding between users and developers. The iterative process recommends the repetition of the various phases in an iterative fashion, with the cycle being repeated until the project's requirements, especially usability objectives, have been attained.

4.3 The Adopted Approach in REACTION

The requirement engineering process in REACTION is inspired by the principles of the ISO 9241-210 standard. This standard provides guidance on human-centred design activities throughout the life cycle of computer-based interactive systems.

The methodology calls for comprehensive iterative requirements and stakeholder analysis based on initial requirements gathered from clinical practice and issue identification, state-of-the-art research into revolutionary chronic disease management as well as medical and clinical scenario thinking.

In accordance with this generally accepted process, the REACTION project has adopted an evolutionary requirements engineering, specification and design methodology underpinned by a strong user centred development that complies with the following iterative template:

- User requirements engineering and refinement
- Architecture design specification and refinement
- Clinical protocol and medical context planning
- Technologies research and development to implement architecture
- Integration and prototype development and field trial preparation
- Field trials in clinical domains
- Conformance testing, usability evaluation and user acceptance testing
- Lessons learned and change analysis

The specific methodologies that have been used include evolutionary design and refinement re-engineering. Lessons learned as the project progress, will be used to adjust initial requirements incorporating emergent requirements. The project partners will be continuously informed of the requirement engineering process in order to enable the necessary and timely modification of design specifications and possible re-engineering of affected modules.

The process, thus, supports the chosen methodology by focusing on the expectation of users, e.g. clinicians that would like to see concrete applications developed and are less interested in architecture and technology and more interested in the clinical usability.

4.4 Objectives

Specifically the objectives of the iterative process used in REACTION are:

- To elicit the generic and specific domain requirements for the full technical, societal and business realisation of the project results in the domain of Public Health Services.
- To maintain a continuous study of the medical, clinical, technological, legal, regulatory, and market developments affecting the REACTION platform as the project progresses.
- To evaluate the potential clinical value and validate the impact on clinical workflows from REACTION applications and field trials in WP8 and its affect on the requirements.
- To evaluate the early adoption of the platform in relevant healthcare environments taking into account socio-economic and regulatory boundary conditions derived in WP9.
- To re-formulate the specific user requirements in terms of updated functionalities from each of the sub-systems. This procedure will feed back results from all WPs to the (re)specification phase enabling the re-engineering of requirements for best technical outcome, conformity to user needs, innovation and market potential.

4.5 Foundation for Initial Requirements Gathering

The procedure for the initial requirement elicitation has been selected according to the overall philosophy of the iterative requirement engineering which foresees an engineering process of initial requirements and an iteration cycle to be performed yearly. The specific methodology includes evolutionary design and refinement engineering. This approach best fits with the uncertainties of future scenarios of healthcare (r)evolution allowing for direction changes. Furthermore, the evolutionary design allows requirement refinement to obtain an accurate match with the real needs of each stakeholder.

The aim of this procedure has been the achievement of a systematic formalisation of all relevant stakeholder initial requirements and subsystem/component initial requirements, mainly based on the outcomes of the 3 workshops that involved all potential stakeholders. Input to the requirement elicitation phase also came from the general project and technical meetings and the deliverable D2.1 of current and future workflows and possible future scenarios and storylines. To accurately understand the context of

use of the REACTION platform, the workshops were held in the clinical sites of the field trials for the Inpatient and Outpatient environments.

The stakeholder requirements and subsystem functionality requirements are of different types such as:

- Functional requirements - what is required from different user perspectives?
- Security and safety requirements – based on the security analysis and risk analysis which include the formulation of a set of security policies.
- Business requirements – what is required to live up to market and business needs, what are required to satisfy existing and new stakeholder involvement and how will current business practices be supported?
- Societal requirements - including requirements related to ethics, inclusion, quality of use, professional liability, regulatory needs, etc.

Functional requirements are related to the use of the REACTION platform in clinical settings. They depict the most important aspects of short-term, mid-term and long-term user expectations. The aim of the initial requirements gathering phase has been to capture functional requirements in such a way that they can drive architectural and technical decisions and be used to validate the various sub-systems and the entire architecture.

4.6 Organization and Structure of Requirements

Each requirement has been shaped mainly according to the Volere template which assigns a specific requirement shell for writing each individual requirement (Robertson2006). Requirements are divided in different categories and labelled as functional, non-functional, or constraints.

- Functional requirements identify what is required from different user perspectives. They are related to the use of the REACTION platform in the clinical settings and to the user expectations. They are the fundamental or essential subject matter of the foreseen platform and describe what the platform has to do and what actions it has to take.
- Non-functional requirements are the properties that the platform must have such as performance, usability, security, legal, ethical, business and they are as important as the functional requirements.
- Constraints are restrictions imposed to the platform due to the budget, the time or the way the platform is designed or will work or interact with third-party components. Constraints are the same as other requirements except that they are mandated usually at the beginning of the project.

The requirement template used in REACTION includes:

- A unique alphanumeric key as requirement unique identifier
- A requirement type (functional, non-functional, constraint)
- A requirement sub-type (different for each requirement type)
- A requirement summary or description (a short statement of the intent of the requirement)
- Rationale (a justification of the requirement)
- Components (one or more components on which the requirements impacts)
- Workpackage (one or more WPs for which the requirement is relevant and has an impact)
- Originator (the document, meeting, workshop where the requirement came up)
- Reporter (the person/partner who reported this requirement)
- Assignee (the person/partner who has been in charged of making the necessary design in the platform in order to satisfy the requirement)

- Fit criterion (a measurement of the requirement such that it is possible to test if the solution matches the original requirement)
- Customer satisfaction (degree of stakeholder happiness if this requirement is successfully implemented (scale from 1 (uninterested) to 5 (extremely pleased)))
- Customer dissatisfaction (measure of stakeholder unhappiness if this requirement is not part of the final platform (scale from 1 (very low unhappiness) to 5 (extreme unhappiness)))
- Priority (a rating of the importance customer assigned to this requirement)
- Conflicts (other requirement(s) that cannot be implemented if this one is)
- Dependencies (other requirement(s) on which the implementation of this requirement will have a change effect)
- Comments

There are different sub-types for the different type of requirements.

A functional requirement can be related to:

- The Inpatient pilot application
- The Outpatient pilot application
- The REACTION platform

This way, requirements can be related to a specific pilot application or can be common to the REACTION platform impacting both pilot applications.

A non-functional requirement can be:

- Look and feel (appearance, mood, feeling, style)
- Usability (ease of use, ergonomic, internationalization, ease of learning, comprehensibility)
- Performance (speed, latency precision, accuracy, reliability, availability, robustness, capacity, scalability, extensibility, longevity)
- Operational (expected physical environment, requirements for interfacing with other systems, installation, configuration, release cycle)
- Maintainability and portability (maintenance, support aspects, multiplatform)
- Security (access, integrity, privacy, audit, immunity)
- Cultural and political (sociological factors, political factors)
- Legal (compliance with law or standards, liability, intellectual property rights (IPR))
- Ethical (inclusion, accessibility, control on personal data)
- Economical and business (business roles, market aspects, support of business practice)

A constraint can be:

- Solution (final product/system, technology)
- Implementation environment (technological environment, physical environment)
- Collaborative applications (external applications, commercial packages, pre-existing in-house applications, interfaces)
- Off-the-Shelf software (commercial software, open source software)
- Off-the-Shelf sensors and devices (features of sensors/devices, behaviour of sensors/devices, interfaces and integration capabilities of sensors/devices)

- End-user workplace environment (characteristics of workplace, social and cultural properties of workplace)
- Schedule (deadlines, windows of opportunity)
- Budget (money, available resources)

Requirements can also be assigned to one or more WPs and to one or more components.

In this initial phase of the project the main components that have been identified are:

- Alarm & alert subsystem (the subsystem for the generation and delivery of alarms and/or alerts)
- Architecture (the overall architecture of the platform or of the Inpatient or Outpatient application)
- Backend middleware (the middleware running in the backend or in the server rooms)
- Communication (all sort of communications between sensors and portable device or from the portable device to the backend middleware)
- Context management (all the operations for providing a context to the acquired data)
- Data management (the storage and structuring of all the data in the platform)
- Glucose control algorithm (all the intelligence for the production of retrofits about glucose control (e.g. information about insulin administration and dosage) to the patient)
- Interfaces with HIS/EPR (the interfaces with third-party systems for HIS and/or EPR)
- Networking (the network interconnection between all the parts of the platform)
- Ontology/terminology (the ontology and terminology available in the platform)
- PAN/BAN (personal area network and body area network realized with the help of the portable device)
- Physiology models (the physiology model of the glucose and insulin interaction in the human body used as main input for the AGC algorithms)
- Portable devices (the mobile/portable device which will be the integrator of all sensors and realize the PAN/BAN integration)
- Portable user interface (the user interface available on the portable device)
- Risk assessment (all the algorithms for the evaluation of the risk of developing further complications in short, medium and long term)
- Security (security, safety and privacy issues)
- Sensors (all sensors medical and environmental)
- Web user interface (the user interface available in the carer's sphere)

Each requirement can impact on one or more components. In the assignment of the requirement to a specific person/partner, especially when a requirement impacts more than one single component, considerations like the component with the highest impact and partner responsibilities and expertise have been taken into account. More details are provided in the next chapter.

4.7 Requirement Analysis and Refinement Phase

Once all requirements have been shaped according to the Volere schema and collected in a common database, a phase of requirements analysis has to be performed. In this phase, a quality control is performed for all requirements. Involved people/partners have the possibility to decide which requirement will become part of the final set and which has to be revised. In this latter case, a feedback to the reporter of the requirement is provided. The quality control is performed by processing requirements along the steps of a workflow which is the schema representing the movements (or transitions) of a requirement through various statuses during its lifecycle.

The foreseen requirement workflow is structured in the following way. When a requirement is inserted in the common database for the first time, its associated status is “open”. If it is complete and unambiguous and all its fields are properly filled with the right values, then it passes the quality check, otherwise it fails. There are several reasons for failing to pass the quality check: incompleteness, ambiguity, some fields filled with meaningless values, loss of sense. If the requirement fails the quality check the reasons are sent to the reporter who can correct and update it and re-pass it through the quality check. If the check fails again the same procedure described above is repeated. Eventually all requirements will pass the quality check. That means that they are complete and all fields are filled with proper values. Requirements that have passed the quality check can no longer be edited.

The last step of requirement refinement involves deciding whether a requirement becomes part of the specification or not. A requirement may not be part of the specification if it is a duplicate, or out of scope of the project. When a requirement has been labelled as “part of specification”, “duplicate”, or “rejected”), its status is “resolved”.

5. Tools for Supporting the Requirement Management

5.1 Introduction

The user-centred approach of REACTION requires management tools that allow requirements storage and monitoring during the various iterations of the evolutionary design and during the entire lifecycle of the project.

In principle, every software or application development project must be clearly defined before development begins. It must address a problem that the organization currently has. A requirement is a condition or capability that must be met or possessed by a system or system component to satisfy a contract, standard, specification, or other formally imposed documents. The Requirements Management (RM) and gathering process is a necessary step in order to come up with a solution appropriate for the organization. The work mostly done in this phase is performed by a person or team referred to as a requirements analyst. Requirements management involves establishing and maintaining an agreement with the customer on the requirements for the software project. The agreement forms the basis for estimating, planning, performing, and tracking the software project's activities throughout the project lifecycle. The primary activities within requirements management include (see fig. 1) (PowerTest2010):

- Planning the requirements phase
- Establishing the requirements process
- Monitoring and controlling requirements changes
- Tracking progress
- Resolving issues

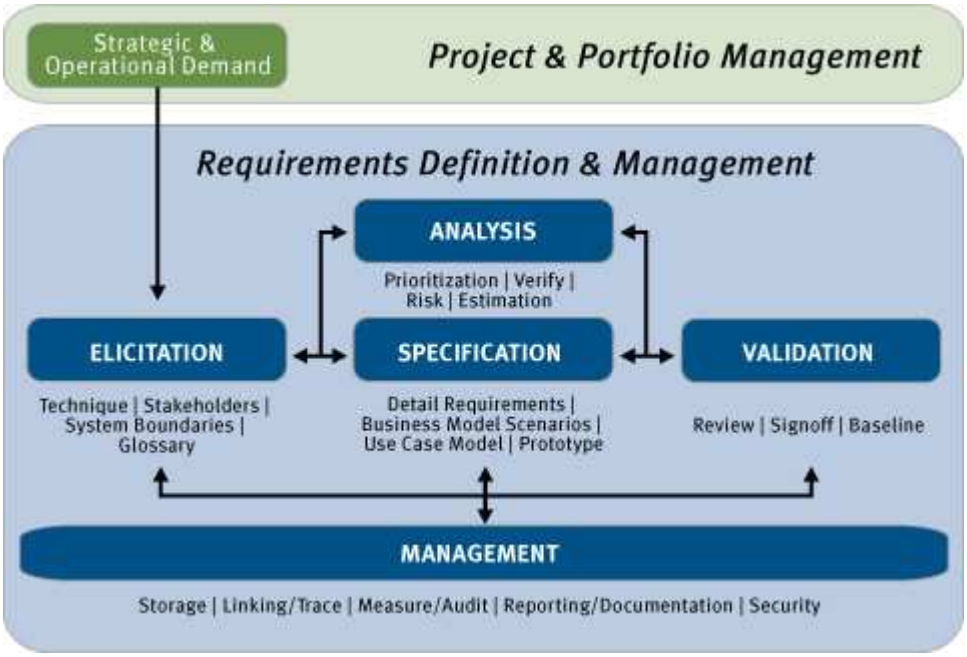

Figure 1: Requirements management process

A requirement is categorized as "functional" if it specifies what the system needs to do. Otherwise, it is categorized as "non-functional." Apart from the above attribute it is important to attach further attributes to the Requirements Management process in order to provide data for continuous improvement, especially around the data used to support the estimating process. Focus should be paid to measures that provide an insight into the effectiveness of the process. The most important attributes between others could include:

- *Requirement status:* It consists of different values which define the status of each requirement in the process.

- *Requirement type:* If the requirement is functional or non-functional as mentioned above.
- *Requirements priority:* This metric provide a priority to our requirement in order to evaluate for example the effort and the prioritization of each one. Blocker, Critical, Major, Minor and Trivial are indicative.

Requirements traceability is another aspect that refers to the "ability to follow the life of a requirement, in both forwards and backwards direction, i.e. from its origins, through its development and specification, to its subsequent deployment and use, and through periods of ongoing refinement and iteration in any of these phases. This ability is an essential feature in the requirements management process.

The key to requirements management is *communication* as well. A good requirements management process helps ensure a high level of communication between stakeholders. For the developers to fully understand the needs of the customers, they must fully understand those needs, and have an open channel of communication among them.

Communication is also crucial when requirements change, as they do in any project. Once changes have been agreed upon, they must be incorporated into the project scope, and be communicated to developers and customers, as well. An effective means of communication is thus essential to getting the project right the first time and avoiding expensive re-work later in the development cycle.

5.2 Requirement Management Tools

In order to manage the large number of requirements many software developers use tools to help them manage requirements more effectively. RM tools can assist organizations in defining and documenting requirements by allowing them to store requirements in a central location. Project teams can then access the requirements to determine what is to be developed, and customers can access the requirements to ensure that their needs were correctly specified.

Customers and team members (developers) can then participate in informed discussions in case of any discrepancies, or seek further clarifications in case of uncertainties. This also aids the process of classifying and prioritizing requirements. Some of the tools are not software applications at all such as pen and paper. Some other tools are general software applications such as Word and Excel. Finally, some tools are commercially available and provide a more sophisticated environment (LCS2009, INCOSE2010) (see Table 1).

TOOL	VENDOR NAME
RTM Workshop	Integrated Chipware
DOORS	Quality Systems and Software Inc.
RequisitePro	Rational Software
Caliber-RM	Technology Builders Inc
Accompa	Accompa Inc.

Table 1: Some commercially available RM software tools

There are some "Requirements" of the RM tools that are crucial and must be satisfied:

- ***Ability to manage versions and/or changes:*** At some stage of development, a project should define a requirements baseline, a specific collection of requirements that a particular release will contain. A requirements management tool must record a history of the changes made to every requirement. This will help explain previous decisions and rationales, thereby minimizing the scope for ambiguity.
- ***Store requirements attributes:*** Comprehensive information and attributes about requirements should be stored to promote understanding, for customers as well as developers. Attributes must be visible to all concerned stakeholders and selected individuals should be able to update values. Requirements management tools should automate the generation of several system defined attributes, such as date created, and allow the definition of additional attributes of various data types. Attributes such as author, person responsible, origin or rationale, status, priority further augment understanding.

- ***Linking requirements:*** Linking individual requirements helps ensure that developers do not inadvertently overlook any requirements during implementation. Different kinds of requirements and between requirements in different subsystems (components) should be able to be linked. When analyzing the impact of a change proposed in a specific requirement, the traceability links reveal the other system elements that the change might affect.

- ***Track Status:*** A good requirements management tool will help tracking the status of each requirement during development thereby supporting overall project status tracking. For instance, if a project manager knows that 55% of the requirements allocated to the next release have been implemented and verified, 28% are implemented but not verified, and 17% are not yet fully implemented, then he or she has good insight into project status.

- ***View requirement subsets:*** RM tools should help sorting, filtering, or querying database(s) of requirements to view subsets of the requirements that have specific attribute values.

- ***Control access:*** Permissions should be able to set for individuals or groups of users. This prevents miscreants and inadvertent accesses to requirements.

- ***Communicate with stakeholders:*** Most requirements management tools let team members discuss requirements issues electronically. Notification system allows E-mail messages that can notify the affected individuals when a new discussion entry is made or a requirement is changed.

Most of the commercial available RM tools support the above features. Several times, especially in case of high-profile RM tools, they have disadvantages which makes difficult to use them. For instance, **tools with a lot of features are complex** because **it takes time and effort to learn how to use them or other tools** are not flexible because the application software and the database schemas are proprietary and it is difficult or impossible to customize. Finally, several tools are **costly in price** (hundreds or thousands of dollars per license), **training**, and **maintenance demands a team to work specifically for this**.

5.3 JIRA Issue Tracker as RM tool

Although there are existing software tools for RM in the market, JIRA issue tracker (JIRA2010) in the other hand could be an alternative and reasonable solution especially if priority is given to ease of use, customizability and low cost. JIRA is a proprietary issue tracking product, developed by Atlassian and allow quite easily prioritizing, assigning, tracking, reporting and auditing project “issues” (i.e. requirements).

More specifically:

- JIRA is an extensive web-based platform that can be customized to meet specific project needs at any time during the project lifecycle. Its functionalities, if needed, can be extended by using more than 100 available plug-ins at low cost (for example: GreenHoper plug-in for “Agile” management, Mockup Designer for creating user interfaces, etc.).

- JIRA has a built-in field builder that essentially lets the end-user choose what fields he wants to add/edit for his requirements. JIRA fields can be configured at a system-wide, project specific and/or issue type level.

- JIRA reporting component (or ‘filters’) makes it easy to extract the desired information out of the system in several formats. It is possible to filter (select) the issues that correspond to specific components, WPs, reporter, assignee, etc., in order to have a more effective way of inspecting the requirements the end-user is interested to.

- JIRA configurable notification mechanism allows communication via email to all interested end-user about any change to any issue. For instance, the notification mechanism can be used to notify the assigned user, the reporter and the potential watchers of each issue when changes are made to their issues.

- Everything is permission based, thus, for instance, people can be allowed viewing status of issues but not changing them.

- JIRA has tracking abilities which provide the capability of tracking and seeing the history of any changes in specific issues. This is crucial as mentioned above in order to see the issue lifecycle and to view the overall progress of the project.
- JIRA has linking capability which allows linking individual requirements.
- JIRA can be integrated with software development tools (i.e. Eclipse) and source code monitoring tools (i.e. SVN).
- JIRA is very simple so that non-technical users can use it easily. In particular, the simplicity of the user-interface is major factor for rapid and trustworthy use.

Finally, the other main advantages of using JIRA in comparison to the existing high-profile RM tools are the **low cost of licensing** (starting from 10$ with 10 registered users), the easiness of installation and configuration and the possibility of performing the overall administration with a single person instead of a dedicated team. Furthermore, it has to be noticed that JIRA issue tracker was used in the past as Requirements Management tool in HYDRA project with success (Prause2008).

For the REACTION project the estimated needs were to have not more than 25 users and to manage not more than hundreds of requirements. This project size was considered very suitable to be managed with JIRA allowing a very low license cost, a reasonable cost for the JIRA server and the possibility of performing effectively the overall administration and configuration with a single person saving money and resources. Comparing the functionalities of JIRA to expensive RM tools it is possible to state that JIRA was much more attractive and suitable for the estimated needs of the REACTION project.

For the above reasons it was decided that JIRA is an ideal solution for the requirements gathering, analysis and management of the REACTION project.

A short user guide for the REACTION requirements is available in Appendix A.

5.4 JIRA Operational Requirements

JIRA is a project management system (or bug tracking system, or issue tracking tool) that helps partners to organize and administer their project/s. The main concept of JIRA is the *issue*. An issue represents a software bug, a task or a general problem concerning to a specific requirement that was specified earlier in a new project. In case JIRA is used as RM tool, then each requirement can be represented with an issue.

JIRA is a 'web application', meaning it runs centrally on a server, and users interact with it through web browsers from any computer. Most requirements therefore relate to the server, and software running on it.

5.4.1 Software Requirements

JIRA is distributed in two formats, **Standalone** and **WAR/Webapp**, with different installation requirements:

- The Standalone distribution **requires Java.** JIRA Standalone comes with a built-in application server and database, and is the preferred format for new users.
- The WAR/Webapp distribution **requires Java**, an application server and a database.

5.4.2 Browser Requirements

JIRA works with any modern browser (IE 6, Mozilla, Firefox, Opera, Safari, etc.). All the main functionalities work also in IE 5.5, however some of the visual effects are missing, as IE 5.5 is becoming quite dated and does not support web standards that are in common use today.

5.4.3 Hardware Requirements

The hardware required to run JIRA heavily depends on the number of issues and users that the specific installation will have, as well as the maximum number of concurrent requests that the system will experience during peak hours. During evaluation JIRA will run well on any reasonably fast workstation computer (e.g. 1.5+ GHz processor). Memory requirements depend on how many projects and issues will be stored, but 256 MB is enough for most evaluation purposes. Most users start by downloading JIRA Standalone, and running it on their local computer. It is easy to move JIRA to a central server later. In

case of a small number of projects (10-20) with 1000 to 5000 issues in total and about 100-200 users, a recent server (2.8+ GHz CPU) with 256-512 MB of RAM free should cater for all needs. In case of a greater number of issues and users, adding more memory will help. JIRA manufacturer states that allocating 1 GB of RAM to JIRA server is sufficient for 100000 issues. In case of a large number of concurrent requests, running JIRA on a multi-CPU machine will increase the concurrency of processing the requests, and therefore speed up the response time.

5.5 JIRA Configuration

JIRA was installed on a server hosted at IN-JET premises and then configured for managing requirements in the REACTION project. The implemented configuration follows the ***Volere Requirements Specification Template***, as shown in fig. 2 (Robertson2006). The Volere template has been used by many organizations when the need of specifying requirements was crucial. The template provides an atomic structure for describing the requirement through specific attributes and has been proved to be appropriate for today's business, scientific and software systems. It also provides a checklist, structure and traceability for requirements. The template is tool independent, and has been successfully used with many RM tools including JIRA.

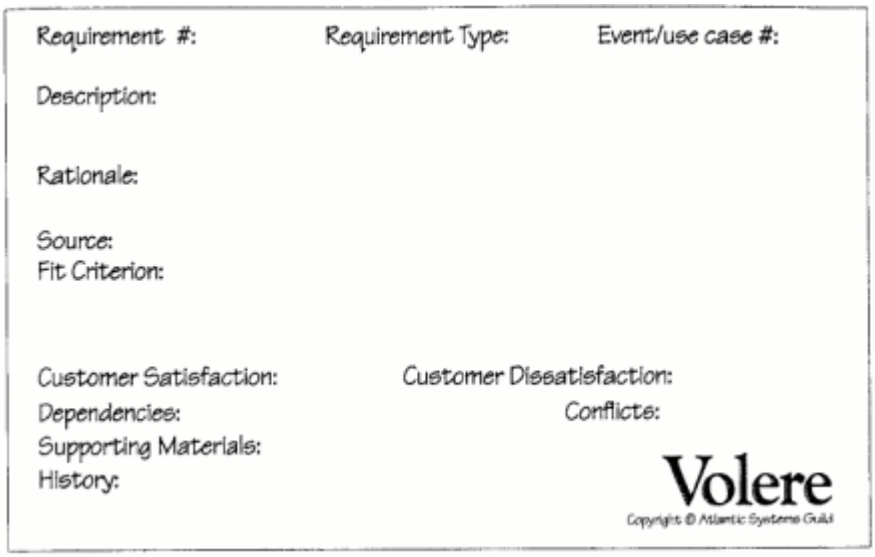

Figure 2: The Volere scheme/template

In this section all the configurations made, based on this schema/template, have been accurately described.

Projects: A new project was added named *REACTION Requirements*. The configuration described below refers to this project.

Issue Types: All the existing issue types were deleted and a new type named *Volere Requirement* was added, in order to be the only available choice in the issue type list. That was done because: a) Volere Scheme is the atomic structure of the REACTION requirements; b) There was the need to simplify the user interface and limit the possibility of errors from a generic user (avoiding the possibility of selecting a different issue type for inserting his requirements).

Customization of fields: In the *Default Field Configuration, several existing fields were not foreseen in the Volere template, thus a custom configuration was performed.* Starting from the default configuration, some custom fields were added and some others (present in the default configuration) were hidden.

In table 2, the atomic structure of the Volere requirement is described in detail with all the fields the user has to fill in order to create a new issue.

Field Name	Description	Type	Value/Values
Requirement #	A 3-digit number that is created by the system when a new issue is added	Auto incremented key	REACTION-XXX
***Requirement Type**	Type of requirement or constraint	Cascading Select (Consists of two Select Lists, where the values shown in the second depend on the value that has been selected in the first)	➢ **Functional** • Inpatient pilot application • Outpatient pilot application • REACTION platform ➢ **Non-functional** • Look and feel • Usability • Performance • Operational • Maintainability and portability • Security • Cultural and political • Legal • Ethical • Economical and business ➢ **Constraint** • Solution • Implementation Environment • Collaborative Applications • Off-the-Shelf Software • Off-the-Shelf Sensors & Devices • End-User Workplace Environment • Schedule • Budget
***Component/s**	Component/s to which the requirement is related	Multi Select List	➢ Alarm & Alert Subsystem ➢ Architecture ➢ Backend Middleware ➢ Communication ➢ Context Management ➢ Data Management ➢ Glucose Control Algorithm ➢ Interfaces with HIS/EPR ➢ Networking ➢ Ontology/Terminology ➢ PAN/BAN ➢ Physiology Models ➢ Portable Devices ➢ Portable User Interface ➢ Risk Assessment ➢ Security ➢ Sensors ➢ Web User Interface
***Workpackage**	Workpackage/s to which the requirement is	Multi Select List	➢ WP1 ➢ WP2 ➢ WP3

	related		➢ WP4 ➢ WP5 ➢ WP6 ➢ WP7 ➢ WP8 ➢ WP9 ➢ WP10 ➢ WP11 ➢ WP12 ➢ WP13
***Priority**	Importance of the requirement	Select List	➢ Blocker ➢ Critical ➢ Major ➢ Minor ➢ Trivial
Asignee	Person in charge of resolving the requirement	Select List	Users Full Names that have access to the "REACTION Requirements" project
Reporter	Person who specified the requirement	Text Field (< 255 characters)	
*** Summary**	A one sentence statement of the intention of the requirement	Text Field (< 255 characters)	
***Rationale**	A justification of the requirement	Free Text	
***Source/Originator**	The source where this requirement was raised	Free Text	
***Fit Criterion**	A measurement of the requirement such that it is possible to test if the solution matches the original requirement	Free Text	
*** Customer Satisfaction**	Measures the desire to have the requirement implemented	Select List	➢ Uninterested ➢ Interested ➢ Pleased ➢ Very Pleased ➢ Extremely Pleased
***Customer Dissatisfaction**	Unhappiness if it is not implemented	Select List	➢ Very Low Unhappiness ➢ Low Unhappiness ➢ Neutral Unhappiness ➢ High Unhappiness ➢ Extreme Unhappiness
Conflicts	Other requirement that cannot be implemented if this one is	Text Field (< 255 characters)	
Dependencies	Other requirements with a change effect	Text Field (< 255 characters)	

*These fields are required to be filled.

Table 2: The fields of an atomic issue for the REACTION project

Notifications: In order to allow communication between the stakeholders it is essential to encapsulate a notification system. JIRA allows adding or editing existing Notification schemes to satisfy the project needs for communication and in essence to assure a better collaboration. For the REACTION project, the Default Notification Scheme was selected, so that for every event on an issue (issue created, issue updated, etc.) the assignee, the reporter and all the potential watchers would be notified about changes in it. The events the users will be notified are presented in table 3.

EVENT	NOTIFICATION
Issue Created	Current Assignee/Reporter/All Watchers
Issue Updated	Current Assignee/Reporter/All Watchers
Issue Assigned	Current Assignee/Reporter/All Watchers
Issue Resolved	Current Assignee/Reporter/All Watchers
Issue Closed	Current Assignee/Reporter/All Watchers
Issue Commented	Current Assignee/Reporter/All Watchers
Issue Commented edited	Current Assignee/Reporter/All Watchers
Issue Reopen	Current Assignee/Reporter/All Watchers
Issue Deleted	Current Assignee/Reporter/All Watchers
Issue Moved	Current Assignee/Reporter/All Watchers
Work Logged on issue	Current Assignee/Reporter/All Watchers
Work Started on issue	Current Assignee/Reporter/All Watchers
Work Stoped on issue	Current Assignee/Reporter/All Watchers
Issue worklog updated	Current Assignee/Reporter/All Watchers
Issue Workloged deleted	Current Assignee/Reporter/All Watchers
Generic Event	Current Assignee/Reporter/All Watchers

Table 3: The Default Notification Scheme

Issue Linking: As mentioned above, linking issues is another essential feature in requirements management process. Even if the default configuration has the issue linking disabled, this functionality can be easily activated by the administrator. In the REACTION project it was activated and the users have the capability of linking issues.

5.5.1 User Management in JIRA

JIRA has a built-in mechanism for user management. The administrator can add new users by filling their personal settings (Username, Password, Full Name and Email address). Additionally, further information (such as Phone number, or location) can be added by specifying key-value pairs (for example: key: “Location”, value: “Iraklion Crete”). In this phase there is the capability to send an automatic confirmation email to inform the user about his registration into the system. In this automatic email there is also a link where the user can change his personals details at any time. Any new user is automatically assigned only to the “jira-users” default group. This means that the user can only view the requirements without the ability to change anything (e.g. create new requirement, change status, comment, etc.). In order to allow the user having an active interaction with the requirements (apply changes, change status, etc.) it is necessary to assign the user also to the “jira-developers” group.

5.5.2 Workflows in JIRA

As mentioned in the previous section 4.7 “Requirements Analysis and Refinements phase”, in order to have the absolute control of the project requirements and of their progresses, there is the possibility in JIRA of enabling a workflow mechanism. The default workflow mechanism of JIRA allows changing and tracking the status of each requirement during its lifecycle (see fig. 3). The status of each requirement has specific transitions or next steps that define its progress. For example, when a requirement is in the “In progress” status the next steps are “Resolve” or “Close”, but it is also possible to go back to its initial status (“Open”). JIRA has the flexibility of adding or editing existing workflow schemes to satisfy the project needs for tracking requirements (customizing the statuses and transitions according to the project needs). At this stage of project, after examining different options of workflow schemes, the default workflow was selected and enabled as the most appropriate for the REACTION project.

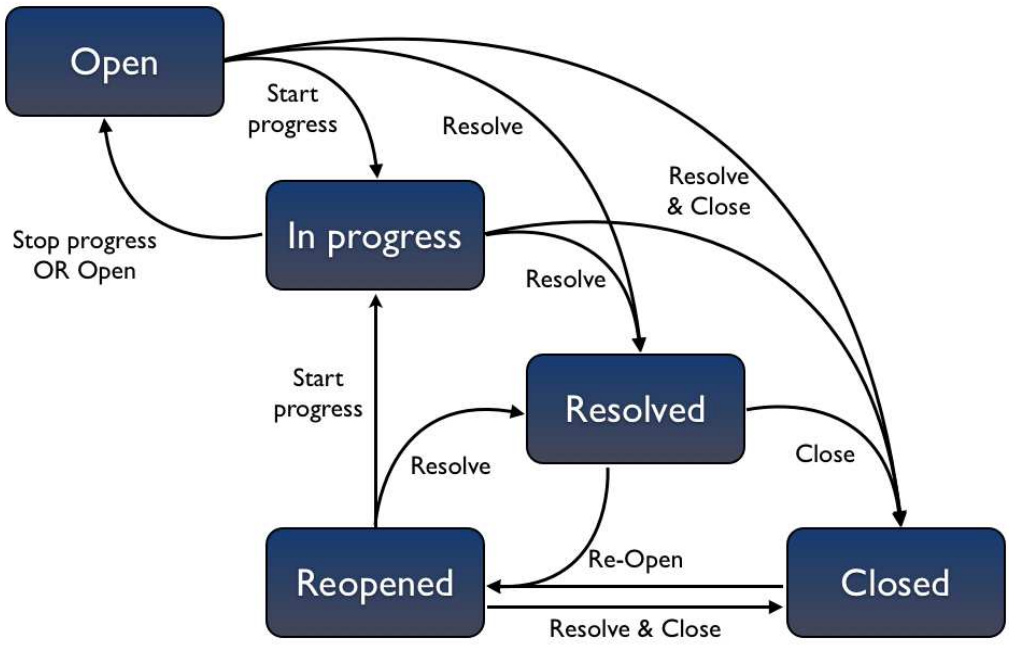

Figure 3: Default workflow scheme

6. Initial Requirements for the REACTION Platform

In this chapter the initial requirements for the REACTION platform are reported per WP and per component showing only the major fields like priority, summary, rationale and fit criterion. Duplicated requirements in the “resolved” status have not been listed even if in some cases they are referred as dependency in some other requirements of the list. A complete list of the initial requirements (excluding the duplicates) which includes all the requirement fields is listed in the last chapter of this deliverable. It has to be noticed that each requirement can have an impact on more than a single WP and on more than a single component. It will be a task of the assignee to coordinate the work during the lifecycle of the REACTION project among different WPs or components in order to assure the requirement will be properly resolved. Eventually this task can be accomplished with the help of sub-tasks splitting the requirement in sub-issues specific for each WP and/or component. Another possible option is the creation of sub-project where the requirements are linked to the ones listed in the REACTION project. In order to give an effective view of the requirements and to avoid an eccessive length for this deliverable, each requirement, even if with an impact on more than a single WP, has been listed only in the WP on which it has a major impact.

It has to be noticed that in the requirement specification the concept of “black box” has been introduced. This term means the overall hardware to be used at the outpatient environment for acquiring and transmitting sensor data from the patient’s sphere to the REACTION middleware.

6.1 Requirements of WP3 – Sensors, Monitoring and Contextualization

6.1.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-129	Functional - REACTION platform	Major	Portable device should allow the notification of alarms & alerts	The use of the same device also for the reception of alarms and alerts simplifies and makes less expensive the overall solution	The reception of alarm and alerts will be checked on the portable device

6.1.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-126	Functional - REACTION platform	Major	Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake)	The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. The possibility to collect this information using the same portable device used for the BAN/PAN integration reduces the overall cost of the acquisition system improving the sustainability of the overall solution. The portable device could eventually be a part of the "black box".	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device
REACTION-128	Functional - REACTION platform	Major	Portable device should allow the display of feedback to patient	In mobile situation the only available device is the portable device and patient should be able to use it for uploading or downloading data. The possibility of using the "black box" also as output device for displaying data related to feedback to patient would help in simplifying cost and complexity of the solution.	The portable user interface should be used also for displaying the clinician feedback to patients, graphical representation of the data acquired in the last week/day/etc.
REACTION-129	Functional - REACTION platform	Major	Portable device should allow the notification of alarms & alerts	The use of the same device also for the reception of alarms and alerts simplifies and makes less expensive the overall solution	The reception of alarm and alerts will be checked on the portable device

6.1.3 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-40	Functional - REACTION platform	Critical	The sensors/devices developed by the consortium which communicate with the platform wirelessly, must be able to connect swiftly to platform and maintain that connection without interruptions, even in a fragmented space from wireless devices.	To guarantee the operation of the portable devices under any circumstances. Consortium developed wireless devices must be able to pair in an acceptable time and maintain connectivity in a electromagnetic interfering environment.	Multiple trials in a real life environment (not only in the fully controlled environment of the laboratory) using multiple WiFi and Bluetooth devices, to ensure the ability of the sensor/device to connect and operate.
REACTION-52	Non-functional - Usability	Minor	If the portable touch device is not capable to connect wirelessly and send the data, then it should be able to connect via USB to a host gateway with connectivity to the Internet & upload the measurement file to the platform.	If no wireless network is available at the user's home environment, then he/she must be given the opportunity to send the measurements from the portable device to database, using the local connection (wired) of the home gateway.	Creation of a service for the home gateway that upon USB connection with the portable device, the service will transmit the cached data of the portable device to the database. The whole procedure must be easy for the user. For this case an internet connection is mandatory for the home gateway.
REACTION-207	Functional	Major	ePatch communication	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.	The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the "black box").

6.1.4 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-33	Functional - REACTION platform	Major	Sensor data as concrete values and CONTINUA compatible	No raw sensor-data processing on REACTION platform	Definition of data transfer protocol compatible to CONTINUA

6.1.5 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-126	Functional - REACTION platform	Major	Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake)	The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. The possibility to collect this information using the same portable device used for the BAN/PAN integration reduces the overall cost of the acquisition system improving the sustainability of the overall solution. The portable device could eventually be a part of the "black box".	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device
REACTION-204	Functional - REACTION platform	Critical	ePatch	The ePatch is the preferred device and technology used to attached and connect sensors to the body. However, it should be possible that data from commercially available sensors not connected to the ePatch can be read by the REACTION platform.	Hardware fabricated.
REACTION-207	Functional	Major	ePatch communication	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.	The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the "black box").
REACTION-236	Functional - Inpatient pilot application	Major	Blood glucose measurements in Inpatient environment	PoC devices are currently used and will be used in Inpatient environment. The procedure is reliable and has been used since several years. Substitution of the used PoC devices with other devices (consortium sensors) in the daily practice can be done only after passing through a very severe procedure. This might not be foreseen (for the daily practice) in this project.	There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose sensors using a procedure which should be quite simple and user friendly.

6.1.6 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-30	Functional - REACTION platform	Major	Power budget of wearable sensor platform	Depending on the measuring intervals (tbd) power must be available for autarkic operation of sensor platform	Definition of total power budget

REACTION-49	Non-functional - Usability	Major	The touch/tablet/phone device must allow the execution of processes in the background	The applications developed for the portable devices should start and stop only when the user wants. If the portable device is a mobile phone when the user receives a phone call or SMS then the application should continue in the background without closing (preventing data loss). Therefore the portable devices should allow applications running in the background.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-50	Non-functional - Usability	Major	The touch/tablet/phone device must support notification messages	The portable device must have the ability to show alert messages to the user. This will allow the device to report promptly to the user if any measurement is not good, if it presents a problem, or even whether to take a medicine, or whether it has an appointment with the doctor.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-51	Functional - Outpatient pilot application	Critical	If the touch/tablet/phone device is not able to send the data to the platform (lack of connectivity), it should store them locally and then send them when the connectivity is re-established.	It is likely that outside the home, the user will not have access to a wireless network. In such a case the mobile device will continue to take measurements but will not be able to transmit them. Therefore in order not to lose the measurements, the device should be able to store them internally (the device must have a decent amount of internal storage, or accept memory cards, and be able to store the measurements there). When the device reconnects to a wireless network then it will send the stored measurements to the database.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-52	Non-functional - Usability	Minor	If the portable touch device is not capable to connect wirelessly and send the data, then it should be able to connect via USB to a host gateway with connectivity to the Internet & upload the measurement file to the platform.	If no wireless network is available at the user's home environment, then he/she must be given the opportunity to send the measurements from the portable device to database, using the local connection (wired) of the home gateway.	Creation of a service for the home gateway that upon USB connection with the portable device, the service will transmit the cached data of the portable device to the database. The whole procedure must be easy for the user. For this case an internet connection is mandatory for the home gateway.

REACTION-53	Non-functional - Usability	Major	*The portable touch device must have at least the following connectivity options: WiFi (802.11g or 802.11n), Bluetooth, USB; *Also it must have built in at least the following sensors: GPS, accelerometer; *If mobile phone it must support 3G networks.	The device must support the latest and most widespread communication protocols. The presence of specialized sensors like the accelerometer, and the GPS will improve the usability of the device, and will allow the collection of additionally useful information.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-55	Non-functional - Usability	Major	The portable touch device must have a display of sufficient screen size & resolution (more than a 3,5" display, more than 320px*480px). If not a stylus operating device then the display must be of capacitive technology & with support for multitouch.	A device with smaller screen estate will compromise its usability, and will make the interaction with user an unattractive and difficult experience. A multitouch display dramatically improves the user interaction. Displays that make use of capacitive technology provide a much better multitouch operation.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-56	Non-functional - Usability	Major	The portable touch device must have a satisfactory operational time. The battery must be able to support the device for at least half a day. If the device supports exchangeable battery that would be an advantage.	The portable device will have to be operated continuously. The small size and weight of the device allows the user to move freely, but the battery life can be a problem. For this reason, the life of the device when powered only by battery should be sufficient to allow the user to leave the house. The portable touch device should be able to operate while the sensors receive measurements simultaneously with the application and its services, for at least five consecutive hours (it is acceptable if the display is not turned on for the whole duration). The extended battery life will allow the user to continue his daily program with a minimal intervention (or no intervention at all), until he/she returns home, where he/she can then charge the portable device.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.

REACTION-80	Non-functional - Usability	Major	Only one or max two categories of different mobile operating systems will be considered for the portable devices	The large spread of existing operating systems does not allow developments on a large number of mobile operating system. The more effective solution is to focus on one or max two common and largely diffuse operating systems.	Internal test and field trials will be performed only using portable devices with one of the selected operating systems
REACTION-126	Functional - REACTION platform	Major	Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake)	The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. The possibility to collect this information using the same portable device used for the BAN/PAN integration reduces the overall cost of the acquisition system improving the sustainability of the overall solution. The portable device could eventually be a part of the "black box".	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device
REACTION-128	Functional - REACTION platform	Major	Portable device should allow the display of feedback to patient	In mobile situation the only available device is the portable device and patient should be able to use it for uploading or downloading data. The possibility of using the "black box" also as output device for displaying data related to feedback to patient would help in simplifying cost and complexity of the solution.	The portable user interface should be used also for displaying the clinician feedback to patients, graphical representation of the data acquired in the last week/day/etc.
REACTION-129	Functional - REACTION platform	Major	Portable device should allow the notification of alarms & alerts	The use of the same device also for the reception of alarms and alerts simplifies and makes less expensive the overall solution	The reception of alarm and alerts will be checked on the portable device
REACTION-236	Functional - Inpatient pilot application	Major	Blood glucose measurements in Inpatient environment	PoC devices are currently used and will be used in Inpatient environment. The procedure is reliable and has been used since several years. Substitution of the used PoC devices with other devices (consortium sensors) in the daily practice can be done only after passing through a very severe procedure. This might not be foreseen (for the daily practice) in this project.	There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose sensors using a procedure which should be quite simple and user friendly.

6.1.7 Portable User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-49	Non-functional - Usability	Major	The touch/tablet/phone device must allow the execution of processes in the background	The applications developed for the portable devices should start and stop only when the user wants. If the portable device is a mobile phone when the user receives a phone call or SMS then the application should continue in the background without closing (preventing data loss). Therefore the portable devices should allow applications running in the background.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-50	Non-functional - Usability	Major	The touch/tablet/phone device must support notification messages	The portable device must have the ability to show alert messages to the user. This will allow the device to report promptly to the user if any measurement is not good, if it presents a problem, or even whether to take a medicine, or whether it has an appointment with the doctor.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-128	Functional - REACTION platform	Major	Portable device should allow the display of feedback to patient	In mobile situation the only available device is the portable device and patient should be able to use it for uploading or downloading data. The possibility of using the "black box" also as output device for displaying data related to feedback to patient would help in simplifying cost and complexity of the solution.	The portable user interface should be used also for displaying the clinician feedback to patients, graphical representation of the data acquired in the last week/day/etc.

6.1.8 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-29	Functional - Outpatient pilot application	Critical	Accurate data acquirement	IR-absorption glucose spectra are strongly temperature dependent	Integration of temperature sensor in the sensor platform
REACTION-30	Functional - REACTION platform	Major	Power budget of wearable sensor platform	Depending on the measuring intervals (tbd) power must be available for autarkic operation of sensor platform	Definition of total power budget

REACTION-180	Functional - REACTION platform	Major	Measurement of glucose should be specific and the glucose sensor should be able to monitor glucose in complex media	If the glucose monitoring is not specific, detection could be disturbed by other components of the ISF or the blood, influencing the accuracy of the sensor. For realisation of a closed-loop-system (glucose measurement + insulin dosage) a highly accurate sensor is required.	Sensor should exhibit a high accuracy even if other media are in contact with the sensor area.
REACTION-183	Functional - REACTION platform	Major	The sensitivity of the glucose sensor should be high, the SNR must be large and changes of glucose concentration in the range 1-15 mM must be detectable.	For a closed loop sensor system (glucose measurement + insulin dosage) especially in the lower concentration range of about 3-4 mM or less a high accuracy is required to avoid mistreatments in the hyperglycaemic range.	Performance of reference measurements on defined samples.
REACTION-204	Functional - REACTION platform	Critical	ePatch	The ePatch is the preferred device and technology used to attached and connect sensors to the body. However, it should be possible that data from commercially available sensors not connected to the ePatch can be read by the REACTION platform.	Hardware fabricated.
REACTION-205	Functional - REACTION platform	Minor	Docking station for the ePatch	Charging of the reusable sensor in the ePatch	Hardware fabricated.
REACTION-206	Functional	Major	ePatch reusable sensor	The ePatch reusable sensor contains the optical and electrical sensor components, electronics, radio, antenna, and battery. Eventually the ePatch might be consisting of two components, one reusable, containing the optics and electronics, and one disposable, containing the optical cell and waste for the dialysis.	Hardware fabricated.
REACTION-207	Functional	Major	ePatch communication	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.	The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the "black box").
REACTION-208	Functional	Major	ePatch adhesive base	The adhesive base forms the contact between the ePatch sensor and the skin surface of a human. Sensors measuring physiological data should be specified.	ePatch can stick to the skin and sensor can measure physiologic data.

REACTION-209	Functional	Major	ePatch adhesive base has unique physical properties	The ePatch adhesive base contains 3 gel electrodes with impedance matched to the skin. The gel or part of the gel is optical transparent in the visible and NIR range of the electromagnetic spectrum.	ePatch can stick to the skin and optical or NIR sensor (if required) can measure physiologic data.
REACTION-210	Functional	Major	ePatch adhesive base has unique adhesive properties	The ePatch adhesive base contains at least two type of adhesive materials: 1) One with good skin adhesive properties 2) An adhesive gel or similar with electrical and optical properties matched to electrical and optical sensors.	Adhesive can stick to skin and sensors can measure.
REACTION-214	Functional - REACTION platform	Major	Activity parameters must be measured (e.g. pulse frequency, body temperature) by sensors	For input to the AGC algorithm to make prediction of glucose levels activity parameters are required. Which ones are still tbd but heart rate and body temperature should be included.	Activity parameter sensors must be integrated into the REACTION e-patch.
REACTION-236	Functional - Inpatient pilot application	Major	Blood glucose measurements in Inpatient environment	PoC devices are currently used and will be used in Inpatient environment. The procedure is reliable and has been used since several years. Substitution of the used PoC devices with other devices (consortium sensors) in the daily practice can be done only after passing through a very severe procedure. This might not be foreseen (for the daily practice) in this project.	There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose sensors using a procedure which should be quite simple and user friendly.
REACTION-265	Functional - REACTION platform	Major	The clinical parameters to be measured must be specified	For sensor development the type of clinical parameter must be specified to adapt sensor properties to the specific parameter.	Clinical parameters given by the clinicians, but also parameters that are necessary for running the physiological model
REACTION-266	Functional - REACTION platform	Major	Type of sensor/signal should be specified	Type of sensor/signal, whether chemical, electrical, optical, etc. is important for integration in e-patch and sensor platform and for the possibility to build an online sensor.	Type of sensor specified by the sensor manufacturers.
REACTION-267	Functional - REACTION platform	Major	Accuracy/precision of sensors should be specified	For all types of sensors the accuracy/precision has to be known. In some sensors a high accuracy can be required, as, for example, for online monitoring of glucose where a high precision is required, especially in the hypoglycaemic regime.	The accuracy/precision should be specified by the sensor manufacturers.
REACTION-268	Functional - REACTION platform	Major	Response time and drift of the sensors should be specified	Response time of the sensor is important for online monitoring and it may not be too long, drift could influence the accuracy and could require regular calibrations.	Response time and drift should be specified by the sensor manufacturers.

REACTION-269	Functional - REACTION platform	Major	Working range of sensors should be specified (linearity and detection limit)	The working range of the sensors should cover the required ranges as defined by the clinicians and ideally should be linear, the detection limit should be well below the minimal relevant measured variable.	Working range of the different sensors should be specified by the sensor manufacturers.
REACTION-270	Functional - REACTION platform	Major	Operating temperature of sensors should be specified	The temperature might influence the result of the measurement and its accuracy.	Either sensor manufacturers should specify the operating temperature of the sensors or the device should be able to adjust the measurement based on the temperature value (in this case a temperature sensor has to be integrated in the device)
REACTION-271	Functional - REACTION platform	Major	The calibration of the sensors should be specified (strategy, intervals, reference, algorithms)	The sensor must be calibrated before usage and might be re-calibrated after a certain time, also might the calibration required to be individual for a single patient.	Calibration routines of the sensors should be specified by the sensor manufacturers.
REACTION-272	Functional - REACTION platform	Major	The body interface of the sensors should be specified	The body interface of the sensors determines whether it is invasive or non-invasive, it probably influences the accuracy and operating time of the sensors.	The body interface should be specified by the sensor manufacturers.
REACTION-273	Functional - REACTION platform	Major	The sensor safety should follow the device directive 93/42/EEC and subsequent amending directives like the directive 2007/47/EC	The safety directive is essential for sensors being operated on patients. The off-the-shelf sensors/devices and the consortium-designed sensors/devices must comply with the device directives in force. In addition document history files among other quality assurance documents must be available to be submitted to the local authorities when conducting clinical trials.	Sensors should be designed in a way that the directive 93/42/EEC is fulfilled.
REACTION-274	Functional - REACTION platform	Major	The cost of the sensor should be specified	The cost of the sensor determines its later potential for a certain application (outpatient or inpatient use) and is influenced by its production effort.	The cost of the sensor should be specified by the sensor manufacturers and be as low as possible.
REACTION-280	Non-functional - Legal	Major	Device manual for clinical trials	For clinical trials a sensor device manual must be available.	Manual available for clinical trials.

6.2 Requirements of WP4 – Data Management and Service Orchestration

6.2.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-161	Functional - Inpatient pilot application	Major	Active alarm system-reminder to perform measurements	The system should remind caregivers to perform measurements	Active alarm system- reminder to perform measurements is available within the inpatient platform
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed	Check the overall procedure in case of acquired measurements in the alarm range.

6.2.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-3	Functional	Major	Support for IEEE medical device standards	To support a wide variety of medical devices, the selected subsets of the IEEE medical device standards should be supported.	Show that REACTION device proxies can be developed for at least 2 different devices from different manufacturers.
REACTION-6	Functional	Major	Any REACTION device should have an associated semantic model (description)	To facilitate device discovery and application development, a device ontology should be part of the architecture.	New devices can be matched against descriptions in the device ontology.
REACTION-14	Functional	Major	Persistent local/global data storage	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).	At least global storage is supported.

REACTION-16	Functional	Major	Individualized targets for patients needs to be stored and retrieved	Needed to determine the effectiveness of different therapies.	Possible to store targets.
REACTION-20	Functional	Major	Dynamically update and change feedback model	Based on evaluation on received patient data it should be possible to change the feedback model - that is which data to measure and collect.	Possible to change.
REACTION-21	Functional	Major	Change log for feedback model	It must be possible to track changes in the feedback model, i.e. which data has been collected at certain times.	All changes to the feedback model are stored in a change log.
REACTION-22	Functional	Major	Local feedback on measured values	It should be possible to provide feedback on measured values, e.g. graphical representations, to those patients that request it.	Patient able to select requested feedback values.
REACTION-24	Non-functional - Maintainability and portability	Critical	Logging of events from components	All software components shall keep a detailed activity log, which will support the tracing and debugging of possible functioning errors, security holes, mis-configurations and other implementation issues.	A log file will be available for each component, containing data which will be defined by the design process.
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-32	Functional - Outpatient pilot application	Major	The architecture should support the Continua WAN interface (WAN-IF)	Need to support Continua	The REACTION system implements at minimum the IHE PCD01 format
REACTION-42	Non-functional - Maintainability and portability	Major	The technical interfaces to the platform must be documented and in such a way that the stakeholders can understand it and use it for integration.	Developers can develop better applications faster. The platform thus could also provide easy access to third party developers.	Writing sufficient documentation for the technical interfaces and also by providing examples and if available simulators.
REACTION-68	Functional - REACTION platform	Major	Component Versioning	In order to have a good development practice	The test facility will take into account also the version of components

REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-76	Non-functional - Usability	Major	Portability	All components should have the capability of running at least under two of the most common operating systems (e.g. Linux and Windows 7 or XP)	Specific test has to be done on each component
REACTION-134	Non-functional - Performance	Major	Any interface between an end-user and the platform shall have a reasonable maximum response time in condition of public network optimally working	Response time should be quick enough except for reasons independent from the technical design of the platform	The platform when the public network is perfectly working at the max speed shall respond in less than 5 sec in 90% of functions activated by the user interface. No response shall take longer than 10 sec.
REACTION-136	Non-functional - Performance	Major	The platform shall cater for 20 simultaneous users in the field trials. In the end product this number is expected to grow to 100.	A maximum number of simultaneous users has to be fixed. These numbers are very reasonable considering the number of potential end-users at the field trial sites and also considering the initial expectations as product on the market.	The platform will be tested with the max number of simultaneous users verifying that the response time for the most common operations are satisfactory
REACTION-137	Non-functional - Performance	Major	The platform should be able to process the existing end users of the outpatient and inpatient field trials. 300 end-users should be enough. In the market this number is expected to grow to 1000.	In the workshops the maximum number of users in the outpatient and inpatient field trials has been estimated.	The possibility of creating such number of end-users will be tested.

REACTION-154	Functional - REACTION platform	Major	Comorbidities have to be registered	Comorbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient	In the design of data management, ontologies and user interfaces the possibility of registering the comorbidities with a basic set of attributes has to be guaranteed
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)	The inpatient pilot application stores data records/charts
REACTION-156	Functional - Inpatient pilot application	Major	Regular backup of data	Inpatient pilot application offers backup system	Regular backup of data
REACTION-157	Functional - Outpatient pilot application	Major	Annual clinical checks	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).
REACTION-158	Functional - Outpatient pilot application	Major	6-month clinical checks	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-161	Functional - Inpatient pilot application	Major	Active alarm system- reminder to perform measurements	The system should remind caregivers to perform measurements	Active alarm system- reminder to perform measurements is available within the inpatient platform

REACTION-163	Functional - Inpatient pilot application	Major	Archive system: data from former admissions of the same patient can be easily retrieved and used for decision making	The system should store and archive patient related information from former admissions	Data is stored in the system and available after re-admission
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy. Frequency depends on: level of blood glucose control, stability of blood glucose control and change in insulin dose or regimen. Clinicians take decision on the optimal frequency.	Specific fields have to be foreseen in data management, ontologies and user interfaces.
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-195	Functional - Outpatient pilot application	Major	Data management should handle different types of complications for the diabetic patients in the outpatient environment	The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management of foot and neuropathy problems.	In the ontology, user interfaces and applications these complications have to be present
REACTION-201	Functional - Outpatient pilot application	Major	Record baseline physiological measurements at the first visit	At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the platform	The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrolment)

REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-211	Functional - Outpatient pilot application	Major	Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at the first visit.	A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and lifestyle plan	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of video-conference	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up
REACTION-213	Functional - Outpatient pilot application	Major	Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and therapeutic intervention (changes in therapy)	The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed	The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and pharmacological treatment
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-218	Functional - Outpatient pilot application	Major	Patient monitor either manual or through the RPM	In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient can be monitored in the traditional way (manually).	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.

REACTION-219	Functional - Inpatient pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.
REACTION-227	Functional - Inpatient pilot application	Major	Initialization of the fever/sugar chart	Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be registered in the fever/sugar chart	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient
REACTION-229	Functional - Inpatient pilot application	Major	Decision on therapy in Inpatient environment	Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history and associated parameters. It might imply changes in the therapy scheme.	Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the administration of carbohydrates is necessary (hypoglycaemic episode).
REACTION-232	Functional - REACTION platform	Major	Continua Manager emulation	The integration of Continua devices requires a Continua Manager component as part of the architecture. In the absence of such a manager, the system should provide an emulation of the corresponding functionality.	A Continua Manager stub exists allowing simulated access to a Continua device.
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.
REACTION-263	Functional - Inpatient pilot application	Major	Improve documentation quality and streamlined access to information	The registration of all measurements, additional information, decision on treatments, drug administration will improve the quality of documentation. The reduction of the number of missing information and an efficient access to all information related to the patient will improve the quality of care.	The platform shall allow the registration of all relevant information and its contextualized retrieval. In the questionnaires used in the evaluation procedures specific questions should be included in order to verify the user satisfaction about the improvement in the documentation and in the streamlined access to information.

REACTION-264	Non-functional - Performance	Major	Increase accuracy and reduce errors	The registration of all relevant data (vital sign and environmental measurements, nutrition and lifestyle, drugs/insulin administration, adverse events) shall allow a reduction in the errors committed in the current workflows and an improvement in the accuracy of the diabetic patient management	Qualitative and quantitative criteria shall be present in the field trial evaluations in order to measure the reduction of errors compared to the existing workflows before the installation of the REACTION platform and a quality improvement in the clinical decision.

6.2.3 Backend Middleware

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-66	Functional - REACTION platform	Major	Component Interface	Interoperability among components should be guaranteed by the use of standard interfaces.	The test facility will be based on the implemented standard
REACTION-68	Functional - REACTION platform	Major	Component Versioning	In order to have a good development practice	The test facility will take into account also the version of components
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-76	Non-functional - Usability	Major	Portability	All components should have the capability of running at least under two of the most common operating systems (e.g. Linux and Windows 7 or XP)	Specific test has to be done on each component

REACTION-156	Functional - Inpatient pilot application	Major	Regular backup of data	Inpatient pilot application offers backup system	Regular backup of data
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-163	Functional - Inpatient pilot application	Major	Archive system: data from former admissions of the same patient can be easily retrieved and used for decision making	The system should store and archive patient related information from former admissions	Data is stored in the system and available after re-admission
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification
REACTION-211	Functional - Outpatient pilot application	Major	Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at the first visit.	A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and lifestyle plan	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of video-conference	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up

REACTION-213	Functional - Outpatient pilot application	Major	Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and therapeutic intervention (changes in therapy)	The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed	The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and pharmacological treatment
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed	Check the overall procedure in case of acquired measurements in the alarm range.

6.2.4 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-3	Functional	Major	Support for IEEE medical device standards	To support a wide variety of medical devices, the selected subsets of the IEEE medical device standards should be supported.	Show that REACTION device proxies can be developed for at least 2 different devices from different manufacturers.
REACTION-17	Functional	Major	Configurable data transfer frequency	Possibility to configure the periodical transfer of the collected sensor data to external services such as WAN devices.	Lowest periodical transfer is once per day.
REACTION-22	Functional	Major	Local feedback on measured values	It should be possible to provide feedback on measured values, e.g. graphical representations, to those patients that request it.	Patient able to select requested feedback values.
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).

REACTION-28	Functional - REACTION platform	Major	Network interoperability	The communication between applications running in different devices will be based on SOAP messages.	Communication with a service should be feasible by SOAP tools and standards, based on a service's published interface.
REACTION-32	Functional - Outpatient pilot application	Major	The architecture should support the Continua WAN interface (WAN-IF)	Need to support Continua	The REACTION system implements at minimum the IHE PCD01 format
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-161	Functional - Inpatient pilot application	Major	Active alarm system-reminder to perform measurements	The system should remind caregivers to perform measurements	Active alarm system- reminder to perform measurements is available within the inpatient platform
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification

6.2.5 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-12	Functional	Major	Automatic update on lifestyle data	Automatic update of lifestyle data based on sensors such as pedometers but also retrieval from health and lifestyle services and databases.	At least one external service is supported.

REACTION-14	Functional	Major	Persistent local/global data storage	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).	At least global storage is supported.
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)	The inpatient pilot application stores data records/charts
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-161	Functional - Inpatient pilot application	Major	Active alarm system-reminder to perform measurements	The system should remind caregivers to perform measurements	Active alarm system- reminder to perform measurements is available within the inpatient platform

REACTION-167	Functional - REACTION platform	Major	Use of contextualized data at medical decision and predictive models	Medical decision and predictive models have to use contextualized data in such a way that measurements will be annotated with context before they can be used by any algorithm	Data for medical decision and predictive models.
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification
REACTION-228	Functional - Inpatient pilot application	Major	Blood glucose measurements have to be contextualized (e.g. before/after meal)	The availability of the blood glucose measurements shall be accompanied also by the context of the measurements	Measurements before any usage have to be contextualized
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.
REACTION-239	Functional - Inpatient pilot application	Major	Special examinations/treatments to be registered in fever chart	For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases the treatment is adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). A problem for the patient may arise if the patient has to wait longer than expected due to unexpected delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). Therefore, the dose of insulin and/or OADs will be adapted, the patient will get some food which he can eat in case of hypoglycaemia and the patient will get insulin which will be injected in case of hyperglycaemia.	These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the therapy scheme.

REACTION-246	Functional - Inpatient pilot application	Major	Multi-user availability and display of the fever chart	The fever chart shall be considered as a central document and collects all the information about the patient stay in the hospital ward (blood glucose level, temperature, vital signs, information about the actual status of the patients, drug administration, nutrition, relevant events, etc.)	Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.
REACTION-284	Functional - Inpatient pilot application	Major	Clinical data to be stored in the Inpatient environment	The data management shall be design in order to allow the storage of the clinical data to be registered at the patient enrolment and other clinical parameters which have to be acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, comorbidities, therapy scheme. Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, estimation of insulin sensitivity and resistance. The possibility of adding further parameters should be foreseen in the design.	The data management shall allow the insertion and the update of all the listed clinical parameters.

6.2.6 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-39	Non-functional - Security	Critical	Platform Integrity (integrity checks for the stored data)	To guarantee the integrity of the stored data in the case of an unwanted happening.	Use of adequate methods like e.g. Hash keys or redundancy codes for the data stored.
REACTION-62	Functional - REACTION platform	Major	Semantics based data management	According to the DoW the monitoring and other data need to be properly annotated with ontological descriptions in order to achieve integration and interoperability	Relevant entries in the REACTION's databases are annoted with semantic concepts

REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-154	Functional - REACTION platform	Major	Comorbidities have to be registered	Comorbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient	In the design of data management, ontologies and user interfaces the possibility of registering the comorbidities with a basic set of attributes has to be guaranteed
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)	The inpatient pilot application stores data records/charts
REACTION-157	Functional - Outpatient pilot application	Major	Annual clinical checks	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).

REACTION-158	Functional - Outpatient pilot application	Major	6-month clinical checks	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-161	Functional - Inpatient pilot application	Major	Active alarm system- reminder to perform measurements	The system should remind caregivers to perform measurements	Active alarm system- reminder to perform measurements is available within the inpatient platform
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy. Frequency depends on: level of blood glucose control, stability of blood glucose control and change in insulin dose or regimen. Clinicians take decision on the optimal frequency.	Specific fields have to be foreseen in data management, ontologies and user interfaces.
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-195	Functional - Outpatient pilot application	Major	Data management should handle different types of complications for the diabetic patients in the outpatient environment	The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management of foot and neuropathy problems.	In the ontology, user interfaces and applications these complications have to be present
REACTION-201	Functional - Outpatient pilot application	Major	Record baseline physiological measurements at the first visit	At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the platform	The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrolment)

REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-211	Functional - Outpatient pilot application	Major	Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at the first visit.	A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and lifestyle plan	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of video-conference	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up
REACTION-213	Functional - Outpatient pilot application	Major	Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and therapeutic intervention (changes in therapy)	The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed	The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and pharmacological treatment
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-218	Functional - Outpatient pilot application	Major	Patient monitor either manual or through the RPM	In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient can be monitored in the traditional way (manually).	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.

REACTION-219	Functional - Inpatient pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.
REACTION-227	Functional - Inpatient pilot application	Major	Initialization of the fever/sugar chart	Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be registered in the fever/sugar chart	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient
REACTION-228	Functional - Inpatient pilot application	Major	Blood glucose measurements have to be contextualized (e.g. before/after meal)	The availability of the blood glucose measurements shall be accompanied also by the context of the measurements	Measurements before any usage have to be contextualized
REACTION-229	Functional - Inpatient pilot application	Major	Decision on therapy in Inpatient environment	Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history and associated parameters. It might imply changes in the therapy scheme.	Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the administration of carbohydrates is necessary (hypoglycaemic episode).
REACTION-232	Functional - REACTION platform	Major	Continua Manager emulation	The integration of Continua devices requires a Continua Manager component as part of the architecture. In the absence of such a manager, the system should provide an emulation of the corresponding functionality.	A Continua Manager stub exists allowing simulated access to a Continua device.
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.

REACTION-238	Functional - Inpatient pilot application	Major	Update and entering of drug administration (OAD and/or insulin) data	Drug administration (time, type, dosage and other relevant information) has to be immediately annotated in the fever chart by the administering nurse.	The nurse through an appropriate user interface can check the last drug administration and insert the relevant data related to the drug administration she has just performed.
REACTION-239	Functional - Inpatient pilot application	Major	Special examinations/treatments to be registered in fever chart	For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases the treatment is adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). A problem for the patient may arise if the patient has to wait longer than expected due to unexpected delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). Therefore, the dose of insulin and/or OADs will be adapted, the patient will get some food which he can eat in case of hypoglycaemia and the patient will get insulin which will be injected in case of hyperglycaemia.	These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the therapy scheme.
REACTION-246	Functional - Inpatient pilot application	Major	Multi-user availability and display of the fever chart	The fever chart shall be considered as a central document and collects all the information about the patient stay in the hospital ward (blood glucose level, temperature, vital signs, information about the actual status of the patients, drug administration, nutrition, relevant events, etc.)	Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.
REACTION-248	Functional - Inpatient pilot application	Major	Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.

REACTION-284	Functional - Inpatient pilot application	Major	Clinical data to be stored in the Inpatient environment	The data management shall be design in order to allow the storage of the clinical data to be registered at the patient enrolment and other clinical parameters which have to be acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, comorbidities, therapy scheme. Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, estimation of insulin sensitivity and resistance. The possibility of adding further parameters should be foreseen in the design.	The data management shall allow the insertion and the update of all the listed clinical parameters.

6.2.7 Glucose Control Algorithms

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-219	Functional - Inpatient pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.

REACTION-251	Functional - Inpatient pilot application	Major	Creation of electronic decision support rules shall be supported	An electronic decision support system with standardised instructions and decisions (e.g. evidence based medicine, support identification of "patients at risk") shall be present. There have to be "guidelines" on how to titrate insulin. An active alarm system would remind the staff to perform measurements/injections.	Suggestions on treatments shall be available in order to facilitate the clinical decision. An available protocol from literature (e.g. RABBIT II trial) should be implemented and improved. Alerts for next insulin administration should be provided together with a support for calculation of insulin amount depending on known (acquired or estimated/evaluated) parameters.

6.2.8 Interfaces with HIS/EPR

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-154	Functional - REACTION platform	Major	Comorbidities have to be registered	Comorbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient	In the design of data management, ontologies and user interfaces the possibility of registering the comorbidities with a basic set of attributes has to be guaranteed

REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)	The inpatient pilot application stores data records/charts
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.

6.2.9 Networking

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-28	Functional - REACTION platform	Major	Network interoperability	The communication between applications running in different devices will be based on SOAP messages.	Communication with a service should be feasible by SOAP tools and standards, based on a service's published interface.
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)	The inpatient pilot application stores data records/charts

REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification

6.2.10 Ontology/Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-154	Functional - REACTION platform	Major	Comorbidities have to be registered	Comorbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient	In the design of data management, ontologies and user interfaces the possibility of registering the comorbidities with a basic set of attributes has to be guaranteed
REACTION-157	Functional - Outpatient pilot application	Major	Annual clinical checks	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).

REACTION-158	Functional - Outpatient pilot application	Major	6-month clinical checks	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy. Frequency depends on: level of blood glucose control, stability of blood glucose control and change in insulin dose or regimen. Clinicians take decision on the optimal frequency.	Specific fields have to be foreseen in data management, ontologies and user interfaces.
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-195	Functional - Outpatient pilot application	Major	Data management should handle different types of complications for the diabetic patients in the outpatient environment	The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management of foot and neuropathy problems.	In the ontology, user interfaces and applications these complications have to be present
REACTION-201	Functional - Outpatient pilot application	Major	Record baseline physiological measurements at the first visit	At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the platform	The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrolment)
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)	An enrolled patient can be assigned to a configurable RPM scheme

REACTION-211	Functional - Outpatient pilot application	Major	Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at the first visit.	A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and lifestyle plan	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of video-conference	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up
REACTION-213	Functional - Outpatient pilot application	Major	Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and therapeutic intervention (changes in therapy)	The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed	The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and pharmacological treatment
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-218	Functional - Outpatient pilot application	Major	Patient monitor either manual or through the RPM	In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient can be monitored in the traditional way (manually).	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.

REACTION-219	Functional - Inpatient pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.
REACTION-231	Functional - Inpatient pilot application	Major	End of process for the diabetic patient in the inpatient environment	The workflows in the Inpatient glycaemic control management ends with the patient discharge from the department. However, there should be a transition of care (from inpatient to outpatient) which should be considered in the discharge management.	At the patient discharge from the department, the workflow related to the patient has to be terminated
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.
REACTION-239	Functional - Inpatient pilot application	Major	Special examinations/treatments to be registered in fever chart	For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases the treatment is adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). A problem for the patient may arise if the patient has to wait longer than expected due to unexpected delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). Therefore, the dose of insulin and/or OADs will be adapted, the patient will get some food which he can eat in case of hypoglycaemia and the patient will get insulin which will be injected in case of hyperglycaemia.	These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the therapy scheme.

REACTION-248	Functional - Inpatient pilot application	Major	Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.

6.2.11 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)	An enrolled patient can be assigned to a configurable RPM scheme

REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.

6.2.12 Physiology Models

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-219	Functional - Inpatient pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.

6.2.13 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-6	Functional	Major	Any REACTION device should have an associated semantic model (description)	To facilitate device discovery and application development, a device ontology should be part of the architecture.	New devices can be matched against descriptions in the device ontology.
REACTION-9	Functional	Major	Formalized feedback model	A model describing which parameters to be collected, the frequency of collection, and target users of the data	System is able to provide feedback in satisfactory time
REACTION-10	Functional	Major	Data fusion model	A description of how different data values are combined into medical data	The system can provide automatic aggregation of data values from at least two different sensors.
REACTION-11	Functional - Outpatient pilot application	Major	Life style baseline data	The system needs to store a set of baseline data regarding life style for each patient.	Life style data can be retrieved and updated per patient
REACTION-14	Functional	Major	Persistent local/global data storage	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).	At least global storage is supported.
REACTION-16	Functional	Major	Individualized targets for patients needs to be stored and retrieved	Needed to determine the effectiveness of different therapies.	Possible to store targets.
REACTION-20	Functional	Major	Dynamically update and change feedback model	Based on evaluation on received patient data it should be possible to change the feedback model - that is which data to measure and collect.	Possible to change.
REACTION-21	Functional	Major	Change log for feedback model	It must be possible to track changes in the feedback model, i.e. which data has been collected at certain times.	All changes to the feedback model are stored in a change log.
REACTION-22	Functional	Major	Local feedback on measured values	It should be possible to provide feedback on measured values, e.g. graphical representations, to those patients that request it.	Patient able to select requested feedback values.
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).

REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.

6.2.14 Portable User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).

REACTION-164	Functional - REACTION platform	Major	Common schema for data exchange between user interface (Health Status Profile) and integrated modules within WP6	It is essential to define and set schemas for the communication and interaction between modules within the Health Status Profile system.	Standardises Interfaces
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.

6.2.15 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data	Platform flexibly supports processing of data from multiple sources

REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-164	Functional - REACTION platform	Major	Common schema for data exchange between user interface (Health Status Profile) and integrated modules within WP6	It is essential to define and set schemas for the communication and interaction between modules within the Health Status Profile system.	Standardises Interfaces
REACTION-167	Functional - REACTION platform	Major	Use of contextualized data at medical decision and predictive models	Medical decision and predictive models have to use contextualized data in such a way that measurements will be annotated with context before they can be used by any algorithm	Data for medical decision and predictive models.
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy. Frequency depends on: level of blood glucose control, stability of blood glucose control and change in insulin dose or regimen. Clinicians take decision on the optimal frequency.	Specific fields have to be foreseen in data management, ontologies and user interfaces.
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed	Check the overall procedure in case of acquired measurements in the alarm range.

REACTION-219	Functional - Inpatient pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.
REACTION-251	Functional - Inpatient pilot application	Major	Creation of electronic decision support rules shall be supported	An electronic decision support system with standardised instructions and decisions (e.g. evidence based medicine, support identification of "patients at risk") shall be present. There have to be "guidelines" on how to titrate insulin. An active alarm system would remind the staff to perform measurements/injections.	Suggestions on treatments shall be available in order to facilitate the clinical decision. An available protocol from literature (e.g. RABBIT II trial) should be implemented and improved. Alerts for next insulin administration should be provided together with a support for calculation of insulin amount depending on known (acquired or estimated/evaluated) parameters.

6.2.16 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-39	Non-functional - Security	Critical	Platform Integrity (integrity checks for the stored data)	To guarantee the integrity of the stored data in the case of an unwanted happening.	Use of adequate methods like e.g. Hash keys or redundancy codes for the data stored.

REACTION-43	Non-functional - Security	Critical	Protection against data loss System must protect against: *Loss or replication of data transferred between two systems; *Concurrency problems; *Disk crash; *Protection against physical means.	Data integrity has to be guaranteed. *Loss or replication of data transferred between two systems (e.g. system shutdown); *Concurrency problems (e.g. 2 doctors interact with the system simutaneously and prescribe different medicines, which one will the system pick?); *Disk crash (e.g. solution could be periodic backup or RAID); *Protection against physical means (e.g. solution could be remote backup)	The functional test should include specific tests in order to verify such circumstances
REACTION-93	Non-functional - Security	Major	Confidentiality: Sensitive information must not be readable by unauthorised persons	Various stakeholders exchange information over the REACTION platform which, without any safeguards, would allow third parties to learn sensitive information of patients	Availability of a mechanism for ensuring data confidentiality
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)	The inpatient pilot application stores data records/charts

6.2.17 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).

REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.

6.2.18 Web User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).

REACTION-154	Functional - REACTION platform	Major	Comorbidities have to be registered	Comorbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient	In the design of data management, ontologies and user interfaces the possibility of registering the comorbidities with a basic set of attributes has to be guaranteed
REACTION-157	Functional - Outpatient pilot application	Major	Annual clinical checks	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).
REACTION-158	Functional - Outpatient pilot application	Major	6-month clinical checks	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).
REACTION-161	Functional - Inpatient pilot application	Major	Active alarm system- reminder to perform measurements	The system should remind caregivers to perform measurements	Active alarm system- reminder to perform measurements is available within the inpatient platform
REACTION-164	Functional - REACTION platform	Major	Common schema for data exchange between user interface (Health Status Profile) and integrated modules within WP6	It is essential to define and set schemas for the communication and interaction between modules within the Health Status Profile system.	Standardises Interfaces
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy. Frequency depends on: level of blood glucose control, stability of blood glucose control and change in insulin dose or regimen. Clinicians take decision on the optimal frequency.	Specific fields have to be foreseen in data management, ontologies and user interfaces.

REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-195	Functional - Outpatient pilot application	Major	Data management should handle different types of complications for the diabetic patients in the outpatient environment	The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management of foot and neuropathy problems.	In the ontology, user interfaces and applications these complications have to be present
REACTION-201	Functional - Outpatient pilot application	Major	Record baseline physiological measurements at the first visit	At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the platform	The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrolment)
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-211	Functional - Outpatient pilot application	Major	Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at the first visit.	A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and lifestyle plan	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of video-conference	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up

REACTION-213	Functional - Outpatient pilot application	Major	Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and therapeutic intervention (changes in therapy)	The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed	The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and pharmacological treatment
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-218	Functional - Outpatient pilot application	Major	Patient monitor either manual or through the RPM	In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient can be monitored in the traditional way (manually).	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.
REACTION-219	Functional - Inpatient pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.
REACTION-227	Functional - Inpatient pilot application	Major	Initialization of the fever/sugar chart	Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be registered in the fever/sugar chart	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient
REACTION-229	Functional - Inpatient pilot application	Major	Decision on therapy in Inpatient environment	Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history and associated parameters. It might imply changes in the therapy scheme.	Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the administration of carbohydrates is necessary (hypoglycaemic episode).

REACTION-231	Functional - Inpatient pilot application	Major	End of process for the diabetic patient in the inpatient environment	The workflows in the Inpatient glycaemic control management ends with the patient discharge from the department. However, there should be a transition of care (from inpatient to outpatient) which should be considered in the discharge management.	At the patient discharge from the department, the workflow related to the patient has to be terminated
REACTION-238	Functional - Inpatient pilot application	Major	Update and entering of drug administration (OAD and/or insulin) data	Drug administration (time, type, dosage and other relevant information) has to be immediately annotated in the fever chart by the administering nurse.	The nurse through an appropriate user interface can check the last drug administration and insert the relevant data related to the drug administration she has just performed.
REACTION-239	Functional - Inpatient pilot application	Major	Special examinations/treatments to be registered in fever chart	For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases the treatment is adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). A problem for the patient may arise if the patient has to wait longer than expected due to unexpected delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). Therefore, the dose of insulin and/or OADs will be adapted, the patient will get some food which he can eat in case of hypoglycaemia and the patient will get insulin which will be injected in case of hyperglycaemia.	These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the therapy scheme.
REACTION-246	Functional - Inpatient pilot application	Major	Multi-user availability and display of the fever chart	The fever chart shall be considered as a central document and collects all the information about the patient stay in the hospital ward (blood glucose level, temperature, vital signs, information about the actual status of the patients, drug administration, nutrition, relevant events, etc.)	Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.

6.3 Requirements of WP5 – Network Management and Service Execution

6.3.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-88	Functional - Outpatient pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None
REACTION-160	Functional - Outpatient pilot application	Major	Alerts for the annual and 6-month clinical checks	When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the action to be taken (content and frequency of the alert should be agreed)	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency
REACTION-252	Functional - Inpatient pilot application	Major	When some measurements are missing the system shall remind it through an active alarm reminder	Sometimes nurses forget to perform measurements. An active alarm system shall remind to perform the missing measurements. Regular measurements are necessary in order to have an optimal clinical decision and to minimize adverse events.	When a configurable time after the expected measurement acquisition time is elapsed, the system should send (at regular intervals) an alert to the nurse(s) in duty in order to perform the missing measurements.

6.3.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-19	Non-functional - Maintainability and portability	Major	Necessity of a mobile solution for the outpatient sphere	People tend to be moving and travelling.	Same service everywhere.
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-87	Non-functional - Operational	Major	Define network architectural model	Handle resources and services in heterogeneous networks (define heterogeneous networks) and dynamically change performance data of the resources without restricting only to IP networks. Analysis on existing models and standards.	None
REACTION-124	Functional - REACTION platform	Major	Portable device should collect all the relevant vital signs measured on the patient	A portable with adequate features/performances should collect all the relevant vital signs measured on the patient realizing the BAN	A commercial portable device will be selected in order to perform the internal tests and the field trials
REACTION-125	Functional - REACTION platform	Major	Portable device should collect also additional environmental measurements	The same portable device used for the BAN integration will be used also for the PAN integration collecting also relevant environmental measurements. This solution reduced the overall cost of the acquisition system increasing the sustainability of the platform.	BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium devices/sensors and by off-the-shelf devices used in the platform

REACTION-127	Functional - REACTION platform	Major	Home and mobile gateway	The portable device should be able to act as home and mobile gateway. When connection to the public wireless network is not available at home, the portable device should be able to use a home gateway (PC) in order to send the acquired information. The home gateway should work only as gateway and not as a data collection device. The mobile gateway function has to be performed by the portable device and not by a further hand-held device.	Specific tests have to be performed when public wireless network is not available at home.
REACTION-160	Functional - Outpatient pilot application	Major	Alerts for the annual and 6-month clinical checks	When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the action to be taken (content and frequency of the alert should be agreed)	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.	RPM module has to be present in the Outpatient field trials
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently	Achieving location independence and multi-user support
REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by clinicians and/or nurses	Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.

6.3.3 Backend Middleware

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-88	Functional - Outpatient pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently	Achieving location independence and multi-user support
REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by clinicians and/or nurses	Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.

6.3.4 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-1	Functional - Outpatient pilot application	Major	Internet communication between patient home and primary/secondary healthcare structures based on public wired or wireless network	A basic communication infrastructure has to be assumed	Tests will be based on this assumption
REACTION-18	Functional	Major	Monitoring devices must be discoverable by existing network infrastructure	Device must be discovered in order to be able to communicate with other devices and platforms.	At least to automatically discover devices using protocols supported in the Hydra middleware such as BT, ZigBee etc.
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-34	Functional - Outpatient pilot application	Major	Define "black box" to be used at outpatient environment	Define the hardware to be used at the outpatient environment for acquiring and transmitting sensor data to the REACTION middleware (use a mobile device or a "home-pc").	None
REACTION-54	Functional	Major	Network & system monitoring	Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements using SNMP and Netflow Records for network monitoring, in order to verify QoS, as well as network and systems' monitoring services.	none
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database

REACTION-87	Non-functional - Operational	Major	Define network architectural model	Handle resources and services in heterogeneous networks (define heterogeneous networks) and dynamically change performance data of the resources without restricting only to IP networks. Analysis on existing models and standards.	None
REACTION-88	Functional - Outpatient pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None
REACTION-89	Functional - REACTION platform	Major	Network management subsets	Define network management subsets for data traffic management between Patient's sphere and Carer's sphere communication. Integration and communication of back-end systems and EHRs with BAN & PAN components.	None
REACTION-123	Functional - REACTION platform	Critical	Define components and services	Define the necessary components, services and orchestration methods under a Service Oriented Architecture perspective.	none
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently	Achieving location independence and multi-user support

6.3.5 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently	Achieving location independence and multi-user support

6.3.6 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-54	Functional	Major	Network & system monitoring	Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements using SNMP and Netflow Records for network monitoring, in order to verify QoS, as well as network and systems' monitoring services.	none
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-123	Functional - REACTION platform	Critical	Define components and services	Define the necessary components, services and orchestration methods under a Service Oriented Architecture perspective.	none
REACTION-160	Functional - Outpatient pilot application	Major	Alerts for the annual and 6-month clinical checks	When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the action to be taken (content and frequency of the alert should be agreed)	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently	Achieving location independence and multi-user support
REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by clinicians and/or nurses	Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.

6.3.7 Glucose Control Algorithms

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by clinicians and/or nurses	Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.

6.3.8 Networking

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-34	Functional - Outpatient pilot application	Major	Define "black box" to be used at outpatient environment	Define the hardware to be used at the outpatient environment for acquiring and transmitting sensor data to the REACTION middleware (use a mobile device or a "home-pc").	None
REACTION-54	Functional	Major	Network & system monitoring	Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements using SNMP and Netflow Records for network monitoring, in order to verify QoS, as well as network and systems' monitoring services.	none

REACTION-87	Non-functional - Operational	Major	Define network architectural model	Handle resources and services in heterogeneous networks (define heterogeneous networks) and dynamically change performance data of the resources without restricting only to IP networks. Analysis on existing models and standards.	None
REACTION-89	Functional - REACTION platform	Major	Network management subsets	Define network management subsets for data traffic management between Patient's sphere and Carer's sphere communication. Integration and communication of back-end systems and EHRs with BAN & PAN components.	None
REACTION-123	Functional - REACTION platform	Critical	Define components and services	Define the necessary components, services and orchestration methods under a Service Oriented Architecture perspective.	none
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently	Achieving location independence and multi-user support

6.3.9 Ontology/Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-160	Functional - Outpatient pilot application	Major	Alerts for the annual and 6-month clinical checks	When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the action to be taken (content and frequency of the alert should be agreed)	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency
REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by clinicians and/or nurses	Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.

6.3.10 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-89	Functional - REACTION platform	Major	Network management subsets	Define network management subsets for data traffic management between Patient's sphere and Carer's sphere communication. Integration and communication of back-end systems and EHRs with BAN & PAN components.	None
REACTION-124	Functional - REACTION platform	Major	Portable device should collect all the relevant vital signs measured on the patient	A portable with adequate features/performances should collect all the relevant vital signs measured on the patient realizing the BAN	A commercial portable device will be selected in order to perform the internal tests and the field trials
REACTION-125	Functional - REACTION platform	Major	Portable device should collect also additional environmental measurements	The same portable device used for the BAN integration will be used also for the PAN integration collecting also relevant environmental measurements. This solution reduced the overall cost of the acquisition system increasing the sustainability of the platform.	BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium devices/sensors and by off-the-shelf devices used in the platform
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.	RPM module has to be present in the Outpatient field trials

6.3.11 Physiology Models

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database

6.3.12 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-34	Functional - Outpatient pilot application	Major	Define "black box" to be used at outpatient environment	Define the hardware to be used at the outpatient environment for acquiring and transmitting sensor data to the REACTION middleware (use a mobile device or a "home-pc").	None
REACTION-54	Functional	Major	Network & system monitoring	Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements using SNMP and Netflow Records for network monitoring, in order to verify QoS, as well as network and systems' monitoring services.	none
REACTION-79	Constraint - Off-the-Shelf Sensors & Devices	Major	Off-the-Shelf Devices	Non standard communication protocols imply a significant development effort. Such development effort can be very huge and very often also not feasible if non standard protocol is non disclosed.	The commercial devices not developed by the consortium have to be compliant with relevant communication standard or, only in special cases, have a full-disclosed protocol
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-88	Functional - Outpatient pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None

REACTION-124	Functional - REACTION platform	Major	Portable device should collect all the relevant vital signs measured on the patient	A portable with adequate features/performances should collect all the relevant vital signs measured on the patient realizing the BAN	A commercial portable device will be selected in order to perform the internal tests and the field trials
REACTION-125	Functional - REACTION platform	Major	Portable device should collect also additional environmental measurements	The same portable device used for the BAN integration will be used also for the PAN integration collecting also relevant environmental measurements. This solution reduced the overall cost of the acquisition system increasing the sustainability of the platform.	BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium devices/sensors and by off-the-shelf devices used in the platform
REACTION-127	Functional - REACTION platform	Major	Home and mobile gateway	The portable device should be able to act as home and mobile gateway. When connection to the public wireless network is not available at home, the portable device should be able to use a home gateway (PC) in order to send the acquired information. The home gateway should work only as gateway and not as a data collection device. The mobile gateway function has to be performed by the portable device and not by a further hand-held device.	Specific tests have to be performed when public wireless network is not available at home.
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.	RPM module has to be present in the Outpatient field trials

6.3.13 Portable User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database

REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.	RPM module has to be present in the Outpatient field trials

6.3.14 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database

6.3.15 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-94	Non-functional - Security	Major	Availability: Patient data and other resources must be available to ensure proper treatment	Non-availability of patient data will hamper further treatment and might even impair the patient's health	REACTION platform should remain operational in case of failures
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently	Achieving location independence and multi-user support

6.3.16 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-79	Constraint - Off-the-Shelf Sensors & Devices	Major	Off-the-Shelf Devices	Non standard communication protocols imply a significant development effort. Such development effort can be very huge and very often also not feasible if non standard protocol is non disclosed.	The commercial devices not developed by the consortium have to be compliant with relevant communication standard or, only in special cases, have a full-disclosed protocol
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database

REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.	RPM module has to be present in the Outpatient field trials

6.3.17 Web User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-160	Functional - Outpatient pilot application	Major	Alerts for the annual and 6-month clinical checks	When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the action to be taken (content and frequency of the alert should be agreed)	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.	RPM module has to be present in the Outpatient field trials
REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by clinicians and/or nurses	Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.

6.4 Requirements of WP6 – Integrative Risk Assessment and Feedback

6.4.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool
REACTION-184	Functional - Outpatient pilot application	Major	Risk values for HbA1c	Maintaining glycated haemoglobin (HbA1c) below 7.5% is likely to minimize risk of developing diabetic complications. If there is evidence of increased arterial disease risk (raised albumin excretion rate, features of metabolic syndrome or other arterial risk factors), HbA1c should be maintained under 6.5% or even less.	Thresholds have to be foreseen in the risk assessment module and advices have to be sent to patients.
REACTION-192	Functional - REACTION platform	Major	Thresholds for hypoglycaemia and hyperglycaemia	Different configurable thresholds shall be present for the detection of serious and life-threatening hypoglycaemic and hyperglycaemic episodes	Once made sure the blood glucose level was correctly measured, values under specific thresholds (hypoglycaemia) or over specific thresholds (hyperglycaemia) should generate alerts or alarms specifically when the episode is considered to be life-threatening.

REACTION-193	Functional - Outpatient pilot application	Major	Alarm & alert generation	The alerts and alarms should not be generated too often in such a way the system will be considered too intrusive for the patient himself. However serious and especially life-threatening situations have to be promptly signalled. ROC analysis might be used in order to tune the alarm and alert system.	Some serious or life-threatening situations can be simulated in the integration environment and the production of adequate alarms can be verified.

6.4.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool

6.4.3 Backend Middleware

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)

6.4.4 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)

6.4.5 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-101	Functional - Inpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence based literature to the decision support system to help clinicians in decision making	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-222	Functional - Inpatient pilot application	Major	Insulin evaluation in Inpatient environment	The data used for the insulin evaluation have to be contextualized before their usage and then passed to mathematical algorithms for the calculation of the required insulin doses. Results have to be fed to dedicated diabetes experts specialized in glycaemic control for verification and evaluation. Their appraisal have to be fed back to physicians and nurses at the point of care in the patient ward.	The glucose control algorithms have to evaluate the insulin based on the parameters described above.

REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).	Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion shall be available
REACTION-243	Functional - Inpatient pilot application	Major	Nutrition has to be taken into account in the calculation of the drug dosage	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
REACTION-244	Functional - Inpatient pilot application	Major	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose-interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.
REACTION-255	Functional - Inpatient pilot application	Major	Management of missing data	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...).	In case of missing data, the Inpatient application shall ask for them or make a good guess on default values based on context. For critical medical parameters (e.g. blood glucose, lab values) instead of offering automatic default values, it would be probably better to show past values and the user has to choose the appropriate one.

6.4.6 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services. Step 1: Use physiology-based model to "in-vitro" validate the decision support system of the inpatient scenario Step 2: Integrate the physiology-based model into the decision support system for more individualized decision support, and finally validate in clinical studies.	Mechanistic physiology-based models are available within the REACTION platform
REACTION-81	Functional - REACTION platform	Major	Long-term risk calculation and patient-oriented presentation	Calculate long-term risk based on patient health profile and: - visualize in a patient-oriented form - present risk-reduction strategies to patient and caregivers to support patient education and empowerment The risk calculator mainly will be used in the outpatient/primary care area for patient empowerment and patient education and also as input for decision support	The REACTION platform offers a service to calculate diabetes dependent long-term risks

REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-222	Functional - Inpatient pilot application	Major	Insulin evaluation in Inpatient environment	The data used for the insulin evaluation have to be contextualized before their usage and then passed to mathematical algorithms for the calculation of the required insulin doses. Results have to be fed to dedicated diabetes experts specialized in glycaemic control for verification and evaluation. Their appraisal have to be fed back to physicians and nurses at the point of care in the patient ward.	The glucose control algorithms have to evaluate the insulin based on the parameters described above.
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).	Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion shall be available
REACTION-243	Functional - Inpatient pilot application	Major	Nutrition has to be taken into account in the calculation of the drug dosage	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
REACTION-244	Functional - Inpatient pilot application	Major	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose-interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.

REACTION-255	Functional - Inpatient pilot application	Major	Management of missing data	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...).	In case of missing data, the Inpatient application shall ask for them or make a good guess on default values based on context. For critical medical parameters (e.g. blood glucose, lab values) instead of offering automatic default values, it would be probably better to show past values and the user has to choose the appropriate one.

6.4.7 Glucose Control Algorithms

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services. Step 1: Use physiology-based model to "in-vitro" validate the decision support system of the inpatient scenario Step 2: Integrate the physiology-based model into the decision support system for more individualized decision support, and finally validate in clinical studies.	Mechanistic physiology-based models are available within the REACTION platform
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)

REACTION-101	Functional - Inpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence based literature to the decision support system to help clinicians in decision making	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-185	Constraint - Solution	Major	Diabetic management for type I diabetic patients	Type I diabetic patients will always be on insulin treatment	Glucose management has to be performed only with insulin (and not OAD) to type I diabetic patients
REACTION-222	Functional - Inpatient pilot application	Major	Insulin evaluation in Inpatient environment	The data used for the insulin evaluation have to be contextualized before their usage and then passed to mathematical algorithms for the calculation of the required insulin doses. Results have to be fed to dedicated diabetes experts specialized in glycaemic control for verification and evaluation. Their appraisal have to be fed back to physicians and nurses at the point of care in the patient ward.	The glucose control algorithms have to evaluate the insulin based on the parameters described above.
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).	Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion shall be available
REACTION-243	Functional - Inpatient pilot application	Major	Nutrition has to be taken into account in the calculation of the drug dosage	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
REACTION-244	Functional - Inpatient pilot application	Major	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose-interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.

6.4.8 Interfaces with HIS/EPR

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services. Step 1: Use physiology-based model to "in-vitro" validate the decision support system of the inpatient scenario Step 2: Integrate the physiology-based model into the decision support system for more individualized decision support, and finally validate in clinical studies.	Mechanistic physiology-based models are available within the REACTION platform
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)

6.4.9 Networking

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform

REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application

6.4.10 Ontology/Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-101	Functional - Inpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence based literature to the decision support system to help clinicians in decision making	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).	Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion shall be available

REACTION-244	Functional - Inpatient pilot application	Major	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose-interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.

6.4.11 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application

6.4.12 Physiology Models

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application

REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services. Step 1: Use physiology-based model to "in-vitro" validate the decision support system of the inpatient scenario Step 2: Integrate the physiology-based model into the decision support system for more individualized decision support, and finally validate in clinical studies.	Mechanistic physiology-based models are available within the REACTION platform
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).	Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion shall be available

6.4.13 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application

REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services. Step 1: Use physiology-based model to "in-vitro" validate the decision support system of the inpatient scenario Step 2: Integrate the physiology-based model into the decision support system for more individualized decision support, and finally validate in clinical studies.	Mechanistic physiology-based models are available within the REACTION platform
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-162	Non-functional - Usability	Major	Documentation of user interface (Health Status Profile)	Documentation for User Interface of the Health Status Profile as part of REACTION.	User manual for user interface of Health Status profile.

6.4.14 Portable User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool

REACTION-98	Functional - Inpatient pilot application	Minor	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital (when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of risk.	If a diabetic patient is not on insulin therapy, the platform shall be able to estimate the risk for the particular patient to become insulin-dependent. Inpatient REACTION pilot decision support tool offers "patients at risk" calculator.
REACTION-101	Functional - Inpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence based literature to the decision support system to help clinicians in decision making	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-162	Non-functional - Usability	Major	Documentation of user interface (Health Status Profile)	Documentation for User Interface of the Health Status Profile as part of REACTION.	User manual for user interface of Health Status profile.

6.4.15 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner

REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services. Step 1: Use physiology-based model to "in-vitro" validate the decision support system of the inpatient scenario Step 2: Integrate the physiology-based model into the decision support system for more individualized decision support, and finally validate in clinical studies.	Mechanistic physiology-based models are available within the REACTION platform
REACTION-81	Functional - REACTION platform	Major	Long-term risk calculation and patient-oriented presentation	Calculate long-term risk based on patient health profile and: - visualize in a patient-oriented form - present risk-reduction strategies to patient and caregivers to support patient education and empowerment The risk calculator mainly will be used in the outpatient/primary care area for patient empowerment and patient education and also as input for decision support	The REACTION platform offers a service to calculate diabetes dependent long-term risks
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-86	Functional - REACTION platform	Major	Estimate short- and mid-term risk and identify successful therapy schemes for patient groups	For the REACTION project data mining methods and heuristic algorithms should be used in order to identify: - risk profiles for short- and mid-term risk based on stratification of population health data in large populations - successful therapy strategies for different patient groups to be used as input for decision support	Health risk profiles (short- and mid-term) are available for risk profiling and knowledge discovery within the data sets can be conducted. Based on a score for "therapy success" more successful therapies can be identified for different patient groups.
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool

REACTION-98	Functional - Inpatient pilot application	Minor	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital (when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of risk.	If a diabetic patient is not on insulin therapy, the platform shall be able to estimate the risk for the particular patient to become insulin-dependent. Inpatient REACTION pilot decision support tool offers "patients at risk" calculator.
REACTION-101	Functional - Inpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence based literature to the decision support system to help clinicians in decision making	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-162	Non-functional - Usability	Major	Documentation of user interface (Health Status Profile)	Documentation for User Interface of the Health Status Profile as part of REACTION.	User manual for user interface of Health Status profile.
REACTION-165	Functional - REACTION platform	Major	Error Messages	Error messages for every component within Health Status profile has to be set up in such a way that will be valuable for the end user.	Services and feedback to user.
REACTION-184	Functional - Outpatient pilot application	Major	Risk values for HbA1c	Maintaining glycated haemoglobin (HbA1c) below 7.5% is likely to minimize risk of developing diabetic complications. If there is evidence of increased arterial disease risk (raised albumin excretion rate, features of metabolic syndrome or other arterial risk factors), HbA1c should be maintained under 6.5% or even less.	Thresholds have to be foreseen in the risk assessment module and advices have to be sent to patients.
REACTION-192	Functional - REACTION platform	Major	Thresholds for hypoglycaemia and hyperglycaemia	Different configurable thresholds shall be present for the detection of serious and life-threatening hypoglycaemic and hyperglycaemic episodes	Once made sure the blood glucose level was correctly measured, values under specific thresholds (hypoglycaemia) or over specific thresholds (hyperglycaemia) should generate alerts or alarms specifically when the episode is considered to be life-threatening.
REACTION-193	Functional - Outpatient pilot application	Major	Alarm & alert generation	The alerts and alarms should not be generated too often in such a way the system will be considered too intrusive for the patient himself. However serious and especially life-threatening situations have to be promptly signalled. ROC analysis might be used in order to tune the alarm and alert system.	Some serious or life-threatening situations can be simulated in the integration environment and the production of adequate alarms can be verified.

REACTION-200	Functional - Outpatient pilot application	Major	eQual & Mental Health Score	These scores have to be evaluated after the insertion of the baseline and clinical history and to be presented to the clinicians and saved in the platform	These scores have to be implemented in the risk assessment component
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).	Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion shall be available
REACTION-243	Functional - Inpatient pilot application	Major	Nutrition has to be taken into account in the calculation of the drug dosage	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
REACTION-244	Functional - Inpatient pilot application	Major	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose-interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.

6.4.16 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform

REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application

6.4.17 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform

6.4.18 Web User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing	eDSS is available for the REACTION platform
REACTION-73	Functional - Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application
REACTION-81	Functional - REACTION platform	Major	Long-term risk calculation and patient-oriented presentation	Calculate long-term risk based on patient health profile and: - visualize in a patient-oriented form - present risk-reduction strategies to patient and caregivers to support patient education and empowerment The risk calculator mainly will be used in the outpatient/primary care area for patient empowerment and patient education and also as input for decision support	The REACTION platform offers a service to calculate diabetes dependent long-term risks

REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool
REACTION-98	Functional - Inpatient pilot application	Minor	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital (when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of risk.	If a diabetic patient is not on insulin therapy, the platform shall be able to estimate the risk for the particular patient to become insulin-dependent. Inpatient REACTION pilot decision support tool offers "patients at risk" calculator.
REACTION-101	Functional - Inpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence based literature to the decision support system to help clinicians in decision making	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-162	Non-functional - Usability	Major	Documentation of user interface (Health Status Profile)	Documentation for User Interface of the Health Status Profile as part of REACTION.	User manual for user interface of Health Status profile.
REACTION-243	Functional - Inpatient pilot application	Major	Nutrition has to be taken into account in the calculation of the drug dosage	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
REACTION-244	Functional - Inpatient pilot application	Major	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose-interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.

6.5 Requirements of WP7 – Security, Privacy and Safety

6.5.1 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-104	Non-functional - Security	Major	Need-to-know Basis: Stakeholders processing information should only learn what is necessary to carry out their specific task	In an information processing chain, several stakeholders might be involved but it might not be necessary for every stakeholder to know which exact data another stakeholder has processed	Process design takes into account the need-to-know principle
REACTION-114	Non-functional - Maintainability and portability	Major	Modularity: the system has to be divided into components	It is easier to implement, exchange, and integrate the modules.	REACTION platform should be modular
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).	Each member of the care space will have specific roles and tasks in the patient's care.
REACTION-259	Functional - Inpatient pilot application	Major	Automated patient identification	Automated patient identification to avoid identification mistakes. Risks of wrong patient identification have to be negligible. The REACTION identification system must be flexible enough to integrate existing identification methods employed on site, e.g., wards in a hospital.	An effective, proper and easy-to-use way for automated patient identification, when mobile device is close to the patient (RFID, NFC?) has to be present. For example, each patient might wear wristband with a barcode which identifies the patient. This is standard in many hospitals and in some wards of the inpatient clinical site these wristbands are in use. This way shall reduce errors in patient identification and speed-up the patient management.

6.5.2 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).	Each member of the care space will have specific roles and tasks in the patient's care.

6.5.3 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-102	Non-functional - Legal	Major	Notice: Natural persons should be notified when, how, and to what extent their personal data are communicated to others	Handling of personal data has to conform to privacy laws	Process design takes into account the fair-processing principle

6.5.4 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).	Each member of the care space will have specific roles and tasks in the patient's care.

REACTION-198	Functional - REACTION platform	Major	Information related to informed consent have to be stored in the REACTION platform	An ethical approved informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION platform.	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the paper form signed informed consent and this procedure shall be completed before any other operation can be performed.

6.5.5 Interfaces with HIS/EPR

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).	Each member of the care space will have specific roles and tasks in the patient's care.

6.5.6 Ontology/Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).	Each member of the care space will have specific roles and tasks in the patient's care.

6.5.7 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-45	Non-functional - Security	Critical	Protection against threats	Medical data are sensible data and protection against threats and and unauthorized access should be provided. The system must protect against: *Unauthorized persons obtaining manager rights through the internet (hacking). *Unauthorized persons getting access to personal data. *The system must conform to Law on Handling of Personal Data.	The functional test should include specific tests in order to verify such circumstances
REACTION-63	Functional - REACTION platform	Major	Security and privacy related to patient data	Privacy concerns are of utmost importance. The patient data should be transfer and maintained in a secure way while any access to them should be monitored and logged (getting advantage of a login mechanism available in the applications).	Verify that any access to patient data is logged and is performed in a secure way
REACTION-90	Non-functional - Security	Major	Identifiability: Recipients and senders of information must be identifiable, though not necessarily personally identifiable	Reports/measurements must be assignable to the 'right' patient file/device	Recipients and senders must have unique identifiers
REACTION-91	Non-functional - Security	Major	Authenticity: Processors of information should be able to determine whether the data being processed is authentic	Medical personnel should know if information relating to their patient originates from a known/trusted source, e.g., the patient's blood glucose sensor or medical personnel, in order to assess the data's quality	Availability of a mechanism that allows to verify the authenticity of some information
REACTION-95	Non-functional - Legal	Major	Accountability: Stakeholders should be held accountable for relevant actions	Certain actions or decisions will have an impact on the person making the decision or on the person affected by it, thus it should be clear, e.g., who made the decision, what kind of decision was made, and when was it made	Availability of a procedure or mechanism allowing to review relevant actions of stakeholders

REACTION-99	Non-functional - Security	Major	Authorisation: Stakeholders must be authorised before they are allowed to perform relevant actions	Certain actions are not permitted for everybody but may only be carried out by authorised personnel	Availability of a procedure or mechanism allowing to authorise relevant actions
REACTION-100	Non-functional - Security	Major	Access control: Access to sensitive information should only by given to authorised personnel	Sharing patient data is necessary in health care to treat patients but access should only be given to persons involved in the treatment	Availability of a mechanism allowing to control access to sensitive data
REACTION-102	Non-functional - Legal	Major	Notice: Natural persons should be notified when, how, and to what extent their personal data are communicated to others	Handling of personal data has to conform to privacy laws	Process design takes into account the fair-processing principle
REACTION-103	Non-functional - Legal	Major	Data reduction and data economy: Personal data shall be collected, processed and used as little as possible.	Handling personal data has to conform to privacy laws. In particular, personal data shall be rendered anonymous or pseudonymous as allowed by the purpose for which they are collected and/or further processed or used. This (might be/) is in conflict with unnecessary collection of personal data, which are not required to fulfil a specific task.	Processes are designed such that personal data are only collected when necessary and anonymisation/pseudonymisation techniques are employed whenever possible
REACTION-104	Non-functional - Security	Major	Need-to-know Basis: Stakeholders processing information should only learn what is necessary to carry out their specific task	In an information processing chain, several stakeholders might be involved but it might not be necessary for every stakeholder to know which exact data another stakeholder has processed	Process design takes into account the need-to-know principle
REACTION-109	Non-functional - Performance	Major	Scalability: the security must not materially impact the performance of the system	the security resources have to scale well with the overall architecture	Security does not significantly impact overall latency of the system

REACTION-114	Non-functional - Maintainability and portability	Major	Modularity: the system has to be divided into components	It is easier to implement, exchange, and integrate the modules.	REACTION platform should be modular
REACTION-115	Non-functional - Usability	Major	Transparency: Security configuration should be hidden from the user as far as possible	Users usually do not have the expertise to choose the 'right' security options.	No, or as few as possible, additional user interactions for security.
REACTION-116	Non-functional - Maintainability and portability	Major	Availability of security mechanisms to manage sensitive data	In REACTION, we are dealing with sensitive data, thus security must be available on all platforms.	Security mechanisms are available for all target platforms of REACTION.
REACTION-118	Non-functional - Legal	Major	Assurance: the architecture and its implementation must provide assurance that it delivers the security and compliance properties it promises	If allegedly secure functions do not live up to their expected functionality, the whole platform could be compromised.	Successful review of expected security functionality.
REACTION-198	Functional - REACTION platform	Major	Information related to informed consent have to be stored in the REACTION platform	An ethical approved informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION platform.	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the paper form signed informed consent and this procedure shall be completed before any other operation can be performed.
REACTION-259	Functional - Inpatient pilot application	Major	Automated patient identification	Automated patient identification to avoid identification mistakes. Risks of wrong patient identification have to be negligible. The REACTION identification system must be flexible enough to integrate existing identification methods employed on site, e.g., wards in a hospital.	An effective, proper and easy-to-use way for automated patient identification, when mobile device is close to the patient (RFID, NFC?) has to be present. For example, each patient might wear wristband with a barcode which identifies the patient. This is standard in many hospitals and in some wards of the inpatient clinical site these wristbands are in use. This way shall reduce errors in patient identification and speed-up the patient management.

6.5.8 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-92	Non-functional - Security	Major	Integrity: Information, in particular health data, must be protected from any kind of unintended changes during transport	Any kind of undetectable changes in patient's data may give rise to wrong treatment and harm patients	Availability of a mechanism for ensuring data integrity

6.5.9 Web User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).	Each member of the care space will have specific roles and tasks in the patient's care.

6.6 Requirements of WP8 – Clinical Practice and Field Trials

6.6.1 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-60	Non-functional - Maintainability and portability	Critical	Restore from malfunctioning	System should be able to restore its previous state and the data when an unexpected problem occurred (wrong usage, hardware error, etc).	There should be no corrupted data or loss of information whatever the action of the user is or whenever the system stops working for any reason.
REACTION-135	Non-functional - Performance	Major	The platform shall be available for use 24 hours per day, 365 days per year	The platform shall guarantee a continuous support for patients and clinicians	No periods of service interruption have to be present
REACTION-253	Functional - REACTION platform	Major	Data entry shall be facilitated as much as possible	Data entry in any information system is an additional task for patients and formal/informal carers. This additional workload has not to be burdensome in order to facilitate the adoption of the platform in the clinical sites.	Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work they have to do and how much this additional work (if any) is useful.
REACTION-261	Non-functional - Usability	Major	The platform shall not generate additional workload for the clinical staff	Additional workflow shall be avoided or allowed only when the advantages produced by this workflow overcome the disadvantages	In the filed trials evaluation additional workflow shall be assessed by questionnaire or quantitative measurements and its advantages/disadvantages properly evaluated

REACTION-262	Non-functional - Performance	Major	Improve productivity and efficiency, reducing cost	The platform shall improve productivity and efficiency and at the same time shall reduce the cost of the diabetic patient workflow and management	Qualitative or quantitative measurements of productivity, efficiency and cost shall be foreseen in the field trials in order to make a proper comparison between the performances before the introduction of the REACTION platform and after the introduction of the REACTION platform. Assessment in field trial will be based on questionnaire for evaluating productivity and efficiency and on cost-benefit analysis estimating the different performances before the introduction of the REACTION platform and after the introduction of the REACTION platform.

6.6.2 Interfaces with HIS/EPR

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-35	Non-functional - Usability	Major	Usage Data (Information about elder and juvenile usage of the platform and resources shall be available)	Reports shall be generated in a way that summarizes the use of the platform to meet the expectations of its users.	A survey shall show the percent of the users that regularly use the platform.

6.6.3 Portable User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-35	Non-functional - Usability	Major	Usage Data (Information about elder and juvenile usage of the platform and resources shall be available)	Reports shall be generated in a way that summarizes the use of the platform to meet the expectations of its users.	A survey shall show the percent of the users that regularly use the platform.

REACTION-253	Functional - REACTION platform	Major	Data entry shall be facilitated as much as possible	Data entry in any information system is an additional task for patients and formal/informal carers. This additional workload has not to be burdensome in order to facilitate the adoption of the platform in the clinical sites.	Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work they have to do and how much this additional work (if any) is useful.

6.6.4 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-275	Non-functional - Legal	Major	Clinical trials, formal application	A formal application is required for clinical trials.	Formal application must be made before clinical trials.
REACTION-276	Non-functional - Legal	Major	Clinical trials, patient's information sheet including informed consent	Patient's information sheet including informed consent is needed for clinical trials.	Patient's information sheet including informed consent must be given before clinical trials.
REACTION-277	Non-functional - Legal	Major	Clinical trials study protocol	A study protocol must be written during clinical trials.	Study protocol must be available after clinical trials. The protocol should fulfil EN ISO 14155-1 and EN ISO 14155-2
REACTION-278	Non-functional - Legal	Major	Clinical trials case report form	For clinical trials a case report form has to be generated.	Case report form was generated for clinical trials.
REACTION-279	Non-functional - Legal	Major	Clinical trials investigators brochure	It is important to create an investigators brochure (sensor development) for clinical trials.	Investigators brochure present for clinical trials.
REACTION-282	Non-functional - Legal	Major	Insurance for clinical trials must be made	Insurance is required for clinical trials otherwise it can not be performed.	Insurance made before clinical trials.
REACTION-283	Non-functional - Legal	Major	Qualification of the investigator for clinical trials	Qualification of investigator must be given for clinical trials.	Qualification of investigator given in advance of clinical trials.

6.6.5 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-279	Non-functional - Legal	Major	Clinical trials investigators brochure	It is important to create an investigators brochure (sensor development) for clinical trials.	Investigators brochure present for clinical trials.

REACTION-281	Non-functional - Legal	Major	Clinical trials CE-certification OR certification that the device fulfils the MDD 93/42/EEC and subsequent amending directives like the directive 2007/47/EC	For clinical trials applied sensors or devices must fulfil the medical device directive (MDD). The clinical sites have to check the requirements (also on sensors/devices which will be used) for starting the clinical trials.	Sensors applied in clinical trials fulfil the MDD.

6.6.6 Web User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-35	Non-functional - Usability	Major	Usage Data (Information about elder and juvenile usage of the platform and resources shall be available)	Reports shall be generated in a way that summarizes the use of the platform to meet the expectations of its users.	A survey shall show the percent of the users that regularly use the platform.
REACTION-253	Functional - REACTION platform	Major	Data entry shall be facilitated as much as possible	Data entry in any information system is an additional task for patients and formal/informal carers. This additional workload has not to be burdensome in order to facilitate the adoption of the platform in the clinical sites.	Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work they have to do and how much this additional work (if any) is useful.

6.7 Requirements of WP9 – Socio-Economic Framework

6.7.1 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-131	Non-functional - Look and feel	Major	The platform shall appear authoritative	Trust of end-users is paramount	After their first encounter with the product, 2/3 of representative end-users shall agree they feel they can trust the platform and its services
REACTION-146	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings	To increase the adoption of REACTION technologies within different social groups, it must adapt were possible to social conventions within each group. This is even more important because individuals are part of several social contexts at the same time.	The application should cater for configuring at least: - language settings - different sets of symbols and icons - user help and documentation to the needs and skill levels of different social groups - flexibility to change privacy preferences - ability to predefine sets of privacy preferences for different social contexts. Does the application allow for changing interface language, symbol/icon sets, help files and documentation? Does the application allow for managing privacy settings to different social contexts?
REACTION-148	Non-functional - Security	Major	The user should be able to trust the application infrastructure	ICT components have to be trustworthy, because otherwise they pose the same risks they try to protect the user from. The application should therefore make the risks in communication known to the user, and make the measures taken to prevent these risks from materialising explicit. It should provide information about how personal data is handled, communicated and protected by the application and how these are handled in the communication channel	Does the application provide information about its trustworthiness? Does the application provide information the infrastructure (network/medium) risks? Does the application provide information about the measures taken to minimise risks during the communication of personal data?

REACTION-149	Non-functional - Cultural and political	Major	The user should be able to trust the operators involved in the application	The application should provide means to strengthen/restore this trust. The application can contribute to trust by: - offering ways to establish the trustworthiness of the transaction partners without revealing each others' identities - making transparent the way personal data is handled by the receiving parties and the arrangements the application offers to prevent or deal with privacy breaches - making transparent the institutional arrangements in place to address disputes - making transparent the institutional arrangements that government can offer to deal with privacy breaches.	Does the application provide ways to establish the trustworthiness of the operators? Does the application provide ways to circumvent the risks causing distrust (e.g., by offering guarantees operators' obligations will be met)?
REACTION-150	Non-functional - Economical and business	Major	The user should be able to obtain and use the application at reasonable cost	The design and/or business model of the application should minimise the costs for acquisition, installation and exploitation/use (both in money and in efforts) for the user	Does the application have a reasonable cost? Is the application easy to install and maintain?

6.7.2 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-143	Non-functional - Ethical	Major	The user should be aware of the essential events, processes, stakeholders and attributes of the collection and use of personal data	In order for data collection and use to be fair (see for instance, preamble 38 Directive 95/46/EC), users have to be aware that their data is requested by a data collector and what will happen with the data. This is also necessary if the user is to be taken as an autonomous individual who should be able to make informed choices about whether or not to engage in interactions and transactions and whether or not to proceed or not with a concrete interaction	The user should be aware of: - when data collection occurs - who collects the (personal) data - for which purpose the data is collected - with whom the data is shared - when the data is set to expire Does the application provide information to the users signalling events relevant to the collection, use, and removal of personal data at the service provider's end?

REACTION-144	Non-functional - Ethical	Major	The user should understand how personal data is handled by the service provider	In order for users to be in control of their personal data, they have to understand what happens with their data if they are disclosed to the service provider. This allows them to make informed choices about whether or not to proceed. Comprehension requires information about relevant events, processes, stakeholders and attributes of the collection and use of personal data to be available in a comprehensible form.	Users should be able to understand: • how their personal data is collected and used • for which purpose the data is being collected • who collects their (personal) data • who processes (uses) their (personal) data Because users have different needs and different backgrounds, what counts as comprehensive information differs from one individual to the next. A layered approach to providing information to the user, starting with simple information and extending to more detailed information on request, is therefore preferable • who will have access to their (personal) data • when their data will be erased • the limitation of their objection to data collection • the data protection rights and limitation

6.7.3 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-147	Non-functional - Cultural and political	Major	The user should be able to use the application with a minimal amount of training	To limit social divides resulting from having access and being able to use the technology, the application should be as easy to use as possible. Access does not only depend upon physical access to the application, but also on the motivation and skills of the potential user. An aim of system development should therefore be to minimise the required skills for gaining access to, and using of, the application.	Does the application provide a set of default settings that cover the needs of the majority of users? Does the application provide a minimum amount of pop-ups and choices in the human computer interaction? Does the application offer customisation options for more experienced users? Does the application provide an easy to use interface? Does the application provide comprehensive tutorials and help files? Does the application provide information about risks and what the application can do to help prevent these risks from materialising?

6.7.4 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-147	Non-functional - Cultural and political	Major	The user should be able to use the application with a minimal amount of training	To limit social divides resulting from having access and being able to use the technology, the application should be as easy to use as possible. Access does not only depend upon physical access to the application, but also on the motivation and skills of the potential user. An aim of system development should therefore be to minimise the required skills for gaining access to, and using of, the application.	Does the application provide a set of default settings that cover the needs of the majority of users? Does the application provide a minimum amount of pop-ups and choices in the human computer interaction? Does the application offer customisation options for more experienced users? Does the application provide an easy to use interface? Does the application provide comprehensive tutorials and help files? Does the application provide information about risks and what the application can do to help prevent these risks from materialising?

6.7.5 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-142	Non-functional - Ethical	Major	The user should have a certain level of control over information relating to him/her	Users are taken to be individuals who can make autonomous choices about their life. Although they can not be said to own their personal data in a legal sense, we may want to attribute them rights similar to those on goods because data about individuals can be used to affect their position in the world and their capabilities of determining their own future.	User control means that the user should be able to: - control of how personal data is handled - be able to object to processing - control how long personal data is stored - be able to exercise the rights to examine and correct personal data

6.8 Requirements of WP10 - Platform Integration and Implementation

6.8.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose measurement (under a certain threshold). In case of episode the reasons for hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered.	A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered and the changes in treatment have to be documented as well.	A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.

6.8.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-13	Functional	Major	To update EPRs with collected data	Provide an interface for updating EPRs.	Support at least IHE-PCD01.
REACTION-23	Functional	Major	Clinician generated feedback to patient	It should be possible for clinician/staff to submit additional information to patients, e.g. for educational or encouragement purposes.	At least to provide a two way communication, e.g. shared white board.
REACTION-26	Functional - REACTION platform	Major	Embedded intelligence	Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions which are not written or specified in published deliverables or manuals. The applications shall not rely to "default" actions, or fall-back scenarios in exceptional cases, unless these are based on agreed scenarios or models.	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.

REACTION-46	Non-functional - Maintainability and portability	Minor	Error messages must be understandable and helpful	When an application fails this must happen gracefully while providing sufficient and easy to understand messages to the user. In this way the user will not get panicked during a failure, while able to understand what happened or whom to contact to report or resolve the problem.	For each application, developers must ensure that error messages should be brief, easy to read, understood even by non-specialists and should also provide some short help (of course they must include the error code that will allow to understand exactly what is wrong).
REACTION-67	Non-functional - Maintainability and portability	Major	Component Repository	A repository for the binary components has to be set-up in order to ease the integration and the internal test	A server for the containment of the components will be set-up
REACTION-69	Functional - REACTION platform	Critical	System Configuration	The components and applications should be made in a way that makes easy the configuration	Theoretically without any recompilation, the application should be easily configurable for the different environments
REACTION-71	Non-functional - Maintainability and portability	Critical	Simulators for the internal tests	The internal test is performed without real users (clinicians & patients) and therefore some devices have to be simulated	Simulated components performing the same operations with exactly the same interface have to be available
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-96	Functional - Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-132	Non-functional - Usability	Major	The platform shall help the user to avoid making mistakes	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows	End-users will be guided through the workflows they have to perform.

REACTION-138	Non-functional - Performance	Major	The platform shall be expected to operate within reasonable maintenance effort for all the duration of the field trials	Problems at the field trials should be minimized	Problems signalled at the field trials should be under a fixed threshold
REACTION-139	Non-functional - Operational	Major	The platform shall be able to be installed and configured at the field trial sites by the local technical partner without too much effort	The local technical partners shall take care of the installation and configuration of the field trials	Adequate installation and configuration manuals have to be provided to the local technical partners.
REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously (mobile access points - e.g. tablet PC at point of care versus fixed access points - e.g. screens at physicians/nurses base)	Clinicians can input relevant information via tablet PC from every place within the hospital ward.

REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality

REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels. RPM and clinical decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients. RPM and decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-179	Functional - Outpatient pilot application	Major	Daily data review by clinicians or telehealth support team	When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the patient progress against individualized targets set up for the patient.	The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or pharmacological treatment.
REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also pharmacological treatment (OAD or insulin) can be reviewed after accurate evaluation of patient kidney functions.	Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the relevant information have to be designed.
REACTION-189	Functional - Outpatient pilot application	Major	Other managements for type I diabetic patients	Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems)	In the care program, management of diabetes (through insulin) should be accompanied by management of complications

REACTION-190	Constraint - Implementation Environment	Major	In the outpatient environment the medications are usually self-administered by the patient himself or by informal carers (rarely)	Usual practice for diabetic patient outside from secondary or tertiary care is self-administration of medications	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home
REACTION-191	Functional - Outpatient pilot application	Major	Structured programme for the management of diabetic patients	The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, education, telephone support, dose titration, dietary understanding, management of acute changes in plasma glucose control, prevention and early detection of medium- and long-term complications, management of hypoglycaemia	The applications shall allow the implementation of the structured programme.
REACTION-194	Functional - Outpatient pilot application	Major	Regular visits/reviews at the Primary Health Care	Outcomes of regular visits at the Primary Health care centre shall be registered in the platform through the use of specific forms/user interfaces for the doctors/nurses.	Specific forms and user interfaces for the doctors/nurses have to be present
REACTION-196	Functional - Outpatient pilot application	Major	End of process for the diabetic patient in the outpatient environment	There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from the practice catchment area or voluntarily stops to be monitored by the REACTION platform.	Patient discharge from the outpatient environment has to be foreseen only in case of a) death; b) patient removal outside from the practice catchment area; c) patient voluntarily stops to be monitored by the REACTION platform.
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-203	Functional - Outpatient pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization

REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of the case conference impacts on the personalized care plan (through potential changes in the non-pharmacological and pharmacological treatments).
REACTION-234	Functional - Inpatient pilot application	Major	Determination of health status in Inpatient environment	At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or adapted to the status of the patient. In the second case a dose-finding procedure for the individual patient will be started associated with education in nutrition and therapy. Type of diabetes has to be registered.	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.
REACTION-235	Functional - Inpatient pilot application	Major	Therapy scheme in Inpatient environment registered immediately after the patient enrolment	The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status and associated conditions (fasting, special diet, diarrhoea, vomiting, infection, fever), nutrition (snacks in between, diminished/absence of appetite), insulin sensitivity (diurnal changes, fever...), planned examinations/treatments (e.g. surgery, endoscopic examinations), interaction with other medication (e.g. glucocorticoids)	The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.	Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication, ease of operation.

6.8.3 Backend Middleware

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-65	Functional - REACTION platform	Major	System availability	The system should be continually monitoring and gathering data about the patients status with no excessive down time. Availability here means that the vital components of the REACTION platform will be in functioning state in order for the patient safety to be supported.	The end user applications and the devices in the vicinity of the patient should always operable
REACTION-71	Non-functional - Maintainability and portability	Critical	Simulators for the internal tests	The internal test is performed without real users (clinicians & patients) and therefore some devices have to be simulated	Simulated components performing the same operations with exactly the same interface have to be available
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously (mobile access points - e.g. tablet PC at point of care versus fixed access points - e.g. screens at physicians/nurses base)	Clinicians can input relevant information via tablet PC from every place within the hospital ward.
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform

REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels. RPM and clinical decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients. RPM and decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of the case conference impacts on the personalized care plan (through potential changes in the non-pharmacological and pharmacological treatments).

REACTION-226	Functional - Inpatient pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.	Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication, ease of operation.

6.8.4 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-23	Functional	Major	Clinician generated feedback to patient	It should be possible for clinician/staff to submit additional information to patients, e.g. for educational or encouragement purposes.	At least to provide a two way communication, e.g. shared white board.
REACTION-57	Non-functional - Performance	Critical	Performance and Scalability	Responsive enough to integrate with the clinician workflow. The response to the users action should be acceptable, depending on how time-critical is the action's response. Each component should scale well when increasing the users and the data that is stored and processed.	Criteria are different depending on the user action. For time-critical actions the response should be almost instant.
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients

REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously (mobile access points - e.g. tablet PC at point of care versus fixed access points - e.g. screens at physicians/nurses base)	Clinicians can input relevant information via tablet PC from every place within the hospital ward.
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-189	Functional - Outpatient pilot application	Major	Other managements for type I diabetic patients	Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems)	In the care program, management of diabetes (through insulin) should be accompanied by management of complications
REACTION-190	Constraint - Implementation Environment	Major	In the outpatient environment the medications are usually self-administered by the patient himself or by informal carers (rarely)	Usual practice for diabetic patient outside from secondary or tertiary care is self-administration of medications	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home
REACTION-191	Functional - Outpatient pilot application	Major	Structured programme for the management of diabetic patients	The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, education, telephone support, dose titration, dietary understanding, management of acute changes in plasma glucose control, prevention and early detection of medium- and long-term complications, management of hypoglycaemia	The applications shall allow the implementation of the structured programme.

REACTION-225	Functional - Inpatient pilot application	Major	PoC device for blood glucose measurement will be used in the first-year prototype	The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the consortium sensors. Furthermore, before their regular use in hospital ward consortium sensors have to obtain special approval. Thus, in the Inpatient environment the devices currently used will continue to be used also in the first-year prototype.	The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. The acquired measurements through an appropriate HL7 interface will be retrieved and made available in the REACTION data management.
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.	Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication, ease of operation.

6.8.5 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-8	Functional	Major	User interface for manual entry of lifestyle data	To supply and support feedback on effectiveness of lifestyle behaviour and therapies to clinicians and patients.	User interface exists.
REACTION-15	Functional	Major	System must keep track of work flow stages	To identify in which stage within the diabetes management the patient is: newly diagnosed, medication titration, and ongoing management.	Individual patient can always be mapped into a work flow stage.
REACTION-23	Functional	Major	Clinician generated feedback to patient	It should be possible for clinician/staff to submit additional information to patients, e.g. for educational or encouragement purposes.	At least to provide a two way communication, e.g. shared white board.
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients

REACTION-96	Functional - Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform

REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also pharmacological treatment (OAD or insulin) can be reviewed after accurate evaluation of patient kidney functions.	Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the relevant information have to be designed.
REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context for the acquired measurements. A suitable user interface has to be provided in order to facilitate patients performing this task (any data entry can be felt as too intrusive for patients). The possibility of integrating existing commercial log-devices used by the patients has to be considered.	There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint display of the acquired measurements and the relevant associated events (giving a context for the measurements)
REACTION-240	Functional - Inpatient pilot application	Major	Intravenous insulin	In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.	The insulin administration shall allow also the IV way in the user interface
REACTION-245	Functional - Inpatient pilot application	Major	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation	Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.

6.8.6 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-61	Functional - REACTION platform	Major	Data exchange with third-party systems	Ideally accepts and integrates information from outside of the managing organization (e.g. pharmacies).	Should be able to import and export data in an interoperable way to third-party systems.
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients

REACTION-96	Functional - Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from the HIS or EPR through interoperable user interfaces	In case an interoperable HIS/EPR is present a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created his data have to be taken from the HIS/EPR.
REACTION-153	Functional - REACTION platform	Major	Symptoms of diabetes or hyperglycaemia	At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).	Specific design in the user interfaces, ontologies and data management
REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously (mobile access points - e.g. tablet PC at point of care versus fixed access points - e.g. screens at physicians/nurses base)	Clinicians can input relevant information via tablet PC from every place within the hospital ward.

REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality

REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels. RPM and clinical decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients. RPM and decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-179	Functional - Outpatient pilot application	Major	Daily data review by clinicians or telehealth support team	When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the patient progress against individualized targets set up for the patient.	The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or pharmacological treatment.
REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also pharmacological treatment (OAD or insulin) can be reviewed after accurate evaluation of patient kidney functions.	Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the relevant information have to be designed.
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-203	Functional - Outpatient pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization

REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of the case conference impacts on the personalized care plan (through potential changes in the non-pharmacological and pharmacological treatments).
REACTION-224	Functional - Inpatient pilot application	Major	Basic workflow is repeated 4 times a day in inpatient environment	The first workflow is in the morning a little before breakfast time (administration of bolus insulin), the second is at midday before lunch time (administration of bolus insulin), the third is in the evening before dinner time (administration of bolus insulin), and finally the fourth is at bedtime (administration of basal insulin and correction of boluses, if necessary).	These 4 loops should be easily identified in the Inpatient application
REACTION-226	Functional - Inpatient pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.
REACTION-230	Functional - Inpatient pilot application	Major	Overall evaluation in Inpatient environment	Supervision of glycaemia and according treatment is performed once a day. Adaptation of therapy or changes of medications have to be evaluated also consulting the physician on duty.	Every day an evaluation report has to be stored and available in the Inpatient application
REACTION-234	Functional - Inpatient pilot application	Major	Determination of health status in Inpatient environment	At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or adapted to the status of the patient. In the second case a dose-finding procedure for the individual patient will be started associated with education in nutrition and therapy. Type of diabetes has to be registered.	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.

REACTION-235	Functional - Inpatient pilot application	Major	Therapy scheme in Inpatient environment registered immediately after the patient enrolment	The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status and associated conditions (fasting, special diet, diarrhoea, vomiting, infection, fever), nutrition (snacks in between, diminished/absence of appetite), insulin sensitivity (diurnal changes, fever...), planned examinations/treatments (e.g. surgery, endoscopic examinations), interaction with other medication (e.g. glucocorticoids)	The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.
REACTION-240	Functional - Inpatient pilot application	Major	Intravenous insulin	In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.	The insulin administration shall allow also the IV way in the user interface
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose measurement (under a certain threshold). In case of episode the reasons for hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered.	A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered and the changes in treatment have to be documented as well.	A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-245	Functional - Inpatient pilot application	Major	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation	Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.

REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.	Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication, ease of operation.
REACTION-250	Functional - Inpatient pilot application	Major	Different contextualization of the patient clinical information	Different modes of visualisation with different relevant parameters for decision support shall be foresee. The relevant data have to be displayed contextualized. The relevant values have to be highlighted.	The possibility of configure the display of the patient clinical data (mainly the fever chart) has to be present.

6.8.7 Glucose Control Algorithms

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-223	Functional - Inpatient pilot application	Major	Basic workflow for insulin treatment in Inpatient environment	The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on additional parameters and insulin administration	The basic workflow should be easily accessible in the REACTION Inpatient application
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose measurement (under a certain threshold). In case of episode the reasons for hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered.	A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered and the changes in treatment have to be documented as well.	A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.

REACTION-245	Functional - Inpatient pilot application	Major	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation	Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.

6.8.8 Interfaces with HIS/EPR

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-37	Non-functional - Usability	Major	Applications guidelines (guidelines for formal carers, in-formal carers and patients) have to be clearly defined	To ensure that the applications will run with the best possible way.	To demonstrate the full functionality of the REACTION platform.
REACTION-41	Non-functional - Maintainability and portability	Major	The tools developed by the consortium must be properly documented in such a way that the end user can understand them and use them for the intended purpose.	Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The well documented tools will allow the users to make full use of their functions and capabilities and will also provide a complete test of the platform's functionality. Design history file is necessary not only for the end user but also for regulatory approval by the authorities which is mandatory for medical devices.	Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely available and easily accessible via the website.
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from the HIS or EPR through interoperable user interfaces	In case an interoperable HIS/EPR is present a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created his data have to be taken from the HIS/EPR.

REACTION-153	Functional - REACTION platform	Major	Symptoms of diabetes or hyperglycaemia	At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).	Specific design in the user interfaces, ontologies and data management
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-225	Functional - Inpatient pilot application	Major	PoC device for blood glucose measurement will be used in the first-year prototype	The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the consortium sensors. Furthermore, before their regular use in hospital ward consortium sensors have to obtain special approval. Thus, in the Inpatient environment the devices currently used will continue to be used also in the first-year prototype.	The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. The acquired measurements through an appropriate HL7 interface will be retrieved and made available in the REACTION data management.

REACTION-258	Functional - Inpatient pilot application	Major	Automated transfer of patient related data from the hospital information system	At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred from the HIS to the platform (when a HIS/EPR is present in the clinical site). This procedure reduces transcription errors and save doctors/nurses time for manual data entry. This procedure must be flexible enough to interface different HIS/EPR HL7-based including the one used at the clinical site.	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.

6.8.9 Networking

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-26	Functional - REACTION platform	Major	Embedded intelligence	Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions which are not written or specified in published deliverables or manuals. The applications shall not rely to "default" actions, or fall-back scenarios in exceptional cases, unless these are based on agreed scenarios or models.	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.
REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients

REACTION-96	Functional - Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously (mobile access points - e.g. tablet PC at point of care versus fixed access points - e.g. screens at physicians/nurses base)	Clinicians can input relevant information via tablet PC from every place within the hospital ward.
REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)

REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.	Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication, ease of operation.

6.8.10 Ontology/Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an adequate front-end	Front-end for therapy-scheme quality presentation

REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels. RPM and clinical decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.

REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients. RPM and decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-179	Functional - Outpatient pilot application	Major	Daily data review by clinicians or telehealth support team	When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the patient progress against individualized targets set up for the patient.	The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or pharmacological treatment.
REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also pharmacological treatment (OAD or insulin) can be reviewed after accurate evaluation of patient kidney functions.	Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the relevant information have to be designed.
REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context for the acquired measurements. A suitable user interface has to be provided in order to facilitate patients performing this task (any data entry can be felt as too intrusive for patients). The possibility of integrating existing commercial log-devices used by the patients has to be considered.	There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint display of the acquired measurements and the relevant associated events (giving a context for the measurements)
REACTION-191	Functional - Outpatient pilot application	Major	Structured programme for the management of diabetic patients	The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, education, telephone support, dose titration, dietary understanding, management of acute changes in plasma glucose control, prevention and early detection of medium- and long-term complications, management of hypoglycaemia	The applications shall allow the implementation of the structured programme.
REACTION-194	Functional - Outpatient pilot application	Major	Regular visits/reviews at the Primary Health Care	Outcomes of regular visits at the Primary Health care centre shall be registered in the platform through the use of specific forms/user interfaces for the doctors/nurses.	Specific forms and user interfaces for the doctors/nurses have to be present

REACTION-196	Functional - Outpatient pilot application	Major	End of process for the diabetic patient in the outpatient environment	There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from the practice catchment area or voluntarily stops to be monitored by the REACTION platform.	Patient discharge from the outpatient environment has to be foreseen only in case of a) death; b) patient removal outside from the practice catchment area; c) patient voluntarily stops to be monitored by the REACTION platform.
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-203	Functional - Outpatient pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization
REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of the case conference impacts on the personalized care plan (through potential changes in the non-pharmacological and pharmacological treatments).
REACTION-223	Functional - Inpatient pilot application	Major	Basic workflow for insulin treatment in Inpatient environment	The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on additional parameters and insulin administration	The basic workflow should be easily accessible in the REACTION Inpatient application
REACTION-226	Functional - Inpatient pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.

REACTION-234	Functional - Inpatient pilot application	Major	Determination of health status in Inpatient environment	At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or adapted to the status of the patient. In the second case a dose-finding procedure for the individual patient will be started associated with education in nutrition and therapy. Type of diabetes has to be registered.	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.
REACTION-240	Functional - Inpatient pilot application	Major	Intravenous insulin	In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.	The insulin administration shall allow also the IV way in the user interface
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose measurement (under a certain threshold). In case of episode the reasons for hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered.	A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered and the changes in treatment have to be documented as well.	A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-245	Functional - Inpatient pilot application	Major	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation	Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.

REACTION-258	Functional - Inpatient pilot application	Major	Automated transfer of patient related data from the hospital information system	At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred from the HIS to the platform (when a HIS/EPR is present in the clinical site). This procedure reduces transcription errors and save doctors/nurses time for manual data entry. This procedure must be flexible enough to interface different HIS/EPR HL7-based including the one used at the clinical site.	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.

6.8.11 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-26	Functional - REACTION platform	Major	Embedded intelligence	Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions which are not written or specified in published deliverables or manuals. The applications shall not rely to "default" actions, or fall-back scenarios in exceptional cases, unless these are based on agreed scenarios or models.	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform

6.8.12 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-13	Functional	Major	To update EPRs with collected data	Provide an interface for updating EPRs.	Support at least IHE-PCD01.
REACTION-15	Functional	Major	System must keep track of work flow stages	To identify in which stage within the diabetes management the patient is: newly diagnosed, medication titration, and ongoing management.	Individual patient can always be mapped into a work flow stage.

REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-96	Functional - Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-170	Functional - Inpatient pilot application	Major	Selection of a mobile device for inpatient glucose control based on given requirements	The devices should be: - Lightweight/portable - Easy to hold / handle and ergonomic design - Spill an drip resistant (easy disinfection) - Inputs for stylus and touch operations (incl. touch keyboard) - Wireless communication - Ease of operations	Devices with desired functionality are available within the project

REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform
REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context for the acquired measurements. A suitable user interface has to be provided in order to facilitate patients performing this task (any data entry can be felt as too intrusive for patients). The possibility of integrating existing commercial log-devices used by the patients has to be considered.	There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint display of the acquired measurements and the relevant associated events (giving a context for the measurements)

6.8.13 Portable User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-37	Non-functional - Usability	Major	Applications guidelines (guidelines for formal carers, in-formal carers and patients) have to be clearly defined	To ensure that the applications will run with the best possible way.	To demonstrate the full functionality of the REACTION platform.
REACTION-41	Non-functional - Maintainability and portability	Major	The tools developed by the consortium must be properly documented in such a way that the end user can understand them and use them for the intended purpose.	Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The well documented tools will allow the users to make full use of their functions and capabilities and will also provide a complete test of the platform's functionality. Design history file is necessary not only for the end user but also for regulatory approval by the authorities which is mandatory for medical devices.	Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely available and easily accessible via the website.
REACTION-44	Non-functional - Security	Critical	Protection against unintended user actions	Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not cause the system to close down, neither on the client nor on the server. All data entered must be checked for format, consistency and validity. In case of doubt, the user must be warned and asked what to do. The user must be able to correct mistakes easily. The user must be able to interrupt long functions (e.g. waiting for a remote data transfer).	The functional test should include specific tests in order to verify such circumstances

REACTION-48	Non-functional - Usability	Major	Support for multilingual user interface	Users from different countries should have access to services.	Any type of text in any graphical user interfaces that will be developed (labels, text fields, labels, etc.) must be able to easily configured and changed using a easily configurable localization file. A first version of the file will be created in English language, and then it will be distributed to the partners. Once decided which languages will be supported, partners must contribute to the localization of the components, by translating them to its native language (if in the set of supported languages)
REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an adequate front-end	Front-end for therapy-scheme quality presentation
REACTION-96	Functional - Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-117	Non-functional - Usability	Major	Cross-platform usability: user experience should be the same on all platforms	Users should only see familiar interfaces in order to adapt to a new platform more easily.	Different platforms do not have significantly different user interfaces, i.e., REACTION should be 'platform agnostic'.
REACTION-130	Non-functional - Look and feel	Major	The platform shall be easily used by elderly people with no specific technological knowledge	Being the diabetes quite common in elderly people, several patients will have no specific knowledge in technology, but they should be able to easily use the platform.	User learning curve (especially with elderly people) should be very quick

REACTION-132	Non-functional - Usability	Major	The platform shall help the user to avoid making mistakes	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows	End-users will be guided through the workflows they have to perform.
REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform

6.8.14 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an adequate front-end	Front-end for therapy-scheme quality presentation
REACTION-96	Functional - Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels. RPM and clinical decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.

REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients. RPM and decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose measurement (under a certain threshold). In case of episode the reasons for hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered.	A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered and the changes in treatment have to be documented as well.	A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-245	Functional - Inpatient pilot application	Major	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation	Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.

6.8.15 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-44	Non-functional - Security	Critical	Protection against unintended user actions	Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not cause the system to close down, neither on the client nor on the server. All data entered must be checked for format, consistency and validity. In case of doubt, the user must be warned and asked what to do. The user must be able to correct mistakes easily. The user must be able to interrupt long functions (e.g. waiting for a remote data transfer).	The functional test should include specific tests in order to verify such circumstances
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-140	Non-functional - Security	Major	The platform shall prevent incorrect data from being introduced	Incorrect data might hamper a correct clinical decision	Check that the user interface and specific procedures protect the end-user from the introduction of incorrect data as much as possible
REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from the HIS or EPR through interoperable user interfaces	In case an interoperable HIS/EPR is present a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created his data have to be taken from the HIS/EPR.

REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support	POCT data is transmitted within short time to the platform

6.8.16 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances

REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-71	Non-functional - Maintainability and portability	Critical	Simulators for the internal tests	The internal test is performed without real users (clinicians & patients) and therefore some devices have to be simulated	Simulated components performing the same operations with exactly the same interface have to be available
REACTION-225	Functional - Inpatient pilot application	Major	PoC device for blood glucose measurement will be used in the first-year prototype	The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the consortium sensors. Furthermore, before their regular use in hospital ward consortium sensors have to obtain special approval. Thus, in the Inpatient environment the devices currently used will continue to be used also in the first-year prototype.	The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. The acquired measurements through an appropriate HL7 interface will be retrieved and made available in the REACTION data management.

6.8.17 Web User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-37	Non-functional - Usability	Major	Applications guidelines (guidelines for formal carers, in-formal carers and patients) have to be clearly defined	To ensure that the applications will run with the best possible way.	To demonstrate the full functionality of the REACTION platform.
REACTION-41	Non-functional - Maintainability and portability	Major	The tools developed by the consortium must be properly documented in such a way that the end user can understand them and use them for the intended purpose.	Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The well documented tools will allow the users to make full use of their functions and capabilities and will also provide a complete test of the platform's functionality. Design history file is necessary not only for the end user but also for regulatory approval by the authorities which is mandatory for medical devices.	Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely available and easily accessible via the website.

REACTION-44	Non-functional - Security	Critical	Protection against unintended user actions	Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not cause the system to close down, neither on the client nor on the server. All data entered must be checked for format, consistency and validity. In case of doubt, the user must be warned and asked what to do. The user must be able to correct mistakes easily. The user must be able to interrupt long functions (e.g. waiting for a remote data transfer).	The functional test should include specific tests in order to verify such circumstances
REACTION-47	Non-functional - Look and feel	Minor	Web pages must be suited for screen readers, scaling to visually-impaired users, and utilizing the full screen size on small as well as large screens.	Will allow the easy interaction with the platform. Will also provide, as much as possible, to people with disabilities the ability to use the platform.	Use of large fonts, use of colours with strong contrast, possible use of audio messages and implementation of other commonly used accessibility options, at the applications developed to be used by patients.
REACTION-48	Non-functional - Usability	Major	Support for multilingual user interface	Users from different countries should have access to services.	Any type of text in any graphical user interfaces that will be developed (labels, text fields, labels, etc.) must be able to easily configured and changed using a easily configurable localization file. A first version of the file will be created in English language, and then it will be distributed to the partners. Once decided which languages will be supported, partners must contribute to the localization of the components, by translating them to its native language (if in the set of supported languages)
REACTION-64	Non-functional - Usability	Major	Friendly applications	The use of end-user applications and the devices both in the in-patient but also (and most importantly perhaps) in the outpatient cases should be intuitive, efficient, and of minor disturbance to the patients, requiring minimal interactions and engagement.	No complex user interfaces, the user should be familiar with the applications in short time (training is foreseen)
REACTION-77	Non-functional - Usability	Major	Browser Compatibility	The web based interface should be perform properly in the last 2 editions of the 5 most common browsers	Specific tests have to be performed

REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an adequate front-end	Front-end for therapy-scheme quality presentation
REACTION-96	Functional - Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-117	Non-functional - Usability	Major	Cross-platform usability: user experience should be the same on all platforms	Users should only see familiar interfaces in order to adapt to a new platform more easily.	Different platforms do not have significantly different user interfaces, i.e., REACTION should be 'platform agnostic'.
REACTION-130	Non-functional - Look and feel	Major	The platform shall be easily used by elderly people with no specific technological knowledge	Being the diabetes quite common in elderly people, several patients will have no specific knowledge in technology, but they should be able to easily use the platform.	User learning curve (especially with elderly people) should be very quick
REACTION-132	Non-functional - Usability	Major	The platform shall help the user to avoid making mistakes	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows	End-users will be guided through the workflows they have to perform.
REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from the HIS or EPR through interoperable user interfaces	In case an interoperable HIS/EPR is present a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created his data have to be taken from the HIS/EPR.

REACTION-153	Functional - REACTION platform	Major	Symptoms of diabetes or hyperglycaemia	At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).	Specific design in the user interfaces, ontologies and data management
REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)	Data entry system will be available for inpatient decision support system with devices (tablet PC)

REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels. RPM and clinical decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients. RPM and decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-179	Functional - Outpatient pilot application	Major	Daily data review by clinicians or telehealth support team	When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the patient progress against individualized targets set up for the patient.	The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or pharmacological treatment.
REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also pharmacological treatment (OAD or insulin) can be reviewed after accurate evaluation of patient kidney functions.	Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the relevant information have to be designed.
REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context for the acquired measurements. A suitable user interface has to be provided in order to facilitate patients performing this task (any data entry can be felt as too intrusive for patients). The possibility of integrating existing commercial log-devices used by the patients has to be considered.	There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint display of the acquired measurements and the relevant associated events (giving a context for the measurements)

REACTION-189	Functional - Outpatient pilot application	Major	Other managements for type I diabetic patients	Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems)	In the care program, management of diabetes (through insulin) should be accompanied by management of complications
REACTION-190	Constraint - Implementation Environment	Major	In the outpatient environment the medications are usually self-administered by the patient himself or by informal carers (rarely)	Usual practice for diabetic patient outside from secondary or tertiary care is self-administration of medications	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home
REACTION-191	Functional - Outpatient pilot application	Major	Structured programme for the management of diabetic patients	The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, education, telephone support, dose titration, dietary understanding, management of acute changes in plasma glucose control, prevention and early detection of medium- and long-term complications, management of hypoglycaemia	The applications shall allow the implementation of the structured programme.
REACTION-194	Functional - Outpatient pilot application	Major	Regular visits/reviews at the Primary Health Care	Outcomes of regular visits at the Primary Health care centre shall be registered in the platform through the use of specific forms/user interfaces for the doctors/nurses.	Specific forms and user interfaces for the doctors/nurses have to be present
REACTION-196	Functional - Outpatient pilot application	Major	End of process for the diabetic patient in the outpatient environment	There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from the practice catchment area or voluntarily stops to be monitored by the REACTION platform.	Patient discharge from the outpatient environment has to be foreseen only in case of a) death; b) patient removal outside from the practice catchment area; c) patient voluntarily stops to be monitored by the REACTION platform.
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-203	Functional - Outpatient pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization

REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of the case conference impacts on the personalized care plan (through potential changes in the non-pharmacological and pharmacological treatments).
REACTION-223	Functional - Inpatient pilot application	Major	Basic workflow for insulin treatment in Inpatient environment	The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on additional parameters and insulin administration	The basic workflow should be easily accessible in the REACTION Inpatient application
REACTION-224	Functional - Inpatient pilot application	Major	Basic workflow is repeated 4 times a day in inpatient environment	The first workflow is in the morning a little before breakfast time (administration of bolus insulin), the second is at midday before lunch time (administration of bolus insulin), the third is in the evening before dinner time (administration of bolus insulin), and finally the fourth is at bedtime (administration of basal insulin and correction of boluses, if necessary).	These 4 loops should be easily identified in the Inpatient application
REACTION-226	Functional - Inpatient pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.
REACTION-230	Functional - Inpatient pilot application	Major	Overall evaluation in Inpatient environment	Supervision of glycaemia and according treatment is performed once a day. Adaptation of therapy or changes of medications have to be evaluated also consulting the physician on duty.	Every day an evaluation report has to be stored and available in the Inpatient application
REACTION-234	Functional - Inpatient pilot application	Major	Determination of health status in Inpatient environment	At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or adapted to the status of the patient. In the second case a dose-finding procedure for the individual patient will be started associated with education in nutrition and therapy. Type of diabetes has to be registered.	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.

REACTION-235	Functional - Inpatient pilot application	Major	Therapy scheme in Inpatient environment registered immediately after the patient enrolment	The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status and associated conditions (fasting, special diet, diarrhoea, vomiting, infection, fever), nutrition (snacks in between, diminished/absence of appetite), insulin sensitivity (diurnal changes, fever...), planned examinations/treatments (e.g. surgery, endoscopic examinations), interaction with other medication (e.g. glucocorticoids)	The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.
REACTION-240	Functional - Inpatient pilot application	Major	Intravenous insulin	In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.	The insulin administration shall allow also the IV way in the user interface
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose measurement (under a certain threshold). In case of episode the reasons for hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered.	A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered and the changes in treatment have to be documented as well.	A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.
REACTION-245	Functional - Inpatient pilot application	Major	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation	Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.

REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.	Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication, ease of operation.
REACTION-250	Functional - Inpatient pilot application	Major	Different contextualization of the patient clinical information	Different modes of visualisation with different relevant parameters for decision support shall be foresee. The relevant data have to be displayed contextualized. The relevant values have to be highlighted.	The possibility of configure the display of the patient clinical data (mainly the fever chart) has to be present.
REACTION-258	Functional - Inpatient pilot application	Major	Automated transfer of patient related data from the hospital information system	At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred from the HIS to the platform (when a HIS/EPR is present in the clinical site). This procedure reduces transcription errors and save doctors/nurses time for manual data entry. This procedure must be flexible enough to interface different HIS/EPR HL7-based including the one used at the clinical site.	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.

REACTION-285	Functional - Inpatient pilot application	Major	User interface for the clinical data stored in the inpatient environment	The user interface shall allow the insertion, modification and visualization of the clinical data registered at the patient enrolment and of the clinical data acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, comorbidities, therapy scheme. Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, estimation of insulin sensitivity and resistance. The possibility of adding further parameters should be foreseen in the design.	There shall be a user interface which allows the insertion and the update of all the listed parameters.

6.9 Requirements of WP13 - Training

6.9.1 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-133	Non-functional - Usability	Major	A patient, informal or formal carers should be able to be productive within a short time (one day of training)	The platform should be easy to use and learn in order to be accepted by end-users	The end-users shall achieve 75% pass rate from the final examination of the training

7. Conclusions

This phase of initial requirement elicitation and engineering has mainly confirmed what was known in the DoW. However, some significant points have been highlighted which are listed here below:

- The need of creating a platform that can be easily configured for two different environments (inpatient and outpatient) is in contrast with the different needs about the diabetes management which are currently required in the two different environments. This will have a significant impact in the architectural design which should take into account the easy configurability of the platform and lead to a single configurable platform.

- Data acquired from sensors have to be collected and merged in the portable device. Since, as stated in the DoW, no portable devices have to be developed by the consortium concerning the display of data or the feedback to patients, these devices must be commercially available systems. The selection of appropriate commercial off the shelf (COTS) portable devices is paramount and very critical. If the required performances cannot be guaranteed at affordable cost by existing COTS portable devices, the implementation of some requirements have to be reconsidered.

- There can be different ways of collecting data from the patients in the patient sphere from what was foreseen in the DoW especially in the inpatient environment. The devices can send measurements directly to the HIS (instead of sending measurements to the REACTION data management) and from there measurements can be retrieved by HL7 agents and uploaded in the REACTION data management. This way of working has to be taken into account especially for the first-year prototype to be installed in the inpatient environment.

- A clear preference for the Continua alliance promoted standards (IEEE 11073) has been shown by the stakeholders. This will have an impact in the devices developed by the REACTION consortium which will have to support this standard and in the selection of off-the-shelf devices which, if supporting these standards, have to be preferred.

- Data collection in the ward is usually performed in a different way than at patient home. In inpatient environment data collection is performed by nurses/physicians – staff which must have all the information typically available at the carer's sphere in order to be able to face promptly any adverse event. That goes in the direction of selecting portable devices like tablet PC for the carer's sphere in the inpatient environment.

- The concept of the "black box" for the measurement collector in the patient sphere has been introduced. However, the black box has to contain a portable device (e.g. SmartPhone, PDA) which should allow also to show the acquired data to the patient or informal carers, to provide feedback and, when necessary, alerts or alarms. The use of such device to perform all these tasks should reduce the overall cost and promote the sustainability of the platform.

- Alert and alarms have to be provided without being too intrusive for the patient himself and the staff. There is a clear need of configuring thresholds and tuning alarms in order to obtain an effective compromise between the need of clinicians of sending alarms and the need of patients to live their lives without being disturbed every while and then.

- Correct decisions can be taken mainly when all data are present. Thus, there is emphasis on data collection, but on the other side the workload for patients and clinicians cannot be increased too much. Therefore, automatic acquirement and availability of information is preferred and also easy user interfaces and procedures for data entry have to be designed and implemented.

- There is the need of information exchange between the outpatient and the inpatient environments so that every time the patient is admitted in the hospital or discharged from the hospital all the information will be promptly available in the other environment in order to assure the best continuity of care.

- In inpatient the main focus is on the safe glycaemic management in order to minimize the short and medium term risks. Other important aspects of the inpatient environment are the implementation of a good transition of care from inpatient to outpatient which includes the discharge location, the patient's ability to comply with therapy and the level of glycaemic control

at discharge. This means, that lifestyle management and patient education must at least start in the hospital, but they are fully implemented in outpatient environment.

- In inpatient environment, dedicated personnel is available for data collection (glucose level, nutrition, etc.), thus reminders for missing data can be more reasonably sent in this environment.

8. Table of figures and tables

8.1 Figures

8.2 Tables

9. References

(Clark1989) Clark P. G., Lobsitz R. M., Shields J. D. (1989): Problems in agile trenches. Proc. IEEE Natl. Aerosp. Electr. Conf. 1819-1826, 1989.

(INCOSE2010) INCOSE Requirements Management Tools Survey. International Council on Systems Engineering. Available at: http://www.incose.org/ProductsPubs/products/rmsurvey.aspx (last accessed on June 25, 2010).

(ISO13407:1999) ISO 13407, Human-centered design processes for interactive systems.

(ISO9241) ISO 9241, Ergonomics of Human System Interaction.

(ISO9241-210:2010) ISO 9241-210, Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems.

(JIRA2010) Bug, Issue and Project Tracking for Software Development – JIRA. Available at: http://www.atlassian.com/software/jira/ (last accessed on June 25, 2010).

(LCS2009) Managing Requirements. Ludwig Consulting Services, LLC. Available at: http://www.jiludwig.com (last accessed on June 25, 2010).

(PowerTest2010) Micro Focus CaliberRM, Requirements Management Software: PowerTest.com. Available at: http://www.powertest.com/software-requirements-definition-management-micro-focus-caliber.html (last accessed on July 14, 2010).

(Prause2008) Prause C. R., Scholten M., Zimmermann A., Reiners R., Eisenhauer M. (2008): Managing the Iterative Requirements Process in a Multi-national Project Using an Issue Tracker. IEEE International Conference on Global Software Engineering, 151-159, 2008.

(Robertson2006) Robertson J., Robertson S. (2006): Volere Requirements Specification Template – Edition 11. Atlantic System Guild Limited.

10. Complete Set of Initial Requirements

[REACTION-1] Internet communication between patient home and primary/secondary healthcare structures based on public wired or wireless network Created: 02/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP3, WP5		
Rationale:	A basic communication infrastructure has to be assumed		
Source/Originator:	Outpatient workshop		
Fit Criterion:	Tests will be based on this assumption		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 2:54 PM]
Main impact is on WP5

[REACTION-3] Support for IEEE medical device standards Created: 02/Jun/10 Updated: 22/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Communication		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	To support a wide variety of medical devices, the selected subsets of the IEEE medical device standards should be supported.		
Source/Originator:	WP4 technical meeting 1, London		
Fit Criterion:	Show that REACTION device proxies can be developed for at least 2 different devices from different manufacturers.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Matts Ahlsen [09/Jun/10 9:22 AM]
Which relevant subset ? need to be more specific

[REACTION-6] Any REACTION device should have an associated semantic model (description) Created: 02/Jun/10 Updated: 07/Jun/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	To facilitate device discovery and application development, a device ontology should be part of the architecture.		
Source/Originator:	WP4 Technical meeting, London.		
Fit Criterion:	New devices can be matched against descriptions in the device ontology.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-8] User interface for manual entry of lifestyle data Created: 07/Jun/10 Updated: 07/Jul/10

Status:	Reopened		
Project:	REACTION requirements		
Component/s:	Context Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional		
Workpackage:	WP3, WP4, WP10		
Rationale:	To supply and support feedback on effectiveness of lifestyle behaviour and therapies to clinicians and patients.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	User interface exists.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	none		
Dependencies:	none		

Comment by Franco Chiarugi [07/Jul/10 2:52 PM]

Main impact is on WP10

[REACTION-9] Formalized feedback model Created: 07/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	A model describing which parameters to be collected, the frequency of collection, and target users of the data		
Source/Originator:	WP4		
Fit Criterion:	System is able to provide feedback in satisfactory time		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-10] Data fusion model Created: 07/Jun/10 Updated: 02/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	A description of how different data values are combined into medical data		
Source/Originator:	WP4 focus group		
Fit Criterion:	The system can provide automatic aggregation of data values from at least two different sensors.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-11] Life style baseline data Created: 07/Jun/10 Updated: 08/Jun/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4		
Rationale:	The system needs to store a set of baseline data regarding life style for each patient.		

Source/Originator:	WP4 CNet focus group
Fit Criterion:	Life style data can be retrieved and updated per patient
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	High Unhappiness

[REACTION-12] Automatic update on lifestyle data Created: 07/Jun/10 Updated: 07/Jun/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	Automatic update of lifestyle data based on sensors such as pedometers but also retrieval from health and lifestyle services and databases.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	At least one external service is supported.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

[REACTION-13] To update EPRs with collected data Created: 07/Jun/10 Updated: 22/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP4, WP10		
Rationale:	Provide an interface for updating EPRs.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	Support at least IHE-PCD01.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	none		
Dependencies:	none		

Comment by Franco Chiarugi [07/Jul/10 2:51 PM]
Main impact is on WP10

[REACTION-14] Persistent local/global data storage Created: 07/Jun/10 Updated: 07/Jun/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Context Management, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).		
Source/Originator:	WP4 CNet focus group		
Fit Criterion:	At least global storage is supported.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Conflicts:	none
Dependencies:	none

[REACTION-15] System must keep track of work flow stages **Created: 07/Jun/10 Updated: 07/Jul/10**			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Context Management, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional		
Workpackage:	WP10		
Rationale:	To identify in which stage within the diabetes management the patient is: newly diagnosed, medication titration, and ongoing management.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	Individual patient can always be mapped into a work flow stage.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

[REACTION-16] Individualized targets for patients needs to be stored and retrieved **Created: 07/Jun/10 Updated: 22/Jun/10**			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	Needed to determine the effectiveness of different therapies.		
Source/Originator:	WP4 CNet focus group		
Fit Criterion:	Possible to store targets.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

[REACTION-17] Configurable data transfer frequency **Created: 07/Jun/10 Updated: 15/Jun/10**			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	Possibility to configure the periodical transfer of the collected sensor data to external services such as WAN devices.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	Lowest periodical transfer is once per day.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	none		
Dependencies:	none		

[REACTION-18] Monitoring devices must be discoverable by existing network infrastructure **Created: 07/Jun/10 Updated: 22/Jun/10**

Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP5		
Rationale:	Device must be discovered in order to be able to communicate with other devices and platforms.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	At least to automatically discover devices using protocols supported in the Hydra middleware such as BT, ZigBee etc.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Conflicts:	none		
Dependencies:	none		

[REACTION-19] Necessity of a mobile solution for the outpatient sphere Created: 07/Jun/10 Updated: 21/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Stelios Louloudakis
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP5, WP4		
Rationale:	People tend to be moving and travelling.		
Source/Originator:	WP4 CNet focus group		
Fit Criterion:	Same service everywhere.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	REACTION-34		

Comment by Franco Chiarugi [02/Jul/10 1:50 PM]
This issue has something in common with issue 34. Issue 34 is related to the implementation for the outpatient environment (thus home and mobile) while this issue generically describe a user need specially in on-the-move situations. Probably the two issues could be merged in a single one (Stelios & Franco)
Comment by Matts Ahlsen [02/Jul/10 2:04 PM]
WP4: we aggree, they can be merged. and assigned to WP5
Comment by Franco Chiarugi [07/Jul/10 2:50 PM]
Not merged but inserted a dependency. Main impact is on WP5

[REACTION-20] Dynamically update and change feedback model Created: 07/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	Based on evaluation on received patient data it should be possible to change the feedback model - that is which data to measure and collect.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	Possible to change.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		

Dependencies:	none

[REACTION-21] Change log for feedback model **Created: 07/Jun/10 Updated: 28/Jul/10**			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	It must be possible to track changes in the feedback model, i.e. which data has been collected at certain times.		
Source/Originator:	WP4 CNet focus group		
Fit Criterion:	All changes to the feedback model are stored in a change log.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

[REACTION-22] Local feedback on measured values **Created: 07/Jun/10 Updated: 08/Jul/10**			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Communication, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional		
Workpackage:	WP4		
Rationale:	It should be possible to provide feedback on measured values, e.g. graphical representations, to those patients that request it.		
Source/Originator:	WP4 CNet focus group		
Fit Criterion:	Patient able to select requested feedback values.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

[REACTION-23] Clinician generated feedback to patient **Created: 07/Jun/10 Updated: 22/Jun/10**			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Communication, Context Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional		
Workpackage:	WP10		
Rationale:	It should be possible for clinician/staff to submit additional information to patients, e.g. for educational or encouragement purposes.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	At least to provide a two way communication, e.g. shared white board.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

[REACTION-24] Logging of events from components **Created: 09/Jun/10 Updated: 07/Jul/10**	
Status:	Open
Project:	REACTION requirements

Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP4, WP5, WP10		
Rationale:	All software components shall keep a detailed activity log, which will support the tracing and debugging of possible functioning errors, security holes, mis-configurations and other implementation issues.		
Source/Originator:	Dow, WP10 Objectives (p. 121)		
Fit Criterion:	A log file will be available for each component, containing data which will be defined by the design process.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [09/Jun/10 3:07 PM]
It is suggested that logging be performed by all components using available logging tools and techniques (such as log4j) so that we can keep track of the logs, define common patterns for many components, connect logs with automated procedures etc.
Comment by Franco Chiarugi [07/Jul/10 2:48 PM]
Main impact is on WP4 (design of components)

[REACTION-25] Fault tolerance to network malfunctioning Created: 09/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Backend Middleware, Communication, Networking, PAN/BAN		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP10, WP4, WP5		
Rationale:	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.		
Source/Originator:	Dow, WP5 Objectives (p. 85)		
Fit Criterion:	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [09/Jun/10 3:12 PM]
Software components should take actions so that no data is lost due to sudden network malfunctioning. When possible, data should be cached locally for later acquisition.
Comment by Franco Chiarugi [01/Jul/10 4:27 PM]
Highest impact should be on WP5

[REACTION-26] Embedded intelligence Created: 09/Jun/10 Updated: 07/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Networking, PAN/BAN		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP5, WP10		
Rationale:	Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions which are not written or specified in published deliverables or manuals. The applications shall not rely to "default" actions, or fall-back scenarios in exceptional cases, unless these are based on agreed scenarios or models.		
Source/Originator:	DoW, WP10, Task T10.1 (p. 122)		
Fit Criterion:	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [09/Jun/10 3:22 PM]
The embedded intelligence techniques should not be hardwired actions into the source code, but as extensively as possible, should be configurable.
Comment by Franco Chiarugi [01/Jul/10 4:30 PM]
Main impact is on WP10.

[REACTION-27] Seamless integration Created: 09/Jun/10 Updated: 22/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Backend Middleware, Communication, Context Management, Data Management, Glucose Control Algorithm, Interfaces with HIS/EPR, Networking, Ontology/Terminology, PAN/BAN, Physiology Models, Portable Devices, Portable User Interface, Risk Assessment, Security, Sensors, Web User Interface		
Type:	Volere Requirement	**Priority:**	Minor
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Look and feel		
Workpackage:	WP4, WP10		
Rationale:	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Low Unhappiness		

Comment by Franco Chiarugi [09/Jun/10 3:58 PM]
A prototype of a common ontology should be designed early in the project.
Comment by Franco Chiarugi [02/Jul/10 10:47 AM]
Main impact is on WP4.
Comment by Matts Ahlsen [02/Jul/10 12:25 PM]
WP4: I cannot see this as a WP4 (data management & service orch.) requirement... It is clearly an integration issue i.e., WP10 only.
Comment by Franco Chiarugi [02/Jul/10 12:50 PM]
The main focus of this issue is on building and maintaining a fully comprehensive ontology. This is a task of WP4. Seamless integration is a smooth consequence of that.

[REACTION-28] Network interoperability Created: 09/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication, Networking		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP5, WP4, WP10		
Rationale:	The communication between applications running in different devices will be based on SOAP messages.		
Source/Originator:	Dow, WP5, Task T5.4 (p. 89)		
Fit Criterion:	Communication with a service should be feasible by SOAP tools and standards, based on a service's published interface.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 2:47 PM]
Main impact is on WP4

[REACTION-29] Accurate data acquirement Created: 11/Jun/10 Updated: 22/Jun/10	
Status:	Open
Project:	REACTION requirements
Component/s:	Sensors

Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP3		
Rationale:	IR-absorption glucose spectra are strongly temperature dependent		
Source/Originator:	Ines Frese (IMM)		
Fit Criterion:	Integration of temperature sensor in the sensor platform		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

[REACTION-30] Power budget of wearable sensor platform Created: 11/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	Depending on the measuring intervals (tbd) power must be available for autarkic operation of sensor platform		
Source/Originator:	Ines Frese (IMM)		
Fit Criterion:	Definition of total power budget		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-32] The architecture should support the Continua WAN interface (WAN-IF) **Created: 11/Jun/10 Updated: 11/Jun/10**			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Communication		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Malcolm Clarke
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4		
Rationale:	Need to support Continua		
Source/Originator:	London tech meeting, CNET WP4 Focus group		
Fit Criterion:	The REACTION system implements at minimum the IHE PCD01 format		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-33] Sensor data as concrete values and CONTINUA compatible Created: 11/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	No raw sensor-data processing on REACTION platform		
Source/Originator:	Ines Frese (IMM)		
Fit Criterion:	Definition of data transfer protocol compatible to CONTINUA		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

[REACTION-34] Define "black box" to be used at outpatient environment Created: 11/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication, Networking, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Stelios Louloudakis	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP5		
Rationale:	Define the hardware to be used at the outpatient environment for acquiring and transmitting sensor data to the REACTION middleware (use a mobile device or a "home-pc").		
Source/Originator:	None		
Fit Criterion:	None		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	None		
Dependencies:	REACTION-19		

[REACTION-35] Usage Data (Information about elder and juvenile usage of the platform and resources shall be available) Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Interfaces with HIS/EPR, Portable User Interface, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Usability		
Workpackage:	WP8, WP10		
Rationale:	Reports shall be generated in a way that summarizes the use of the platform to meet the expectations of its users.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	A survey shall show the percent of the users that regularly use the platform.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 2:43 PM]
Main impact is on WP8

[REACTION-36] Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible) Created: 14/Jun/10 Updated: 27/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Backend Middleware, Networking, Portable Devices, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP10		
Rationale:	Failure to a component may result in a severe breakdown.		
Source/Originator:	Technical meeting in London		
Fit Criterion:	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [27/Jul/10 4:58 PM]
Lowered priority and customer satisfaction and dissatisfaction in order to address Thomas's comments

[REACTION-37] Applications guidelines (guidelines for formal carers, in-formal carers and patients) have to

be clearly defined **Created: 14/Jun/10 Updated: 07/Jul/10**			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Interfaces with HIS/EPR, Portable User Interface, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Usability		
Workpackage:	WP8, WP10		
Rationale:	To ensure that the applications will run with the best possible way.		
Source/Originator:	DoW		
Fit Criterion:	To demonstrate the full functionality of the REACTION platform.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-38] Integration plan (combining the various components) Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Backend Middleware, Networking, PAN/BAN, Portable Devices, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Operational		
Workpackage:	WP10		
Rationale:	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.		
Source/Originator:	DoW		
Fit Criterion:	For each interface/interconnection specify the data content and physical material content.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-39] Platform Integrity (integrity checks for the stored data) Created: 14/Jun/10 Updated: 22/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management, Security		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Security		
Workpackage:	WP4, WP7, WP10		
Rationale:	To guarantee the integrity of the stored data in the case of an unwanted happening.		
Source/Originator:	DoW		
Fit Criterion:	Use of adequate methods like e.g. Hash keys or redundancy codes for the data stored.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 6:38 PM]
The rational only speaks of the central security framework while the title talks about the whole platform - it should be clarified what is meant. Also, hash keys are only one option to guarantee data integrity as needed here, e.g., redundancy codes are another one. Thus, the fit criterion should probably be expressed in a more general way.
Comment by Franco Chiarugi [07/Jul/10 2:40 PM]
Changed the rationale and the fit criterion trying to address Matthias's comments
Comment by Franco Chiarugi [07/Jul/10 2:41 PM]
Main impact is on WP4

[REACTION-40] The sensors/devices developed by the consortium which communicate with the platform wirelessly, must be able to connect swiftly to platform and maintain that connection without interruptions, even in a fragmented space from wireless devices. Created: 14/Jun/10 Updated: 08/Jul/10	
Status:	Open

Project:	REACTION requirements		
Component/s:	Communication		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP10		
Rationale:	To guarantee the operation of the portable devices under any circumstances. Consortium developed wireless devices must be able to pair in an acceptable time and maintain connectivity in a electromagnetic interfering environment.		
Source/Originator:	DoW		
Fit Criterion:	Multiple trials in a real life environment (not only in the fully controlled environment of the laboratory) using multiple WiFi and Bluetooth devices, to ensure the ability of the sensor/device to connect and operate.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 2:35 PM]
Main impact is on WP3

[REACTION-41] The tools developed by the consortium must be properly documented in such a way that the end user can understand them and use them for the intended purpose. Created: 14/Jun/10 Updated: 28/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Interfaces with HIS/EPR, Portable User Interface, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP10		
Rationale:	Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The well documented tools will allow the users to make full use of their functions and capabilities and will also provide a complete test of the platform's functionality. Design history file is necessary not only for the end user but also for regulatory approval by the authorities which is mandatory for medical devices.		
Source/Originator:	DoW		
Fit Criterion:	Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely available and easily accessible via the website.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [28/Jul/10 11:06 AM]
Changed the rationale in order to address Lukas's comments

[REACTION-42] The technical interfaces to the platform must be documented and in such a way that the stakeholders can understand it and use it for integration. Created: 14/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP4, WP10		
Rationale:	Developers can develop better applications faster. The platform thus could also provide easy access to third party developers.		
Source/Originator:	DoW		
Fit Criterion:	Writing sufficient documentation for the technical interfaces and also by providing examples and if available simulators.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 2:34 PM]
Main impact is on WP4

[REACTION-43] Protection against data loss System must protect against: *Loss or replication of data transferred between two systems; *Concurrency problems; *Disk crash; *Protection against physical means. **Created: 14/Jun/10 Updated: 22/Jul/10**			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Security		
Workpackage:	WP4, WP7		
Rationale:	Data integrity has to be guaranteed. *Loss or replication of data transferred between two systems (e.g. system shutdown); *Concurrency problems (e.g. 2 doctors interact with the system simutaneously and prescribe different medicines, which one will the system pick?); *Disk crash (e.g. solution could be periodic backup or RAID); *Protection against physical means (e.g. solution could be remote backup)		
Source/Originator:	DoW		
Fit Criterion:	The functional test should include specific tests in order to verify such circumstances		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 6:26 PM]
I would propose to re-assign this issue to WP4 since WP7 is only concerned with data integrity when it comes to the transfer of data over networks.
Comment by Franco Chiarugi [07/Jul/10 2:33 PM]
Addressed Matthias's comments. Main impact is on WP4.

[REACTION-44] Protection against unintended user actions Created: 14/Jun/10 Updated: 22/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Portable User Interface, Security, Web User Interface		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Security		
Workpackage:	WP4, WP7, WP10		
Rationale:	Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not cause the system to close down, neither on the client nor on the server. All data entered must be checked for format, consistency and validity. In case of doubt, the user must be warned and asked what to do. The user must be able to correct mistakes easily. The user must be able to interrupt long functions (e.g. waiting for a remote data transfer).		
Source/Originator:	DoW		
Fit Criterion:	The functional test should include specific tests in order to verify such circumstances		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 6:20 PM]
This seems to be more an issue with appropriate data interfaces for users, thus WP4 and WP10 should be involved instead of WP7.
Comment by Franco Chiarugi [07/Jul/10 2:32 PM]
Addressed Matthias's comments. Main impact is on WP10.

[REACTION-45] Protection against threats Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Security		

Workpackage:	WP7, WP10
Rationale:	Medical data are sensible data and protection against threats and and unauthorized access should be provided. The system must protect against: *Unauthorized persons obtaining manager rights through the internet (hacking). *Unauthorized persons getting access to personal data. *The system must conform to Law on Handling of Personal Data.
Source/Originator:	DoW
Fit Criterion:	The functional test should include specific tests in order to verify such circumstances
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Matthias Enzmann [01/Jul/10 6:17 PM]
Rights elevation is often a problem of poorly designed user interfaces, thus WP10 should probably also be involved.
Comment by Franco Chiarugi [07/Jul/10 2:30 PM]
Main impact is on WP7

[REACTION-46] Error messages must be understandable and helpful Created: 14/Jun/10 Updated: 07/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Minor
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP4, WP10		
Rationale:	When an application fails this must happen gracefully while providing sufficient and easy to understand messages to the user. In this way the user will not get panicked during a failure, while able to understand what happened or whom to contact to report or resolve the problem.		
Source/Originator:	DoW		
Fit Criterion:	For each application, developers must ensure that error messages should be brief, easy to read, understood even by non-specialists and should also provide some short help (of course they must include the error code that will allow to understand exactly what is wrong).		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [14/Jun/10 2:01 PM]
This issue is related to the architecture because all the error messages (the ones encountered by users, and also the developers) must actually mean something and must be documented.
Comment by Franco Chiarugi [07/Jul/10 2:30 PM]
Main impact is on WP10

[REACTION-47] Web pages must be suited for screen readers, scaling to visually-impaired users, and utilizing the full screen size on small as well as large screens. Created: 14/Jun/10 Updated: 08/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Web User Interface		
Type:	Volere Requirement	**Priority:**	Minor
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Look and feel		
Workpackage:	WP10		
Rationale:	Will allow the easy interaction with the platform. Will also provide, as much as possible, to people with disabilities the ability to use the platform.		
Source/Originator:	DoW		
Fit Criterion:	Use of large fonts, use of colours with strong contrast, possible use of audio messages and implementation of other commonly used accessibility options, at the applications developed to be used by patients.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [14/Jun/10 2:01 PM]
The pages follow the HTML guidelines (W3C) for Accessibility.

[REACTION-48] Support for multilingual user interface Created: 14/Jun/10 Updated: 08/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Portable User Interface, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Usability		
Workpackage:	WP10		
Rationale:	Users from different countries should have access to services.		
Source/Originator:	DoW		
Fit Criterion:	Any type of text in any graphical user interfaces that will be developed (labels, text fields, labels, etc.) must be able to easily configured and changed using a easily configurable localization file. A first version of the file will be created in English language, and then it will be distributed to the partners. Once decided which languages will be supported, partners must contribute to the localization of the components, by translating them to its native language (if in the set of supported languages)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-49] The touch/tablet/phone device must allow the execution of processes in the background Created: 14/Jun/10 Updated: 09/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices, Portable User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Non-functional - Usability		
Workpackage:	WP3		
Rationale:	The applications developed for the portable devices should start and stop only when the user wants. If the portable device is a mobile phone when the user receives a phone call or SMS then the application should continue in the background without closing (preventing data loss). Therefore the portable devices should allow applications running in the background.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-50] The touch/tablet/phone device must support notification messages Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices, Portable User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Non-functional - Usability		
Workpackage:	WP3		
Rationale:	The portable device must have the ability to show alert messages to the user. This will allow the device to report promptly to the user if any measurement is not good, if it presents a problem, or even whether to take a medicine, or whether it has an appointment with the doctor.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-106		

Comment by Jesper Thestrup [29/Jun/10 6:45 PM]
This appears to be a duplicate of issue 106 /Helene

Comment by Franco Chiarugi [07/Jul/10 2:23 PM]
#106 is a duplicate of this requirement

[REACTION-51] If the touch/tablet/phone device is not able to send the data to the platform (lack of connectivity), it should store them locally and then send them when the connectivity is re-established.
Created: 14/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP3		
Rationale:	It is likely that outside the home, the user will not have access to a wireless network. In such a case the mobile device will continue to take measurements but will not be able to transmit them. Therefore in order not to lose the measurements, the device should be able to store them internally (the device must have a decent amount of internal storage, or accept memory cards, and be able to store the measurements there). When the device reconnects to a wireless network then it will send the stored measurements to the database.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-119 & REACTION-120		

Comment by Tamas Toth [01/Jul/10 10:47 AM]
Also a duplicate of #119
Comment by Franco Chiarugi [07/Jul/10 2:21 PM]
#119 and #120 are duplicates of this requirement

[REACTION-52] If the portable touch device is not capable to connect wirelessly and send the data, then it should be able to connect via USB to a host gateway with connectivity to the Internet & upload the measurement file to the platform. Created: 14/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication, Portable Devices		
Type:	Volere Requirement	**Priority:**	Minor
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Non-functional - Usability		
Workpackage:	WP3		
Rationale:	If no wireless network is available at the user's home environment, then he/she must be given the opportunity to send the measurements from the portable device to database, using the local connection (wired) of the home gateway.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	Creation of a service for the home gateway that upon USB connection with the portable device, the service will transmit the cached data of the portable device to the database. The whole procedure must be easy for the user. For this case an internet connection is mandatory for the home gateway.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Low Unhappiness		
Dependencies:	REACTION-108		

Comment by Franco Chiarugi [14/Jun/10 2:03 PM]
To examine if this is supported by any portable touch device. If not then this has no meaning. If it is supported an extra service must be implemented to handle the connection and the uploading of the data.
Comment by Franco Chiarugi [21/Jul/10 3:26 PM]
#108 is a duplicate of this requirement

[REACTION-53] *The portable touch device must have at least the following connectivity options: WiFi (802.11g or 802.11n), Bluetooth, USB; *Also it must have built in at least the following sensors: GPS, accelerometer; *If mobile phone it must support 3G networks. Created: 14/Jun/10 Updated: 20/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Non-functional - Usability		
Workpackage:	WP3		
Rationale:	The device must support the latest and most widespread communication protocols. The presence of specialized sensors like the accelerometer, and the GPS will improve the usability of the device, and will allow the collection of additionally useful information.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-121		

Comment by Jesper Thestrup [29/Jun/10 5:49 PM]
This is (another) duplicate of issue 121 /Helene
Comment by Franco Chiarugi [01/Jul/10 3:03 PM]
this statement is similiar to N-121 (Lukas)
Comment by Franco Chiarugi [07/Jul/10 2:15 PM]
#121 is a duplicate of this requirement

[REACTION-54] Network & system monitoring Created: 14/Jun/10 Updated: 14/Jun/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication, Data Management, Networking, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Stelios Louloudakis	**Assignee:**	Antonis Miliarakis
Requirement Type:	Functional		
Workpackage:	WP5		
Rationale:	Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements using SNMP and Netflow Records for network monitoring, in order to verify QoS, as well as network and systems' monitoring services.		
Source/Originator:	WP5		
Fit Criterion:	none		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	None		
Dependencies:	Heterogenous networks		

[REACTION-55] The portable touch device must have a display of sufficient screen size & resolution (more than a 3,5" display, more than 320px*480px). If not a stylus operating device then the display must be of capacitive technology & with support for multitouch. Created: 14/Jun/10 Updated: 20/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Non-functional - Usability		
Workpackage:	WP3		
Rationale:	A device with smaller screen estate will compromise its usability, and will make the interaction with user an unattractive and difficult experience. A multitouch display dramatically improves the user interaction. Displays that make use of capacitive technology provide a much better multitouch operation.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		

Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	Extreme Unhappiness
Dependencies:	REACTION-111

Comment by Franco Chiarugi [01/Jul/10 3:05 PM]

This statement is similar to N-111 (Lukas)

Comment by Franco Chiarugi [02/Jul/10 3:58 PM]

This statement is similar to N-121 (Thomas, IMM)

Comment by Franco Chiarugi [07/Jul/10 2:12 PM]

#111 is a duplicate of this requirement

[REACTION-56] The portable touch device must have a satisfactory operational time. The battery must be able to support the device for at least half a day. If the device supports exchangeable battery that would be an advantage. Created: 14/Jun/10 Updated: 20/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Non-functional - Usability		
Workpackage:	WP3		
Rationale:	The portable device will have to be operated continuously. The small size and weight of the device allows the user to move freely, but the battery life can be a problem. For this reason, the life of the device when powered only by battery should be sufficient to allow the user to leave the house. The portable touch device should be able to operate while the sensors receive measurements simultaneously with the application and its services, for at least five consecutive hours (it is acceptable if the display is not turned on for the whole duration). The extended battery life will allow the user to continue his daily program with a minimal intervention (or no intervention at all), until he/she returns home, where he/she can then charge the portable device.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-122		

Comment by Franco Chiarugi [02/Jul/10 3:52 PM]

this statement is similar to N-111 (Thomas, IMM)

Comment by Franco Chiarugi [07/Jul/10 2:10 PM]

#122 is a duplicate of this requirement

[REACTION-57] Performance and Scalability Created: 14/Jun/10 Updated: 07/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Communication		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Performance		
Workpackage:	WP4, WP10		
Rationale:	Responsive enough to integrate with the clinician workflow. The response to the users action should be acceptable, depending on how time-critical is the action's response. Each component should scale well when increasing the users and the data that is stored and processed.		
Source/Originator:	DoW		
Fit Criterion:	Criteria are different depending on the user action. For time-critical actions the response should be almost instant.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 1:32 PM]

Main impact is on WP10

[REACTION-60] Restore from malfunctioning Created: 14/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP4, WP8, WP10		
Rationale:	System should be able to restore its previous state and the data when an unexpected problem occurred (wrong usage, hardware error, etc).		
Source/Originator:	DoW		
Fit Criterion:	There should be no corrupted data or loss of information whatever the action of the user is or whenever the system stops working for any reason.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 1:49 PM]
Main impact is on WP8

[REACTION-61] Data exchange with third-party systems Created: 14/Jun/10 Updated: 22/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP10		
Rationale:	Ideally accepts and integrates information from outside of the managing organization (e.g. pharmacies).		
Source/Originator:	DoW		
Fit Criterion:	Should be able to import and export data in an interoperable way to third-party systems.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-62] Semantics based data management Created: 14/Jun/10 Updated: 22/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP10		
Rationale:	According to the DoW the monitoring and other data need to be properly annotated with ontological descriptions in order to achieve integration and interoperability		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	Relevant entries in the REACTION's databases are annoted with semantic concepts		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 1:46 PM]
Main impact is on WP4

[REACTION-63] Security and privacy related to patient data Created: 14/Jun/10 Updated: 22/Jul/10	
Status:	Open
Project:	REACTION requirements

Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matthias Enzmann
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP7, WP10		
Rationale:	Privacy concerns are of utmost importance. The patient data should be transfer and maintained in a secure way while any access to them should be monitored and logged (getting advantage of a login mechanism available in the applications).		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	Verify that any access to patient data is logged and is performed in a secure way		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	REACTION-103		

Comment by Matthias Enzmann [01/Jul/10 5:50 PM]
The implications of the Title/Summary are much wider than the Rationale and the Fit Criterion.
Comment by Franco Chiarugi [07/Jul/10 1:44 PM]
Changed summary, rationale and fit criterion in order to address Matthias's comments
Comment by Franco Chiarugi [07/Jul/10 1:44 PM]
Main impact is on WP7

[REACTION-64] Friendly applications Created: 14/Jun/10 Updated: 08/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Usability		
Workpackage:	WP10		
Rationale:	The use of end-user applications and the devices both in the in-patient but also (and most importantly perhaps) in the outpatient cases should be intuitive, efficient, and of minor disturbance to the patients, requiring minimal interactions and engagement.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	No complex user interfaces, the user should be familiar with the applications in short time (training is foreseen)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Jesper Thestrup [29/Jun/10 6:15 PM]
Compare with issue 133 'One day of training' /Helene
Comment by Franco Chiarugi [07/Jul/10 1:36 PM]
#133 and this requirement complement each other, but #133 is focused on the quality of training while this requirement is focused on easy and user-friendly user interface

[REACTION-65] System availability Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Backend Middleware		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP8, WP10		
Rationale:	The system should be continually monitoring and gathering data about the patients status with no excessive down time. Availability here means that the vital components of the REACTION platform will be in functioning state in order for the patient safety to be supported.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	The end user applications and the devices in the vicinity of the patient should always operable		
Customer Satisfaction:	Very Pleased		
Customer	High Unhappiness		

Dissatisfaction:	

Comment by Franco Chiarugi [14/Jun/10 2:48 PM]
To better achieve this requirement standard software engineering practices like for example replication of the data and distribution of the computations among worker components with load balancing and failover should be followed.
Comment by Franco Chiarugi [07/Jul/10 1:34 PM]
Main impact is on WP10

[REACTION-66] Component Interface Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Backend Middleware		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP10		
Rationale:	Interoperability among components should be guaranteed by the use of standard interfaces.		
Source/Originator:	DoW & Technical Meetings		
Fit Criterion:	The test facility will be based on the implemented standard		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:31 PM]
Main impact is on WP4.

[REACTION-67] Component Repository Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP10		
Rationale:	A repository for the binary components has to be set-up in order to ease the integration and the internal test		
Source/Originator:	Technical Meetings		
Fit Criterion:	A server for the containment of the components will be set-up		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-68] Component Versioning Created: 14/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP10		
Rationale:	In order to have a good development practice		
Source/Originator:	Technical Meetings		
Fit Criterion:	The test facility will take into account also the version of components		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [14/Jun/10 2:52 PM]
This issue was also suggested by CNET.

Comment by Franco Chiarugi [01/Jul/10 4:33 PM]
Main impact is on WP4.

[REACTION-69] System Configuration Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP10		
Rationale:	The components and applications should be made in a way that makes easy the configuration		
Source/Originator:	Technical Meetings		
Fit Criterion:	Theoretically without any recompilation, the application should be easily configurable for the different environments		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-70] Processing of multi-parametric clinical and non-clinical data from different sources Created: 14/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Context Management, Data Management, Interfaces with HIS/EPR, Networking, Ontology/Terminology, PAN/BAN, Physiology Models, Portable Devices, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Blocker
Reporter:	Peter Beck	**Assignee:**	Peter Rosengren
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP4, WP5, WP6, WP8, WP10		
Rationale:	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data		
Source/Originator:	Call, DoW, D2.1/MSG		
Fit Criterion:	Platform flexibly supports processing of data from multiple sources		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:55 PM]
Main impact is on WP4

[REACTION-71] Simulators for the internal tests Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Sensors		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP10		
Rationale:	The internal test is performed without real users (clinicians & patients) and therefore some devices have to be simulated		
Source/Originator:	Technical Meetings		
Fit Criterion:	Simulated components performing the same operations with exactly the same interface have to be available		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-72] Provide decision support for insulin dosing for clinicians (in-hospital) Created: 14/Jun/10 Updated: 23/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Communication, Context Management, Data Management, Glucose Control Algorithm, Interfaces with HIS/EPR, Networking, Ontology/Terminology, Physiology Models, Portable Devices, Portable User Interface, Risk Assessment, Security, Sensors, Web User Interface		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Peter Beck	**Assignee:**	Stephan Spat
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP8, WP6, WP5, WP3, WP10		
Rationale:	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system (eDSS) to suggest insulin dosing		
Source/Originator:	DoW, D2.1 (p.62)/MSG		
Fit Criterion:	eDSS is available for the REACTION platform		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:53 PM]
Main impact is on WP6

[REACTION-73] Provide decision support for insulin dosing for physicians and/or patients (outpatient)
Created: 14/Jun/10 Updated: 23/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Backend Middleware, Communication, Context Management, Data Management, Glucose Control Algorithm, Interfaces with HIS/EPR, Networking, Ontology/Terminology, PAN/BAN, Physiology Models, Portable Devices, Portable User Interface, Risk Assessment, Security, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Stephan Spat
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP6, WP8, WP10		
Rationale:	Type 2 diabetes: Support to titrate insulin dose is suggested by decision support system based on monitoring data. Type 1 diabetes: Short-term support for insulin self administration is generated from monitoring data and given to patients.		
Source/Originator:	DoW, D2.1 (p.42)/MSG		
Fit Criterion:	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:52 PM]
Main impact is on WP6

[REACTION-74] Formalization of pre-existing clinical data (semantic structure) Created: 14/Jun/10 Updated: 23/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Context Management, Data Management, Ontology/Terminology, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Peter Beck	**Assignee:**	Tamas Toth
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP6, WP4, WP10		
Rationale:	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS		
Source/Originator:	DoW/MSG		
Fit Criterion:	External data from EPR/HIS are available in a formalized manner		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:51 PM]
Main impact is on WP6
Comment by Peter Beck [08/Jul/10 6:08 PM]
According to the DOW this work should be mainly done in T6.4 (ALL). (WP6)

[REACTION-75] Maintain and continuously update a patient health status profile Created: 14/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Context Management, Data Management, Glucose Control Algorithm, Interfaces with HIS/EPR, Networking, PAN/BAN, Physiology Models, Portable Devices, Risk Assessment, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Peter Rosengren
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP4, WP6, WP8		
Rationale:	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)		
Source/Originator:	DoW/MSG		
Fit Criterion:	Up-to-date data are available in the REACTION platform as a basis for higher level functionality		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:50 PM]
Main impact is on WP4

[REACTION-76] Portability Created: 14/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Usability		
Workpackage:	WP4, WP10		
Rationale:	All components should have the capability of running at least under two of the most common operating systems (e.g. Linux and Windows 7 or XP)		
Source/Originator:	Technical meetings		
Fit Criterion:	Specific test has to be done on each component		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:34 PM]
Main impact is on WP4.
Comment by Franco Chiarugi [28/Jul/10 10:21 AM]
Changed the rationale in order to address Lukas's comments

[REACTION-77] Browser Compatibility Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Usability		
Workpackage:	WP10		
Rationale:	The web based interface should be perform properly in the last 2 editions of the 5 most common browsers		
Source/Originator:	Technical Meetings		

Fit Criterion:	Specific tests have to be performed
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

[REACTION-78] Mechanistic physiology-based models of insulin and glucose kinetics Created: 14/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management, Glucose Control Algorithm, Interfaces with HIS/EPR, Physiology Models, Portable Devices, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Joerg Lippert
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP6, WP8		
Rationale:	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services. Step 1: Use physiology-based model to "in-vitro" validate the decision support system of the inpatient scenario Step 2: Integrate the physiology-based model into the decision support system for more individualized decision support, and finally validate in clinical studies.		
Source/Originator:	DoW/MSG		
Fit Criterion:	Mechanistic physiology-based models are available within the REACTION platform		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:43 PM]
Main impact is on WP6

[REACTION-79] Off-the-Shelf Devices Created: 14/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Constraint - Off-the-Shelf Sensors & Devices		
Workpackage:	WP3, WP5		
Rationale:	Non standard communication protocols imply a significant development effort. Such development effort can be very huge and very often also not feasible if non standard protocol is non disclosed.		
Source/Originator:	Technical Meetings		
Fit Criterion:	The commercial devices not developed by the consortium have to be compliant with relevant communication standard or, only in special cases, have a full-disclosed protocol		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:42 PM]
Main impact is on WP5

[REACTION-80] Only one or max two categories of different mobile operating systems will be considered for the portable devices Created: 14/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Non-functional - Usability		
Workpackage:	WP3		
Rationale:	The large spread of existing operating systems does not allow developments on a large number of mobile operating system. The more effective solution is to focus on one or max two common and largely diffuse operating systems.		

Source/Originator:	Technical Meetings
Fit Criterion:	Internal test and field trials will be performed only using portable devices with one of the selected operating systems
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Franco Chiarugi [02/Jul/10 3:51 PM]

Continua? (Thomas, IMM)

Comment by Franco Chiarugi [07/Jul/10 12:41 PM]

This issue refers to the portable device to be used in the "black box", thus to the measurement collector (BAN integration node). Several types of portable devices (PDA, SmartPhone, mobile phone, etc.) are available in the market with different operating systems. We have to focus on one or max two of them.

[REACTION-81] Long-term risk calculation and patient-oriented presentation Created: 14/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Stephan Spat
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP6, WP8		
Rationale:	Calculate long-term risk based on patient health profile and: - visualize in a patient-oriented form - present risk-reduction strategies to patient and caregivers to support patient education and empowerment The risk calculator mainly will be used in the outpatient/primary care area for patient empowerment and patient education and also as input for decision support		
Source/Originator:	D2.1 (p.21, p.31)/MSG		
Fit Criterion:	The REACTION platform offers a service to calculate diabetes dependent long-term risks		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:36 PM]

Main impact is on WP6

[REACTION-82] Contextualized and personalized feedback to patients and carers Created: 14/Jun/10 Updated: 08/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Backend Middleware, Communication, Context Management, Data Management, Glucose Control Algorithm, Interfaces with HIS/EPR, Ontology/Terminology, Portable Devices, Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP6, WP8, WP10		
Rationale:	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability		
Source/Originator:	DoW, D2.1 (p. 27, p. 31, p. 61)/MUG		
Fit Criterion:	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:36 PM]

Main impact is on WP6

[REACTION-83] Interface to clinical data from "near" real-time observations for decision support Created: 14/Jun/10 Updated: 22/Jul/10

Status:	Open

Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Backend Middleware, Communication, Context Management, Data Management, Glucose Control Algorithm, PAN/BAN, Physiology Models, Portable Devices, Portable User Interface, Risk Assessment, Security, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP5, WP4, WP3, WP6		
Rationale:	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)		
Source/Originator:	DoW, D2.1 (p.49, p.62)/MSG		
Fit Criterion:	Data will be available shortly after measurement in the REACTION database		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Jesper Thestrup [29/Jun/10 5:20 PM]
Check potential overlap with issue 172 and compare with Fit Criterion of issue 57 /Helene
Comment by Franco Chiarugi [07/Jul/10 12:31 PM]
Main impact is on WP5
Comment by Franco Chiarugi [07/Jul/10 12:33 PM]
#172 is specific for glucose measurement while this requirement refers to all data/measurements necessary for the insulin dosage evaluation. #57 refers to the response time of generic functions of the system, while this requirement is focused on the decision support.

[REACTION-84] Interface to patients health history information from EPR/HIS Created: 14/Jun/10 Updated: 23/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Context Management, Data Management, Interfaces with HIS/EPR, Networking, Ontology/Terminology, Risk Assessment, Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP8, WP6, WP4, WP10		
Rationale:	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information		
Source/Originator:	DoW, D2.1 (p.61)/MSG		
Fit Criterion:	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:28 PM]
Main impact is on WP10

[REACTION-85] Present effectiveness of medication therapies to patients and carers Created: 14/Jun/10 Updated: 08/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Context Management, Ontology/Terminology, Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP6, WP10		
Rationale:	In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an adequate front-end		
Source/Originator:	D2.1 (p.42)/MSG		
Fit Criterion:	Front-end for therapy-scheme quality presentation		

Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Low Unhappiness

Comment by Franco Chiarugi [07/Jul/10 12:26 PM]
Main impact is on WP10

[REACTION-86] Estimate short- and mid-term risk and identify successful therapy schemes for patient groups Created: 14/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Stephan Spat
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP6, WP8		
Rationale:	For the REACTION project data mining methods and heuristic algorithms should be used in order to identify: - risk profiles for short- and mid-term risk based on stratification of population health data in large populations - successful therapy strategies for different patient groups to be used as input for decision support		
Source/Originator:	DoW/MSG		
Fit Criterion:	Health risk profiles (short- and mid-term) are available for risk profiling and knowledge discovery within the data sets can be conducted. Based on a score for "therapy success" more successful therapies can be identified for different patient groups.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:24 PM]
Main impact is on WP6

[REACTION-87] Define network architectural model Created: 14/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Communication, Networking		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Stelios Louloudakis	**Assignee:**	Antonis Miliarakis
Requirement Type:	Non-functional - Operational		
Workpackage:	WP5, WP4, WP3		
Rationale:	Handle resources and services in heterogeneous networks (define heterogeneous networks) and dynamically change performance data of the resources without restricting only to IP networks. Analysis on existing models and standards.		
Source/Originator:	DoW		
Fit Criterion:	None		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	None		
Dependencies:	None		

Comment by Franco Chiarugi [05/Jul/10 9:15 AM]
I think this issue is related to WP4 & WP5
Comment by Franco Chiarugi [07/Jul/10 12:23 PM]
Changed the involved WPs in order to address Franco's comments
Comment by Franco Chiarugi [07/Jul/10 12:24 PM]
Main impact is on WP5

[REACTION-88] Define the provided input for SMS communication Created: 14/Jun/10 Updated: 07/Jul/10

Status:	Open
Project:	REACTION requirements

Component/s:	Alarm & Alert Subsystem, Backend Middleware, Communication, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Stelios Louloudakis	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP5		
Rationale:	Define the attributes of the provided input for the instant communication method (on SMS).		
Source/Originator:	DoW		
Fit Criterion:	None		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	None		
Dependencies:	Based on the input that will be provided from the Reaction middleware (Decision support issues)		

Comment by Franco Chiarugi [07/Jul/10 12:22 PM]
Main impact is on WP5

[REACTION-89] Network management subsets Created: 14/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication, Networking, PAN/BAN		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Stelios Louloudakis	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP5, WP10		
Rationale:	Define network management subsets for data traffic management between Patient's sphere and Carer's sphere communication. Integration and communication of back-end systems and EHRs with BAN & PAN components.		
Source/Originator:	DoW		
Fit Criterion:	None		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	None		
Dependencies:	Define back-end systems		

Comment by Franco Chiarugi [07/Jul/10 12:22 PM]
Main impact is on WP5

[REACTION-90] Identifiability: Recipients and senders of information must be identifiable, though not necessarily personally identifiable Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Security		
Workpackage:	WP7		
Rationale:	Reports/measurements must be assignable to the 'right' patient file/device		
Source/Originator:	DoW/SIT		
Fit Criterion:	Recipients and senders must have unique identifiers		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-91] Authenticity: Processors of information should be able to determine whether the data being processed is authentic Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open
Project:	REACTION requirements

Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Security		
Workpackage:	WP7		
Rationale:	Medical personnel should know if information relating to their patient originates from a known/trusted source, e.g., the patient's blood glucose sensor or medical personnel, in order to assess the data's quality		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a mechanism that allows to verify the authenticity of some information		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-92] Integrity: Information, in particular health data, must be protected from any kind of unintended changes during transport Created: 14/Jun/10 Updated: 27/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Security		
Workpackage:	WP7		
Rationale:	Any kind of undetectable changes in patient's data may give rise to wrong treatment and harm patients		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a mechanism for ensuring data integrity		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [27/Jul/10 4:54 PM]
Addressed Thomas's comments changing summary and rationale

[REACTION-93] Confidentiality: Sensitive information must not be readable by unauthorised persons Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Security		
Workpackage:	WP4, WP7		
Rationale:	Various stakeholders exchange information over the REACTION platform which, without any safeguards, would allow third parties to learn sensitive information of patients		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a mechanism for ensuring data confidentiality		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-58 & REACTION-59		

Comment by Franco Chiarugi [07/Jul/10 12:21 PM]
Main impact is on WP4
Comment by Franco Chiarugi [21/Jul/10 3:30 PM]
#58 & #59 are duplicates of this requirement

[REACTION-94] Availability: Patient data and other resources must be available to ensure proper treatment Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open
Project:	REACTION requirements

Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Stelios Louloudakis
Requirement Type:	Non-functional - Security		
Workpackage:	WP7, WP5		
Rationale:	Non-availability of patient data will hamper further treatment and might even impair the patient's health		
Source/Originator:	DoW/SIT		
Fit Criterion:	REACTION platform should remain operational in case of failures		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [21/Jul/10 12:06 PM]
Although non-availability might become a security problem, it is not per se a security issue but one of network connectivity, IMHO. Even in DDoS attacks, which are considered a security problem, countermeasures I know of are mostly on the network layer and do not involve security mechanisms. Thus, I push this issue to WP4. Feel free to disagree ;-)
Comment by Franco Chiarugi [21/Jul/10 3:33 PM]
Better to involve WP5 which is focused on Network Management

[REACTION-95] Accountability: Stakeholders should be held accountable for relevant actions Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Legal		
Workpackage:	WP7		
Rationale:	Certain actions or decisions will have an impact on the person making the decision or on the person affected by it, thus it should be clear, e.g., who made the decision, what kind of decision was made, and when was it made		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a procedure or mechanism allowing to review relevant actions of stakeholders		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-96] Visualization individual patient data to support glucose control (decision support) Created: 14/Jun/10 Updated: 22/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Context Management, Data Management, Networking, Portable Devices, Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Stephan Spat
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP6, WP10		
Rationale:	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy to reconfigure (personal configuration) - easy selection of relevant parameters, quick assembling and presentation of data - overview screen "all patient's blood glucose" - parameters ordered hierarchically in individual patient display		
Source/Originator:	D2.1 (p.62)/MSG		
Fit Criterion:	Inpatient REACTION pilot offers dynamic visualization module for decision support		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:19 PM]
Main impact is on WP10

Comment by Peter Beck [08/Jul/10 5:39 PM]
in close collaboration with WP6 (MSG)

[REACTION-97] Quality analysis for ward personnel Created: 14/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Minor
Reporter:	Peter Beck	**Assignee:**	Stephan Spat
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP6, WP8		
Rationale:	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)		
Source/Originator:	D2.1 (p.63)/MSG		
Fit Criterion:	Inpatient REACTION pilot offers quality tool		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Low Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:18 PM]
Main impact is on WP6

[REACTION-98] Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital Created: 14/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Minor
Reporter:	Peter Beck	**Assignee:**	Stephan Spat
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP6, WP8		
Rationale:	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital (when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of risk.		
Source/Originator:	D2.1 (p.63)/MSG		
Fit Criterion:	If a diabetic patient is not on insulin therapy, the platform shall be able to estimate the risk for the particular patient to become insulin-dependent. Inpatient REACTION pilot decision support tool offers "patients at risk" calculator.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Low Unhappiness		
Dependencies:	REACTION-256		

Comment by Tamas Toth [01/Jul/10 10:51 AM]
overlap with #256
Comment by Franco Chiarugi [07/Jul/10 12:17 PM]
#256 is a duplicate of this requirement. Main impact is on WP6

[REACTION-99] Authorisation: Stakeholders must be authorised before they are allowed to perform relevant actions Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Security		
Workpackage:	WP7		
Rationale:	Certain actions are not permitted for everybody but may only be carried out by authorised personnel		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a procedure or mechanism allowing to authorise relevant actions		

Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness
Dependencies:	REACTION-58 & REACTION-59

Comment by Franco Chiarugi [21/Jul/10 3:35 PM]
#58 & #59 are duplicates of this requirement

[REACTION-100] Access control: Access to sensitive information should only by given to authorised personnel Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Security		
Workpackage:	WP7		
Rationale:	Sharing patient data is necessary in health care to treat patients but access should only be given to persons involved in the treatment		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a mechanism allowing to control access to sensitive data		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-58 & REACTION-59		

Comment by Franco Chiarugi [21/Jul/10 3:36 PM]
#58 & #59 are duplicates of this requirement

[REACTION-101] Display / link to evidence based medicine information for decision support Created: 14/Jun/10 Updated: 23/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Glucose Control Algorithm, Ontology/Terminology, Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Minor
Reporter:	Peter Beck	**Assignee:**	Stephan Spat
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP6, WP8		
Rationale:	Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence based literature to the decision support system to help clinicians in decision making		
Source/Originator:	D2.1 (p.63)/MSG		
Fit Criterion:	Decision support systems implements a module to link relevant literature to help clinicians in decision making		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:15 PM]
Main impact is on WP6

[REACTION-102] Notice: Natural persons should be notified when, how, and to what extent their personal data are communicated to others Created: 14/Jun/10 Updated: 20/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Legal		
Workpackage:	WP7		
Rationale:	Handling of personal data has to conform to privacy laws		

Source/Originator:	DoW/SIT
Fit Criterion:	Process design takes into account the fair-processing principle
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Eugenio Mantovani [01/Jul/10 5:59 PM]

I beg to disagree. REACTION-148 talks about "trust". Being notified about "when, how, and to what extent personal data is communicated to other" is important to achieve trust, but does not tell it all. Some users may care very little about being notified when, how etc..., while they may value very dearly that the system is properly built. Knowing that the application takes care about risks and that the application gave a thought about how to prevent them from surfacing, is important to feel secure.

Comment by Franco Chiarugi [07/Jul/10 12:14 PM]

#148 offers a complete picture about trust, while this requirement is related to the notification of communication of personal data. Notification is important but end-users should know in advance that communication of personal data can happen and in which specific circumstances

[REACTION-103] Data reduction and data economy: Personal data shall be collected, processed and used as little as possible. Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Legal		
Workpackage:	WP7		
Rationale:	Handling personal data has to conform to privacy laws. In particular, personal data shall be rendered anonymous or pseudonymous as allowed by the purpose for which they are collected and/or further processed or used. This (might be/) is in conflict with unnecessary collection of personal data, which are not required to fulfil a specific task.		
Source/Originator:	DoW/SIT		
Fit Criterion:	Processes are designed such that personal data are only collected when necessary and anonymisation/pseudonymisation techniques are employed whenever possible		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-104] Need-to-know Basis: Stakeholders processing information should only learn what is necessary to carry out their specific task Created: 14/Jun/10 Updated: 21/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Security		
Workpackage:	WP7		
Rationale:	In an information processing chain, several stakeholders might be involved but it might not be necessary for every stakeholder to know which exact data another stakeholder has processed		
Source/Originator:	DoW/SIT		
Fit Criterion:	Process design takes into account the need-to-know principle		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-109] Scalability: the security must not materially impact the performance of the system Created: 14/Jun/10 Updated: 14/Jun/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Performance		
Workpackage:	WP7		

Rationale:	the security resources have to scale well with the overall architecture
Source/Originator:	DoW/ATOS
Fit Criterion:	Security does not significantly impact overall latency of the system
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

[REACTION-114] Modularity: the system has to be divided into components Created: 14/Jun/10 Updated: 14/Jun/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP7		
Rationale:	It is easier to implement, exchange, and integrate the modules.		
Source/Originator:	DoW/ATOS		
Fit Criterion:	REACTION platform should be modular		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-115] Transparency: Security configuration should be hidden from the user as far as possible Created: 14/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Usability		
Workpackage:	WP7		
Rationale:	Users usually do not have the expertise to choose the 'right' security options.		
Source/Originator:	DoW/SIT		
Fit Criterion:	No, or as few as possible, additional user interactions for security.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-116] Availability of security mechanisms to manage sensitive data Created: 14/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Maintainability and portability		
Workpackage:	WP7		
Rationale:	In REACTION, we are dealing with sensitive data, thus security must be available on all platforms.		
Source/Originator:	DoW/SIT		
Fit Criterion:	Security mechanisms are available for all target platforms of REACTION.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Jesper Thestrup [29/Jun/10 12:54 PM]
The implications of the Title/Summary are much wider than the Rationale /Helene
Comment by Franco Chiarugi [07/Jul/10 11:41 AM]
Changed the title/summary in order to address Helene's comments

[REACTION-117] Cross-platform usability: user experience should be the same on all platforms Created: 14/Jun/10 Updated: 20/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable User Interface, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Usability		
Workpackage:	WP10		
Rationale:	Users should only see familiar interfaces in order to adapt to a new platform more easily.		
Source/Originator:	DoW/ATOS		
Fit Criterion:	Different platforms do not have significantly different user interfaces, i.e., REACTION should be 'platform agnostic'.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [20/Jul/10 10:18 AM]
Interface design should be handled in WP 10/11, thus, this task should be assigned to Forth or CNET

[REACTION-118] Assurance: the architecture and its implementation must provide assurance that it delivers the security and compliance properties it promises Created: 14/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matthias Enzmann	**Assignee:**	Matthias Enzmann
Requirement Type:	Non-functional - Legal		
Workpackage:	WP7		
Rationale:	If allegedly secure functions do not live up to their expected functionality, the whole platform could be compromised.		
Source/Originator:	DoW/ATOS		
Fit Criterion:	Successful review of expected security functionality.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-123] Define components and services Created: 15/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication, Data Management, Networking		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Antonis Miliarakis	**Assignee:**	Antonis Miliarakis
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP5, WP4		
Rationale:	Define the necessary components, services and orchestration methods under a Service Oriented Architecture perspective.		
Source/Originator:	DoW,		
Fit Criterion:	none		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 9:12 AM]
I think this issue is mainly related to WP4 & WP5
Comment by Franco Chiarugi [07/Jul/10 11:36 AM]
Added WP4 in order to address Franco's comments
Comment by Franco Chiarugi [07/Jul/10 11:37 AM]

Main impact is on WP5

[REACTION-124] Portable device should collect all the relevant vital signs measured on the patient Created: 15/Jun/10 Updated: 07/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, PAN/BAN, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP5		
Rationale:	A portable with adequate features/performances should collect all the relevant vital signs measured on the patient realizing the BAN		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	A commercial portable device will be selected in order to perform the internal tests and the field trials		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 1:56 PM]
This issue has something in common with issue 34. In this case the black box should contain a commercial portable device which collects all the acquired relevant vital signs (Stelios & Franco)
Comment by Franco Chiarugi [07/Jul/10 11:35 AM]
Main impact is on WP5

[REACTION-125] Portable device should collect also additional environmental measurements Created: 15/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, PAN/BAN, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP5		
Rationale:	The same portable device used for the BAN integration will be used also for the PAN integration collecting also relevant environmental measurements. This solution reduced the overall cost of the acquisition system increasing the sustainability of the platform.		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium devices/sensors and by off-the-shelf devices used in the platform		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 1:58 PM]
The portable device could eventually be a part of the "black box" defined in issue 34 (Stelios & Franco)
Comment by Franco Chiarugi [02/Jul/10 3:47 PM]
This does not comply with the DOW, I think additional sensors other than described in the DOW can not be developed here (Thomas, IMM)
Comment by Franco Chiarugi [07/Jul/10 11:34 AM]
Main impact is on WP5

[REACTION-126] Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake) Created: 15/Jun/10 Updated: 26/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, PAN/BAN, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP5		

Rationale:	The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. The possibility to collect this information using the same portable device used for the BAN/PAN integration reduces the overall cost of the acquisition system improving the sustainability of the overall solution. The portable device could eventually be a part of the "black box".
Source/Originator:	DoW and Technical Meetings
Fit Criterion:	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Franco Chiarugi [02/Jul/10 1:58 PM]
The portable device could eventually be a part of the "black box" defined in issue 34 (Stelios & Franco)
Comment by Franco Chiarugi [02/Jul/10 3:46 PM]
Probably the same as REACTION-215 and REACTION-243 (Thomas, IMM)
Comment by Franco Chiarugi [05/Jul/10 3:38 PM]
Changed the rationale in order to address Stelios's comments
Comment by Franco Chiarugi [07/Jul/10 11:32 AM]
Main impact is on WP3 (graphical user interfaces)

[REACTION-127] Home and mobile gateway Created: 15/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP5		
Rationale:	The portable device should be able to act as home and mobile gateway. When connection to the public wireless network is not available at home, the portable device should be able to use a home gateway (PC) in order to send the acquired information. The home gateway should work only as gateway and not as a data collection device. The mobile gateway function has to be performed by the portable device and not by a further hand-held device.		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	Specific tests have to be performed when public wireless network is not available at home.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 11:31 AM]
Main impact is on WP5

[REACTION-128] Portable device should allow the display of feedback to patient Created: 15/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Portable Devices, Portable User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP5, WP10		
Rationale:	In mobile situation the only available device is the portable device and patient should be able to use it for uploading or downloading data. The possibility of using the "black box" also as output device for displaying data related to feedback to patient would help in simplifying cost and complexity of the solution.		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	The portable user interface should be used also for displaying the clinician feedback to patients, graphical representation of the data acquired in the last week/day/etc.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 2:00 PM]

In case of "black box", the possibility of using the black box also as output device for displaying data related to feedback to patient would help (Stelios & Franco)
Comment by Franco Chiarugi [05/Jul/10 3:35 PM]
Changed the rationale in order to address Stelios's comments
Comment by Franco Chiarugi [07/Jul/10 11:30 AM]
Main impact is on WP3 (graphical user inetrfaces)

[REACTION-129] Portable device should allow the notification of alarms & alerts Created: 15/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP5		
Rationale:	The use of the same device also for the reception of alarms and alerts simplifies and makes less expensive the overall solution		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	The reception of alarm and alerts will be checked on the portable device		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 11:29 AM]
Main impact is on WP3

[REACTION-130] The platform shall be easily used by elderly people with no specific technological knowledge Created: 15/Jun/10 Updated: 21/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Portable User Interface, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Look and feel		
Workpackage:	WP3, WP5, WP10		
Rationale:	Being the diabetes quite common in elderly people, several patients will have no specific knowledge in technology, but they should be able to easily use the platform.		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	User learning curve (especially with elderly people) should be very quick		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:45 PM]
Is probably the same as REACTION-186 (Thomas, IMM)
Comment by Franco Chiarugi [05/Jul/10 10:42 AM]
In some way it is similar to #147 but #147 is focused on generic user while this requirement is focused on elrderly patients
Comment by Franco Chiarugi [07/Jul/10 11:28 AM]
Main impact is on WP10

[REACTION-131] The platform shall appear authoritative Created: 15/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Look and feel		
Workpackage:	WP9, WP7, WP6, WP5, WP4, WP3, WP10		

Rationale:	Trust of end-users is paramount
Source/Originator:	DoW and Technical Meetings
Fit Criterion:	After their first encounter with the product, 2/3 of representative end-users shall agree they feel they can trust the platform and its services
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Franco Chiarugi [01/Jul/10 4:36 PM]
Main impact is on WP9.
Comment by Franco Chiarugi [02/Jul/10 3:40 PM]
If data are entered into the platform by the patient (outpatient) this should be stored somewhere in the platform for security reasons?! (Thomas, IMM)

[REACTION-132] The platform shall help the user to avoid making mistakes Created: 15/Jun/10 Updated: 07/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Portable User Interface, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Usability		
Workpackage:	WP3, WP10		
Rationale:	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows		
Source/Originator:	DoW and workshops		
Fit Criterion:	End-users will be guided through the workflows they have to perform.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 11:27 AM]
Main impact is on WP10

[REACTION-133] A patient, informal or formal carers should be able to be productive within a short time (one day of training) Created: 15/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Malcolm Clarke
Requirement Type:	Non-functional - Usability		
Workpackage:	WP10, WP13		
Rationale:	The platform should be easy to use and learn in order to be accepted by end-users		
Source/Originator:	DoW and workshops		
Fit Criterion:	The end-users shall achieve 75% pass rate from the final examination of the training		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 11:26 AM]
Main impact is on WP13
Comment by Franco Chiarugi [07/Jul/10 1:39 PM]
#64 and this requirement complement each other, but this requirement is focused on the quality of training while #64 is focused on easy and user-friendly user interface

[REACTION-134] Any interface between an end-user and the platform shall have a reasonable maximum response time in condition of public network optimally working Created: 15/Jun/10 Updated: 28/Jul/10

Status:	Open
Project:	REACTION requirements
Component/s:	Architecture

Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Performance		
Workpackage:	WP4, WP10		
Rationale:	Response time should be quick enough except for reasons independent from the technical design of the platform		
Source/Originator:	DoW and workshops		
Fit Criterion:	The platform when the public network is perfectly working at the max speed shall respond in less than 5 sec in 90% of functions activated by the user interface. No response shall take longer than 10 sec.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:39 PM]
Main impact is on WP4.

[REACTION-135] The platform shall be available for use 24 hours per day, 365 days per year Created: 15/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Performance		
Workpackage:	WP8, WP10		
Rationale:	The platform shall guarantee a continuous support for patients and clinicians		
Source/Originator:	DoW and Workshops		
Fit Criterion:	No periods of service interruption have to be present		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matts Ahlsen [18/Jun/10 1:55 PM]
not a proper WP4 requirement
Comment by Franco Chiarugi [07/Jul/10 11:22 AM]
Deleted WP4 and added WP8 addressing Matts's comments. Main impact is on WP8

[REACTION-136] The platform shall cater for 20 simultaneous users in the field trials. In the end product this number is expected to grow to 100. Created: 15/Jun/10 Updated: 07/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Performance		
Workpackage:	WP4, WP10		
Rationale:	A maximum number of simultaneous users has to be fixed. These numbers are very reasonable considering the number of potential end-users at the field trial sites and also considering the initial expectations as product on the market.		
Source/Originator:	DoW and workshops		
Fit Criterion:	The platform will be tested with the max number of simultaneous users verifying that the response time for the most common operations are satisfactory		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:40 PM]
Main impact is on WP4.

[REACTION-137] The platform should be able to process the existing end users of the outpatient and

inpatient field trials. 300 end-users should be enough. In the market this number is expected to grow to 1000.
Created: 15/Jun/10 Updated: 06/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Performance		
Workpackage:	WP4, WP10		
Rationale:	In the workshops the maximum number of users in the outpatient and inpatient field trials has been estimated.		
Source/Originator:	DoW and workshops		
Fit Criterion:	The possibility of creating such number of end-users will be tested.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:40 PM]

Main impact is on WP4.

[REACTION-138] The platform shall be expected to operate within reasonable maintenance effort for all the duration of the field trials Created: 15/Jun/10 Updated: 06/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Performance		
Workpackage:	WP10		
Rationale:	Problems at the field trials should be minimized		
Source/Originator:	DoW and workshops		
Fit Criterion:	Problems signalled at the field trials should be under a fixed threshold		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 3:44 PM]

remote access for remote service? (Lukas)

[REACTION-139] The platform shall be able to be installed and configured at the field trial sites by the local technical partner without too much effort Created: 15/Jun/10 Updated: 06/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Operational		
Workpackage:	WP10		
Rationale:	The local technical partners shall take care of the installation and configuration of the field trials		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	Adequate installation and configuration manuals have to be provided to the local technical partners.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-140] The platform shall prevent incorrect data from being introduced Created: 15/Jun/10 Updated: 06/Jul/10

Status:	In Progress
Project:	REACTION requirements
Component/s:	Security

Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Security		
Workpackage:	WP7, WP10		
Rationale:	Incorrect data might hamper a correct clinical decision		
Source/Originator:	DoW and workshops		
Fit Criterion:	Check that the user interface and specific procedures protect the end-user from the introduction of incorrect data as much as possible		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 5:03 PM]
Main impact is on WP10

[REACTION-141] The user should have choices regarding all data collection activities concerning his personal data Created: 15/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Legal		
Workpackage:	WP9		
Rationale:	User control implies the option to make choices, even if this means the end of an interaction or transaction. Choice is also mandated by consent, which is an important ground for legitimate collection and use of personal data (see EC Directive 95/46/EC article 7 sub a.: Member States shall provide that personal data may be processed only if: a) the data subject has unambiguously given his consent.). Choice is interpreted as leaving the user as much room to decide which personal data to disclose as possible. This, for instance, means that mandatory data should be limited. Instead, the user should be left the choice to leave certain fields empty. The user should have choices regarding all data collection activities concerning his personal data		
Source/Originator:	DOW		
Fit Criterion:	Offering the user opt-in and opt-out choices for particular uses of collected data is an element of choice. When there is a choice to provide the user with an opt-in or opt-out option, the one that limits the user's efforts is to be preferred. Questions to be asked: Does the application have mandatory data entry fields only for data necessary for providing a service (also a data minimisation requirement)? Does the application provide the users with choices with respect to the use and secondary use of their data, for instance by providing options with respect to: - whether or not to provide personal data - what personal data is to be shared - for what purpose data can be used - when and how long data may be used		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Low Unhappiness		
Conflicts:	n/a		
Dependencies:	n/a		

[REACTION-142] The user should have a certain level of control over information relating to him/her Created: 15/Jun/10 Updated: 06/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	PAN/BAN		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Ethical		
Workpackage:	WP9		
Rationale:	Users are taken to be individuals who can make autonomous choices about their life. Although they can not be said to own their personal data in a legal sense, we may want to attribute them rights similar to those on goods because data about individuals can be used to affect their position in the world and their capabilities of determining their own future.		
Source/Originator:	DOW		

Fit Criterion:	User control means that the user should be able to: - control of how personal data is handled - be able to object to processing - control how long personal data is stored - be able to exercise the rights to examine and correct personal data
Customer Satisfaction:	Interested
Customer Dissatisfaction:	Extreme Unhappiness

[REACTION-143] The user should be aware of the essential events, processes, stakeholders and attributes of the collection and use of personal data Created: 15/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Ethical		
Workpackage:	WP9		
Rationale:	In order for data collection and use to be fair (see for instance, preamble 38 Directive 95/46/EC), users have to be aware that their data is requested by a data collector and what will happen with the data. This is also necessary if the user is to be taken as an autonomous individual who should be able to make informed choices about whether or not to engage in interactions and transactions and whether or not to proceed or not with a concrete interaction		
Source/Originator:	DOW		
Fit Criterion:	The user should be aware of: - when data collection occurs - who collects the (personal) data - for which purpose the data is collected - with whom the data is shared - when the data is set to expire Does the application provide information to the users signalling events relevant to the collection, use, and removal of personal data at the service provider's end?		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-144] The user should understand how personal data is handled by the service provider Created: 15/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Ethical		
Workpackage:	WP9		
Rationale:	In order for users to be in control of their personal data, they have to understand what happens with their data if they are disclosed to the service provider. This allows them to make informed choices about whether or not to proceed. Comprehension requires information about relevant events, processes, stakeholders and attributes of the collection and use of personal data to be available in a comprehensible form.		
Source/Originator:	DOW		
Fit Criterion:	Users should be able to understand: • how their personal data is collected and used • for which purpose the data is being collected • who collects their (personal) data • who processes (uses) their (personal) data Because users have different needs and different backgrounds, what counts as comprehensive information differs from one individual to the next. A layered approach to providing information to the user, starting with simple information and extending to more detailed information on request, is therefore preferable • who will have access to their (personal) data • when their data will be erased • the limitation of their objection to data collection • the data protection rights and limitation		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-145] The user must consent to the collection of personal data whenever possible Created: 15/Jun/10 Updated: 20/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Legal		
Workpackage:	WP9		
Rationale:	The user is taken to be an autonomous individual who, in principle, decides what personal data to disclose and to whom. Of course this is not an absolute right, because legal obligations such as the law, contractual obligations, but also consequences of the performance of a contract, may overrule the right for the individual to withhold consent. Consent contributes to the realisation of a number of fundamental human values founding modern (western) societies, such as individuality, autonomy, dignity and civility.		
Source/Originator:	DOW		
Fit Criterion:	The fact that consent is instrumental to a number of fundamental values, means that it has to be revocable when it turns out that the effects of the previously given consent are different than the user may have expected given the available information at the time. Consent requires the user to be able to: • give informed agreement to the collection and processing of personal data • give explicit permission to the entity collecting the personal data to perform the servcies contracted for • give specific, unambiguous agreement to the collection and processing of sensitive data • give special consent when data will not be editable • agree to the automatic collection and processing of (personal) data (the main reasons for which this requirement has been inserted) Questions to be asked: Does the application offer the user ways to provide explicit consent to (personal) data disclosure? Does the application offer the user ways to provide explicit permission to use certain data for performing the service contracted for? Does the application offer ways to treat sensitive personal data different from the way it treats other personal data? Does the application provide special warnings when data is not editable after disclosure? Does the application offer ways for the user to explicitly agree to the automatic collection and processing of (personal) data Does the application offer ways to revoke previously given consent?		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-146] It should be possible to configure the application to different socio-cultural settings Created: 15/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Cultural and political		
Workpackage:	WP9		
Rationale:	To increase the adoption of REACTION technologies within different social groups, it must adapt were possible to social conventions within each group. This is even more important because individuals are part of several social contexts at the same time.		
Source/Originator:	DOW		
Fit Criterion:	The application should cater for configuring at least: - language settings - different sets of symbols and icons - user help and documentation to the needs and skill levels of different social groups - flexibility to change privacy preferences - ability to predefine sets of privacy preferences for different social contexts. Does the application allow for changing interface language, symbol/icon sets, help files and documentation? Does the application allow for managing privacy settings to different social contexts?		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-147] The user should be able to use the application with a minimal amount of training Created: 15/Jun/10 Updated: 08/Jul/10	
Status:	Open

Project:	REACTION requirements		
Component/s:	Context Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Cultural and political		
Workpackage:	WP9		
Rationale:	To limit social divides resulting from having access and being able to use the technology, the application should be as easy to use as possible. Access does not only depend upon physical access to the application, but also on the motivation and skills of the potential user. An aim of system development should therefore be to minimise the required skills for gaining access to, and using of, the application.		
Source/Originator:	DOW		
Fit Criterion:	Does the application provide a set of default settings that cover the needs of the majority of users? Does the application provide a minimum amount of pop-ups and choices in the human computer interaction? Does the application offer customisation options for more experienced users? Does the application provide an easy to use interface? Does the application provide comprehensive tutorials and help files? Does the application provide information about risks and what the application can do to help prevent these risks from materialising?		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-148] The user should be able to trust the application infrastructure Created: 15/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Security		
Workpackage:	WP9		
Rationale:	ICT components have to be trustworthy, because otherwise they pose the same risks they try to protect the user from. The application should therefore make the risks in communication known to the user, and make the measures taken to prevent these risks from materialising explicit. It should provide information about how personal data is handled, communicated and protected by the application and how these are handled in the communication channel		
Source/Originator:	DOW		
Fit Criterion:	Does the application provide information about its trustworthiness? Does the application provide information the infrastructure (network/medium) risks? Does the application provide information about the measures taken to minimise risks during the communication of personal data?		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 5:24 PM]
The rational might be misleading for IT professionals because 'transparent' in IT usually means that something is invisible to users, whereas in the legal context it means the opposite, namely that something must be made known to the user. We already have a requirement with respect to notification of users when data is communicated, see REACTION-102.
Comment by Eugenio Mantovani [01/Jul/10 5:50 PM]
I see. Legally speaking, transparency of the data management means that the data controller (which is usually the entity running the application) makes explicit risks and measures taken to avoid those risks. Having said that, I'll rephrase: " The application should therefore make the risks in communication known to the user, and make the measures taken to prevent these risks from materialising explicit"
Comment by Matthias Enzmann [01/Jul/10 7:16 PM]
I apologize, the reference to REACTION-102 was not meant to imply that it covers all/any issue of this requirement. I merely placed the reference here to make you aware of another (technical) notification mechanism.
Comment by Franco Chiarugi [05/Jul/10 3:29 PM]
Applied the change suggested by Eugenio

[REACTION-149] The user should be able to trust the operators involved in the application Created: 15/Jun/10 Updated: 08/Jul/10

Status:	Open
Project:	REACTION requirements
Component/s:	Architecture

Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Cultural and political		
Workpackage:	WP9		
Rationale:	The application should provide means to strengthen/restore this trust. The application can contribute to trust by: - offering ways to establish the trustworthiness of the transaction partners without revealing each others' identities - making transparent the way personal data is handled by the receiving parties and the arrangements the application offers to prevent or deal with privacy breaches - making transparent the institutional arrangements in place to address disputes - making transparent the institutional arrangements that government can offer to deal with privacy breaches.		
Source/Originator:	DOW		
Fit Criterion:	Does the application provide ways to establish the trustworthiness of the operators? Does the application provide ways to circumvent the risks causing distrust (e.g., by offering guarantees operators' obligations will be met)?		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 4:04 PM]
What is meant by 'without revealing each others identities'? Do you mean communication by using pseudonyms, e.g., patients and doctors, both communicating through pseudonyms, are able to ensure that one is a doctor and the other one is an insurant. Strictly speaking, a pseudonym is also an identity, thus this requirement implies that total anonymity is required.

[REACTION-150] The user should be able to obtain and use the application at reasonable cost Created: 15/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Economical and business		
Workpackage:	WP9		
Rationale:	The design and/or business model of the application should minimise the costs for acquisition, installation and exploitation/use (both in money and in efforts) for the user		
Source/Originator:	DOW		
Fit Criterion:	Does the application have a reasonable cost? Is the application easy to install and maintain?		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-151] The user must be able to correct, rectify, block or erase personal data that has been disclosed Created: 15/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Eugenio Mantovani	**Assignee:**	Eugenio Mantovani
Requirement Type:	Non-functional - Legal		
Workpackage:	WP9		
Rationale:	People make mistakes and novel information may render earlier decisions unfortunate. This goes for users and service providers alike. User control mandates that users can correct mistakes they, or the service providers, make with respect to their data. A step further is that users also have the possibility to reset choices they made. If users are not content with the way their data is used, they should be able to recall or change the access rights to their data. In legal terms, this requirement derives from article 12 of the Data Protection Directive which provides a right to the user to access personal data provided. Access to the data is a prerequisite to rectify, or even block or erase, the personal data that is stored.		
Source/Originator:	DOW		
Fit Criterion:	Levels of ex-post user control that can be distinguished are: - rectify: the power to change or update personal data that a party possesses. - block: the power to cancel or change the rights that parties have to use the personal data		

	- erase: the power to delete the personal data that parties possess Does the application show the user's rights to access, rectify, block or erase disclosed (personal) data and the procedures to execute these right?
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

[REACTION-152] Patient recruitment (or enrolment) Created: 16/Jun/10 Updated: 23/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management, Interfaces with HIS/EPR, Security, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP10		
Rationale:	When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from the HIS or EPR through interoperable user interfaces		
Source/Originator:	DoW and workshops		
Fit Criterion:	In case an interoperable HIS/EPR is present a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created his data have to be taken from the HIS/EPR.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 5:11 PM]
From the text, I don't see the relation to security. If the relation is implied by the transfer of personal data, I think this is already covered in REACTION-93, REACTION-99 and REACTION-100.
Comment by Franco Chiarugi [06/Jul/10 4:54 PM]
Addressed Matthias's comments. Main impact is in WP10

[REACTION-153] Symptoms of diabetes or hyperglycaemia Created: 16/Jun/10 Updated: 23/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management, Interfaces with HIS/EPR, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP10		
Rationale:	At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	Specific design in the user interfaces, ontologies and data management		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 4:53 PM]
Main impact on WP10

[REACTION-154] Comorbidities have to be registered Created: 16/Jun/10 Updated: 23/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Interfaces with HIS/EPR, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - REACTION platform		

Workpackage:	WP4, WP10
Rationale:	Comorbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient
Source/Originator:	D2-1 and workshops
Fit Criterion:	In the design of data management, ontologies and user interfaces the possibility of registering the comorbidities with a basic set of attributes has to be guaranteed
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Franco Chiarugi [06/Jul/10 4:52 PM]

Main impact is on WP4

[REACTION-155] Electronic paperless data record Created: 16/Jun/10 Updated: 06/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Context Management, Data Management, Interfaces with HIS/EPR, Networking, Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)		
Source/Originator:	D2.1 (p.62)/MSG		
Fit Criterion:	The inpatient pilot application stores data records/charts		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-156] Regular backup of data Created: 16/Jun/10 Updated: 22/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	Inpatient pilot application offers backup system		
Source/Originator:	D2.1 (p.62)/MSG		
Fit Criterion:	Regular backup of data		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-157] Annual clinical checks Created: 16/Jun/10 Updated: 28/Jul/10			
Status:	Reopened		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).		
Source/Originator:	D2-1 (pag. 44) and workshops		

Fit Criterion:	Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt thesefields (e.g. to add new parameters or to delete obsolete ones).
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by Franco Chiarugi [01/Jul/10 3:46 PM]
Clinical protocol or clinical checks? (Lukas)
Comment by Franco Chiarugi [01/Jul/10 4:44 PM]
Main impact is on WP4 (ontology).
Comment by Franco Chiarugi [05/Jul/10 3:16 PM]
Changed clinical protocol with clinical checks (addressing Lukas's comments)
Comment by Franco Chiarugi [28/Jul/10 11:17 AM]
Changed the fit criterion in order to address Lukas's comments

[REACTION-158] 6-month clinical checks Created: 16/Jun/10 Updated: 28/Jul/10

Status:	Reopened		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).		
Source/Originator:	D2-1 (pag.44) and workshops		
Fit Criterion:	Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt thesefields (e.g. to add new parameters or to delete obsolete ones).		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 3:47 PM]
Clinical protocol or clinical checks? (Lukas)
Comment by Franco Chiarugi [01/Jul/10 4:44 PM]
Main impact is on WP4 (ontology).
Comment by Franco Chiarugi [05/Jul/10 3:15 PM]
Changed clinical protocol with clinical checks (addressing Lukas's comments)
Comment by Franco Chiarugi [28/Jul/10 11:18 AM]
Changed the fit criterion in order to address Lukas's comments

[REACTION-159] Logging mechanisms Created: 16/Jun/10 Updated: 16/Jun/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Context Management, Data Management, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Peter Rosengren
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4		
Rationale:	Using logging from all components within Health Status Profile it's easier to integrate and control the system.		
Source/Originator:	FORTH		
Fit Criterion:	A logging mechanism is implemented in the REACTION platform		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-160] Alerts for the annual and 6-month clinical checks Created: 16/Jun/10 Updated: 06/Jul/10

Status:	Reopened		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP5, WP10		
Rationale:	When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the action to be taken (content and frequency of the alert should be agreed)		
Source/Originator:	DoW and workshops		
Fit Criterion:	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Low Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 3:47 PM]
Clinical protocol or clinical checks? (Lukas)
Comment by Franco Chiarugi [05/Jul/10 3:15 PM]
Changed clinical protocol with clinical checks (addressing Lukas's comments)
Comment by Franco Chiarugi [06/Jul/10 4:49 PM]
Main impact is on WP5

[REACTION-161] Active alarm system- reminder to perform measurements Created: 16/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Communication, Context Management, Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	The system should remind caregivers to perform measurements		
Source/Originator:	D2.1 (p.62)/MSG		
Fit Criterion:	Active alarm system- reminder to perform measurements is available within the inpatient platform		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 3:48 PM]
This statement is similar to N-193 (Lukas)
Comment by Franco Chiarugi [06/Jul/10 3:49 PM]
#193 refers to alarm and alert in general and to the need of not being too intrusive. This requirement is just related to reminders.
Comment by Peter Beck [08/Jul/10 5:25 PM]
OK! This is a special reminder for performing measurements.

[REACTION-162] Documentation of user interface (Health Status Profile) Created: 16/Jun/10 Updated: 09/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable Devices, Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Franco Chiarugi
Requirement Type:	Non-functional - Usability		
Workpackage:	WP6, WP10		
Rationale:	Documentation for User Interface of the Health Status Profile as part of REACTION.		
Source/Originator:	DoW		
Fit Criterion:	User manual for user interface of Health Status profile.		
Customer Satisfaction:	Extremely Pleased		

Customer Dissatisfaction:	Neutral Unhappiness

Comment by Peter Beck [08/Jul/10 6:16 PM]
Main work is on WP6

[REACTION-163] Archive system: data from former admissions of the same patient can be easily retrieved and used for decision making Created: 16/Jun/10 Updated: 22/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	The system should store and archive patient related information from former admissions		
Source/Originator:	D2.1 (p.62)/MSG		
Fit Criterion:	Data is stored in the system and available after re-admission		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Dependencies:	REACTION-166 & REACTION-260		

Comment by Tamas Toth [01/Jul/10 10:40 AM]
(almost) same as #260
Comment by Franco Chiarugi [06/Jul/10 3:52 PM]
#166 and #260 are duplicates of this issue

[REACTION-164] Common schema for data exchange between user interface (Health Status Profile) and integrated modules within WP6 Created: 16/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Peter Rosengren
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4		
Rationale:	It is essential to define and set schemas for the communication and interaction between modules within the Health Status Profile system.		
Source/Originator:	DoW/FORTH		
Fit Criterion:	Standardises Interfaces		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-165] Error Messages Created: 16/Jun/10 Updated: 06/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP6		
Rationale:	Error messages for every component within Health Status profile has to be set up in such a way that will be valuable for the end user.		
Source/Originator:	DoW/FORTH		
Fit Criterion:	Services and feedback to user.		
Customer Satisfaction:	Extremely Pleased		
Customer	Neutral Unhappiness		

Dissatisfaction:	

[REACTION-167] Use of contextualized data at medical decision and predictive models Created: 16/Jun/10 Updated: 09/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4, WP6		
Rationale:	Medical decision and predictive models have to use contextualized data in such a way that measurements will be annotated with context before they can be used by any algorithm		
Source/Originator:	Dow/FORTH		
Fit Criterion:	Data for medical decision and predictive models.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Low Unhappiness		

Comment by Peter Beck [08/Jul/10 6:20 PM]
Main impact of contextualisation is on WP4
Comment by Franco Chiarugi [09/Jul/10 12:07 PM]
Changed the assignee, addressing Peter's comments (main impact is on WP4)

[REACTION-168] Remote Patient Monitoring (RPM) Created: 16/Jun/10 Updated: 21/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, PAN/BAN, Portable Devices, Portable User Interface, Sensors, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP3, WP4, WP5, WP7, WP10		
Rationale:	RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	RPM module has to be present in the Outpatient field trials		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:47 PM]
Main impact is on WP5.

[REACTION-169] Display and input of data should be possible at different locations simultaneously (centrally managed data repositories) Created: 16/Jun/10 Updated: 06/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Data Management, Networking		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP10		
Rationale:	A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously (mobile access points - e.g. tablet PC at point of care versus fixed access points - e.g. screens at physicians/nurses base)		
Source/Originator:	D.2.1 (p. 62)/MSG		
Fit Criterion:	Clinicians can input relevant information via tablet PC from every place within the hospital ward.		
Customer Satisfaction:	Extremely Pleased		

Customer Dissatisfaction:	Neutral Unhappiness

[REACTION-170] Selection of a mobile device for inpatient glucose control based on given requirements
Created: 16/Jun/10 Updated: 08/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Portable Devices		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP10		
Rationale:	The devices should be: - Lightweight/portable - Easy to hold / handle and ergonomic design - Spill an drip resistant (easy disinfection) - Inputs for stylus and touch operations (incl. touch keyboard) - Wireless communication - Ease of operations		
Source/Originator:	D 2.1 (p. 62)/MSG		
Fit Criterion:	Devices with desired functionality are available within the project		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-171] Data input application for inpatient glucose control Created: 16/Jun/10 Updated: 20/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Context Management, Data Management, Networking, Ontology/Terminology, Portable Devices, Portable User Interface, Security, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP10		
Rationale:	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...) Parameters for documentation (once, at initialisation) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight/BMI/waist to hip ratio 4. HbA1c 5. fever, infection 6. diarrhoea 7. hypoglycaemia (last 3 days) 8. limited renal/hepatic function 9. pancreas operation Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, ...)		
Source/Originator:	D 2.61 (p.62/63) / MSG		
Fit Criterion:	Data entry system will be available for inpatient decision support system with devices (tablet PC)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		
Dependencies:	REACTION-254		

Comment by Franco Chiarugi [01/Jul/10 3:52 PM]
this is similar to N-254 (Lukas)
Comment by Franco Chiarugi [06/Jul/10 3:43 PM]
Inserted the dependency from #254 addressing Lukas's comments
Comment by Franco Chiarugi [20/Jul/10 5:11 PM]

#254 is a duplicate of this requirement

[REACTION-172] Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!) Created: 16/Jun/10 Updated: 22/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Context Management, Data Management, Interfaces with HIS/EPR, Networking, PAN/BAN, Portable Devices, Portable User Interface, Security		
Type:	Volere Requirement	**Priority:**	Blocker
Reporter:	Peter Beck	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support		
Source/Originator:	D 2.61 (p.62/63)/MSG		
Fit Criterion:	POCT data is transmitted within short time to the platform		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 3:52 PM]
this statement is similar to N-225? (Lukas)
Comment by Franco Chiarugi [01/Jul/10 4:49 PM]
Main impact is on WP10 (interfaces to HIS).
Comment by Peter Beck [08/Jul/10 4:19 PM]
N225 describes the use of a POCT device in the first year. N172 describes the requirement for automatic transfer of POCT device data into the platform in order to have electronic decision support.

[REACTION-173] Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data) Created: 16/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Context Management, Data Management, Networking, Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP5, WP10		
Rationale:	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently		
Source/Originator:	D 2.1 (p. 62/63) / MSG		
Fit Criterion:	Achieving location independence and multi-user support		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matts Ahlsen [18/Jun/10 1:34 PM]
This requirement may fit better in WP10 and / or WP5.
Comment by Franco Chiarugi [01/Jul/10 4:51 PM]
Main impact is on WP5.
Comment by Franco Chiarugi [02/Jul/10 2:09 PM]
Probably the title could be reviewed such to explain better the requirement itself. Our suggestion is: platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data) (Stelios & Franco)
Comment by Franco Chiarugi [05/Jul/10 3:10 PM]
The title (summary) has been reviewed in order to address Stelios's comments
Comment by Peter Beck [08/Jul/10 4:54 PM]
OK!

[REACTION-174] Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario
Created: 16/Jun/10 Updated: 22/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Data Management, Interfaces with HIS/EPR, Networking		
Type:	Volere Requirement	**Priority:**	Blocker
Reporter:	Peter Beck	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario		
Source/Originator:	D 2.61 (p. 62/63)/MSG		
Fit Criterion:	Data structures and data management functionality		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 3:38 PM]
HIS/EPR interface is foreseen in WP10. Thus main impact is on WP10

[REACTION-175] Automated identification of users (caregivers) working with REACTION front-end in the hospital Created: 16/Jun/10 Updated: 16/Jun/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Context Management, Interfaces with HIS/EPR, Networking		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Peter Beck	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)		
Source/Originator:	D 2.61 (p.62/63)/MSG		
Fit Criterion:	Automated user identification		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-177] Investigative stage Created: 16/Jun/10 Updated: 23/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Data Management, Ontology/Terminology, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels. RPM and clinical decision support algorithms can be used in this stage for an optimal clinical support.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	Specific fields have to be present in data management, ontologies and web user interfaces.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:56 PM]
Main impact is on WP10.
Comment by Peter Beck [09/Jul/10 9:51 AM]
At this stage (it is not clear if REACTION should be a disease management project or a telemonitoring project (especially in the primary care / outpatient area). For a disease management project the rationale would be important.
Comment by Franco Chiarugi [09/Jul/10 12:06 PM]

The view is that telemonitoring should help in better disease management. At this moment we should proceed with this view.

[REACTION-178] Ongoing management Created: 16/Jun/10 Updated: 23/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Data Management, Ontology/Terminology, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients. RPM and decision support algorithms can be used in this stage for an optimal clinical support.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	Specific fields have to be present in data management, ontologies and web user interfaces.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:56 PM]
Main impact is on WP10.
Comment by Peter Beck [09/Jul/10 9:52 AM]
@ comment: see #177
Comment by Franco Chiarugi [09/Jul/10 12:06 PM]
The view is that telemonitoring should help in better disease management. At this moment we should proceed with this view.

[REACTION-179] Daily data review by clinicians or telehealth support team Created: 16/Jun/10 Updated: 23/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the patient progress against individualized targets set up for the patient.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or pharmacological treatment.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:56 PM]
Main impact is on WP10.

[REACTION-180] Measurement of glucose should be specific and the glucose sensor should be able to monitor glucose in complex media Created: 16/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	If the glucose monitoring is not specific, detection could be disturbed by other components of the ISF or the blood, influencing the accuracy of the sensor. For realisation of a closed-loop-system (glucose measurement +		

	insulin dosage) a highly accurate sensor is required.
Source/Originator:	L. Ben Mohammadi
Fit Criterion:	Sensor should exhibit a high accuracy even if other media are in contact with the sensor area.
Customer Satisfaction:	Interested
Customer Dissatisfaction:	Neutral Unhappiness

Comment by Franco Chiarugi [02/Jul/10 3:39 PM]
Is correlated to REACTION-267 (Thomas, IMM)

[REACTION-181] Decision on therapy in Outpatient environment Created: 16/Jun/10 Updated: 23/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Context Management, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also pharmacological treatment (OAD or insulin) can be reviewed after accurate evaluation of patient kidney functions.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the relevant information have to be designed.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:59 PM]
Main impact is on WP10.

[REACTION-182] Measurement of HbA1c Created: 16/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy. Frequency depends on: level of blood glucose control, stability of blood glucose control and change in insulin dose or regimen. Clinicians take decision on the optimal frequency.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	Specific fields have to be foreseen in data management, ontologies and user interfaces.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 3:36 PM]
Main impact is on WP4

[REACTION-183] The sensitivity of the glucose sensor should be high, the SNR must be large and changes of glucose concentration in the range 1-15 mM must be detectable. Created: 16/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		

Workpackage:	WP3
Rationale:	For a closed loop sensor system (glucose measurement + insulin dosage) especially in the lower concentration range of about 3-4 mM or less a high accuracy is required to avoid mistreatments in the hyperglycaemic range.
Source/Originator:	L. Ben Mohammadi
Fit Criterion:	Performance of reference measurements on defined samples.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Franco Chiarugi [02/Jul/10 3:37 PM]
Is correlated to REACTION-267 (Thomas, IMM)
Comment by Franco Chiarugi [28/Jul/10 11:21 AM]
Changed the rationale in order to address Lukas's comments

[REACTION-184] Risk values for HbA1c Created: 16/Jun/10 Updated: 06/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP5, WP6		
Rationale:	Maintaining glycated haemoglobin (HbA1c) below 7.5% is likely to minimize risk of developing diabetic complications. If there is evidence of increased arterial disease risk (raised albumin excretion rate, features of metabolic syndrome or other arterial risk factors), HbA1c should be maintained under 6.5% or even less.		
Source/Originator:	D2-1 (pag. 45)		
Fit Criterion:	Thresholds have to be foreseen in the risk assessment module and advices have to be sent to patients.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 3:35 PM]
Main impact is on WP6

[REACTION-185] Diabetic management for type I diabetic patients Created: 16/Jun/10 Updated: 09/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Glucose Control Algorithm		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Constraint - Solution		
Workpackage:	WP6		
Rationale:	Type I diabetic patients will always be on insulin treatment		
Source/Originator:	DoW and workshops		
Fit Criterion:	Glucose management has to be performed only with insulin (and not OAD) to type I diabetic patients		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Peter Beck [09/Jul/10 10:05 AM]
I think this requirement is not clear to me. What means "Only insulin treatment has to be provided to type I diabetic patients". I think type 1 diabetic patients also need more support within REACTION than insulin control like regular medical examinations and medical advice by clinicians and nurses. Therefore I think REACTION can also support the data management for type 1.
Comment by Franco Chiarugi [09/Jul/10 10:14 AM]
Changed the fit criterion in order to address Peter's comments

[REACTION-186] The sensor platform should be robust and simple to be used, enabling the device to be operated by the patient himself Created: 16/Jun/10 Updated: 06/Jul/10

Status:	Open
Project:	REACTION requirements

Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP3		
Rationale:	Sensor platform has to be worn for several days and should not hinder the patient in his normal activities.		
Source/Originator:	L. Ben Mohammadi		
Fit Criterion:	Simplicity and reliability in patient trials is to be demonstrated.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:37 PM]
Is probably the same as #130 (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 2:58 PM]
#130 is referred to easy usability of the entire platform especially by elderly people

[REACTION-187] Storage of administered insulin Created: 16/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Portable User Interface, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP3, WP4, WP6, WP10		
Rationale:	Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).		
Source/Originator:	DoW and workshops		
Fit Criterion:	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:56 PM]
Main impact is on WP4

[REACTION-188] Storage of events for context of measurements Created: 16/Jun/10 Updated: 28/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Context Management, Ontology/Terminology, Portable Devices, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP4, WP10		
Rationale:	Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context for the acquired measurements. A suitable user interface has to be provided in order to facilitate patients performing this task (any data entry can be felt as too intrusive for patients). The possibility of integrating existing commercial log-devices used by the patients has to be considered.		
Source/Originator:	Workshops		
Fit Criterion:	There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint display of the acquired measurements and the relevant associated events (giving a context for the measurements)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:36 PM]
What is meant by "Events"? (Thomas, IMM)

Comment by Franco Chiarugi [06/Jul/10 2:55 PM]
Changed the rationale in order to address Thomas's comments
Comment by Franco Chiarugi [06/Jul/10 2:55 PM]
Main impact is on WP10
Comment by Franco Chiarugi [28/Jul/10 11:23 AM]
Changed the rationale in order to address Lukas's comments

[REACTION-189] Other managements for type I diabetic patients Created: 17/Jun/10 Updated: 23/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Communication, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP10, WP6		
Rationale:	Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems)		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the care program, management of diabetes (through insulin) should be accompanied by management of complications		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Jesper Thestrup [28/Jun/10 4:36 PM]
1) This is relevant for all diabetes patients, not just Type 1. 2) Check potential overlap with issue 195 /Helene
Comment by Franco Chiarugi [01/Jul/10 1:54 PM]
Complications in this issue and in issue 195 should be the same (Helene)
Comment by Franco Chiarugi [05/Jul/10 3:00 PM]
Changed the rationale in order to address Helene's comments. Now complications are the same as in #195.
Comment by Franco Chiarugi [06/Jul/10 2:53 PM]
Main impact is on WP10
Comment by Peter Beck [09/Jul/10 9:24 AM]
Here I would like to refer to the e-mail from of Peter Beck from 1st of July: "Is REACTION a TELEMONITORING project, or should it become a DISEASE MANAGEMENT project?"
Comment by Franco Chiarugi [09/Jul/10 12:00 PM]
The view is that telemonitoring should help in better disease management. At this moment we should proceed with this view.

[REACTION-190] In the outpatient environment the medications are usually self-administered by the patient himself or by informal carers (rarely) Created: 17/Jun/10 Updated: 06/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Communication, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Constraint - Implementation Environment		
Workpackage:	WP10		
Rationale:	Usual practice for diabetic patient outside from secondary or tertiary care is self-administration of medications		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-191] Structured programme for the management of diabetic patients Created: 17/Jun/10 Updated: 09/Jul/10	
Status:	In Progress
Project:	REACTION requirements

Component/s:	Architecture, Communication, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, education, telephone support, dose titration, dietary understanding, management of acute changes in plasma glucose control, prevention and early detection of medium- and long-term complications, management of hypoglycaemia		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The applications shall allow the implementation of the structured programme.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:59 PM]
Main impact is on WP10.
Comment by Peter Beck [09/Jul/10 10:07 AM]
Depends on what REACTION should be: TELEMONITORING project, or DISEASE MANAGEMENT project
Comment by Franco Chiarugi [09/Jul/10 11:59 AM]
The view is that telemonitoring should help in better disease management. At this moment we should proceed with this view.

[REACTION-192] Thresholds for hypoglycaemia and hyperglycaemia Created: 17/Jun/10 Updated: 09/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP5, WP6		
Rationale:	Different configurable thresholds shall be present for the detection of serious and life-threatening hypoglycaemic and hyperglycaemic episodes		
Source/Originator:	Workshops		
Fit Criterion:	Once made sure the blood glucose level was correctly measured, values under specific thresholds (hypoglycaemia) or over specific thresholds (hyperglycaemia) should generate alerts or alarms specifically when the episode is considered to be life-threatening.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-241 & REACTION-242		

Comment by Franco Chiarugi [06/Jul/10 2:52 PM]
Main impact is on WP6
Comment by Franco Chiarugi [09/Jul/10 11:57 AM]
There are dependencies with #241 and #242, but this requirement is more focused on the presence of different configurable thresholds while the other requirements are more focused on the management of the adverse episode

[REACTION-193] Alarm & alert generation Created: 17/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP5, WP6		
Rationale:	The alerts and alarms should not be generated too often in such a way the system will be considered too intrusive for the patient himself. However serious and especially life-threatening situations have to be promptly signalled. ROC analysis might be used in order to tune the alarm and alert system.		
Source/Originator:	Workshops		
Fit Criterion:	Some serious or life-threatening situations can be simulated in the integration environment and the production of		

	adequate alarms can be verified.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Franco Chiarugi [01/Jul/10 3:57 PM]
Very important point. Evaluation using ROC-analysis (Lukas)
Comment by Franco Chiarugi [06/Jul/10 2:51 PM]
Changed the rationale in order to address Lukas's comments. Main impact is on WP6

[REACTION-194] Regular visits/reviews at the Primary Health Care Created: 17/Jun/10 Updated: 23/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Outcomes of regular visits at the Primary Health care centre shall be registered in the platform through the use of specific forms/user interfaces for the doctors/nurses.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Specific forms and user interfaces for the doctors/nurses have to be present		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 5:03 PM]
Main impact is on WP10 (but also on ontology and data management).

[REACTION-195] Data management should handle different types of complications for the diabetic patients in the outpatient environment Created: 17/Jun/10 Updated: 23/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management of foot and neuropathy problems.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the ontology, user interfaces and applications these complications have to be present		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 1:54 PM]
Complications in this issue and in issue 189 should be the same (Helene)
Comment by Franco Chiarugi [05/Jul/10 3:02 PM]
Changed the rationale in order to address Helene's comments. Now complications are the same as in #189.
Comment by Franco Chiarugi [06/Jul/10 2:49 PM]
Main impact is in WP4 (data management and ontology)

[REACTION-196] End of process for the diabetic patient in the outpatient environment Created: 17/Jun/10 Updated: 23/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major

Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from the practice catchment area or voluntarily stops to be monitored by the REACTION platform.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Patient discharge from the outpatient environment has to be foreseen only in case of a) death; b) patient removal outside from the practice catchment area; c) patient voluntarily stops to be monitored by the REACTION platform.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Low Unhappiness		

Comment by Franco Chiarugi [17/Jun/10 12:01 PM]
Probably we should consider also the case in which patient would like voluntarily to leave the REACTION platform (it is usually foreseen in the informed consent)
Comment by Franco Chiarugi [01/Jul/10 5:03 PM]
Main impact is on WP10.
Comment by Franco Chiarugi [06/Jul/10 2:48 PM]
Changed rationale and fit criterion in order to address Franco's comments

[REACTION-197] Care spaces in the outpatient environment Created: 17/Jun/10 Updated: 23/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Communication, Data Management, Interfaces with HIS/EPR, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matthias Enzmann
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP5, WP7, WP8, WP10		
Rationale:	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Each member of the care space will have specific roles and tasks in the patient's care.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 5:00 PM]
The rational talks about roles and care spaces which have to be defined in order to develop some kind of interaction model between the roles. However, the fit criterion implies that it is sufficient to have some kind of access control mechanisms in place, which seems to be less than the rational asks for.
Comment by Franco Chiarugi [01/Jul/10 5:01 PM]
Main impact is on WP7.
Comment by Franco Chiarugi [06/Jul/10 2:45 PM]
Changed the rationale and the fit criterion in order to address Matthias's comments

[REACTION-198] Information related to informed consent have to be stored in the REACTION platform Created: 17/Jun/10 Updated: 23/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management, Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matthias Enzmann
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP7, WP4, WP9		
Rationale:	An ethical approved informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION platform.		

Source/Originator:	D2.1 and workshops
Fit Criterion:	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the paper form signed informed consent and this procedure shall be completed before any other operation can be performed.
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Matthias Enzmann [01/Jul/10 4:46 PM]
By 'signed informed consent', do you mean digitally signed or signed in paper form? Also, shouldn't WP9 be assigned to this requirement as well?
Comment by Franco Chiarugi [06/Jul/10 2:37 PM]
Added WP9 in order to address Matthias's comments and changed the rationale and the fit criterion
Comment by Franco Chiarugi [06/Jul/10 2:40 PM]
Main impact on WP7

[REACTION-199] Baseline and clinical history should be handled by the data management system Created: 17/Jun/10 Updated: 28/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Data Management, Interfaces with HIS/EPR, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:36 PM]
Main impact is on WP10 (especially for retrieving the values from HIS)

[REACTION-200] eQual & Mental Health Score Created: 17/Jun/10 Updated: 06/Jul/10

Status:	Reopened		
Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP6		
Rationale:	These scores have to be evaluated after the insertion of the baseline and clinical history and to be presented to the clinicians and saved in the platform		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	These scores have to be implemented in the risk assessment component		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Low Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 3:58 PM]
do not know if clinicians want these scores (Lukas)
Comment by Franco Chiarugi [05/Jul/10 2:56 PM]
Inserted because mentioned in D2.1, but changed the customer satisfaction and dissatisfaction to lower values in order to address Lukas's comments

[REACTION-201] Record baseline physiological measurements at the first visit Created: 17/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the platform		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrolment)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:35 PM]
Main impact is on WP4

[REACTION-202] Setup remote patient monitoring scheme Created: 17/Jun/10 Updated: 23/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, PAN/BAN, Portable Devices, Sensors, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP5, WP10		
Rationale:	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	An enrolled patient can be assigned to a configurable RPM scheme		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:33 PM]
Main impact on WP4

[REACTION-203] Care plan (defined for each patient) has to be personalized Created: 17/Jun/10 Updated: 23/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:31 PM]
Main impact is on WP10

[REACTION-204] ePatch Created: 17/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	PAN/BAN, Sensors		
Type:	Volere Requirement	**Priority:**	Critical
Reporter:	Rasmus Gronebek Haahr	**Assignee:**	Rasmus Gronebek Haahr
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	The ePatch is the preferred device and technology used to attached and connect sensors to the body. However, it should be possible that data from commercially available sensors not connected to the ePatch can be read by the REACTION platform.		
Source/Originator:	DELTA		
Fit Criterion:	Hardware fabricated.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Dependencies:	BAN/PAN		

Comment by Franco Chiarugi [02/Jul/10 3:35 PM]
Is this really a requirement? Sounds more like a definition (Thomas, IMM)
Comment by Franco Chiarugi [28/Jul/10 9:36 AM]
Changed the rationale in order to address Lukas's comments

[REACTION-205] Docking station for the ePatch Created: 17/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Minor
Reporter:	Rasmus Gronebek Haahr	**Assignee:**	Rasmus Gronebek Haahr
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	Charging of the reusable sensor in the ePatch		
Source/Originator:	DELTA		
Fit Criterion:	Hardware fabricated.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		
Dependencies:	ePatch		

Comment by Franco Chiarugi [28/Jul/10 10:14 AM]
This requirements referes to the recharging of reusable sensors and not to the portable device

[REACTION-206] ePatch reusable sensor Created: 17/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Rasmus Gronebek Haahr	**Assignee:**	Rasmus Gronebek Haahr
Requirement Type:	Functional		
Workpackage:	WP3		
Rationale:	The ePatch reusable sensor contains the optical and electrical sensor components, electronics, radio, antenna, and battery. Eventually the ePatch might be consisting of two components, one reusable, containing the optics and electronics, and one disposable, containing the optical cell and waste for the dialysis.		
Source/Originator:	DELTA		
Fit Criterion:	Hardware fabricated.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Dependencies:	ePatch

Comment by Franco Chiarugi [02/Jul/10 3:34 PM]
The ePatch might be consisting of two components, one reusable containing the optics and electronics and one disposable, containing the optical cell and waste for the dialysis (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 2:28 PM]
Changed the rationale in order to address Thomas's comments

[REACTION-207] ePatch communication Created: 17/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Communication, PAN/BAN, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Rasmus Gronebek Haahr	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional		
Workpackage:	WP5, WP3		
Rationale:	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.		
Source/Originator:	DELTA		
Fit Criterion:	The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the "black box").		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:26 PM]
Main impact is on WP3 (communication protocol implemented on the ePatch side)
Comment by Franco Chiarugi [27/Jul/10 2:26 PM]
Addressed Thomas's comments changing the rationale

[REACTION-208] ePatch adhesive base Created: 17/Jun/10 Updated: 06/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Rasmus Gronebek Haahr	**Assignee:**	Rasmus Gronebek Haahr
Requirement Type:	Functional		
Workpackage:	WP3		
Rationale:	The adhesive base forms the contact between the ePatch sensor and the skin surface of a human. Sensors measuring physiological data should be specified.		
Source/Originator:	DELTA		
Fit Criterion:	ePatch can stick to the skin and sensor can measure physiologic data.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:33 PM]
Specify sensors for which this is relevant (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 2:23 PM]
Changed the rationale in order to address Thomas's comments

[REACTION-209] ePatch adhesive base has unique physical properties Created: 17/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Rasmus Gronebek Haahr	**Assignee:**	Rasmus Gronebek Haahr
Requirement Type:	Functional		
Workpackage:	WP3		

Rationale:	The ePatch adhesive base contains 3 gel electrodes with impedance matched to the skin. The gel or part of the gel is optical transparent in the visible and NIR range of the electromagnetic spectrum.
Source/Originator:	DELTA
Fit Criterion:	ePatch can stick to the skin and optical or NIR sensor (if required) can measure physiologic data.
Customer Satisfaction:	Uninterested
Customer Dissatisfaction:	Neutral Unhappiness

Comment by Franco Chiarugi [02/Jul/10 3:32 PM]
The optical sensor of IMM will be connected to the patient via a microdialysis needle. Therefore, a measurement through the adhesive is not required (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 2:20 PM]
Changed the fit criterion in order to address Thomas's comments.

[REACTION-210] ePatch adhesive base has unique adhesive properties Created: 17/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Rasmus Gronebek Haahr	**Assignee:**	Rasmus Gronebek Haahr
Requirement Type:	Functional		
Workpackage:	WP3		
Rationale:	The ePatch adhesive base contains at least two type of adhesive materials: 1) One with good skin adhesive properties 2) An adhesive gel or similar with electrical and optical properties matched to electrical and optical sensors.		
Source/Originator:	DELTA		
Fit Criterion:	Adhesive can stick to skin and sensors can measure.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-211] Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at the first visit. Created: 18/Jun/10 Updated: 23/Jul/10

Status:	Reopened		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP8, WP6, WP4, WP10		
Rationale:	A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and lifestyle plan		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	These 3 components should be part of the care management for any diabetic patient		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 4:37 PM]
It seems to be a less detailed repetition of issue 203
Comment by Franco Chiarugi [05/Jul/10 2:54 PM]
Changed the rationale in this issue and in #203 in order to address the previous comments. Not anymore a repetition of #203.
Comment by Franco Chiarugi [06/Jul/10 2:17 PM]
Main impact is on WP4 (definition in the data management and in ontologies of the 3 plans)
Comment by Peter Beck [09/Jul/10 10:21 AM]
The main work to establish a disease management plan would be in WP6 and WP8. The technical implementation (data management, ..) would be part of WP4.
Comment by Franco Chiarugi [09/Jul/10 11:53 AM]
Added WP8 in order to address Peter's comments

[REACTION-212] Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine Created: 18/Jun/10 Updated: 26/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of video-conference		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Jesper Thestrup [29/Jun/10 10:57 AM]
Video conferencing would be just one of several ways to set up a case conference /Helene
Comment by Franco Chiarugi [06/Jul/10 2:15 PM]
Changed the rationale and the fit criterion in order to address Helene's comments. Main impact is on WP4

[REACTION-213] Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and therapeutic intervention (changes in therapy) Created: 18/Jun/10 Updated: 26/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and pharmacological treatment		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:13 PM]
Main impact is on WP4

[REACTION-214] Activity parameters must be measured (e.g. pulse frequency, body temperature) by sensors Created: 18/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	For input to the AGC algorithm to make prediction of glucose levels activity parameters are required. Which ones are still tbd but heart rate and body temperature should be included.		
Source/Originator:	T. Klotzbuecher		
Fit Criterion:	Activity parameter sensors must be integrated into the REACTION e-patch.		
Customer Satisfaction:	Pleased		
Customer	Neutral Unhappiness		

Dissatisfaction:	

Comment by Franco Chiarugi [02/Jul/10 3:29 PM]
Is correlated to REACTION-265, since activity parameters are part of the clinical parameters (Thomas, IMM)

[REACTION-216] Conference report has to be stored for any issued case conference Created: 18/Jun/10 Updated: 26/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	A conference report has to be stored for any issued case conference		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of the case conference impacts on the personalized care plan (through potential changes in the non-pharmacological and pharmacological treatments).		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:12 PM]
Main impact is on WP10

[REACTION-217] Acquired values in the alarm range Created: 18/Jun/10 Updated: 06/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Architecture, Backend Middleware, Data Management, Ontology/Terminology, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP5, WP6, WP10		
Rationale:	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Check the overall procedure in case of acquired measurements in the alarm range.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:11 PM]
Main impact is on WP4 (alarm & alert handling)

[REACTION-218] Patient monitor either manual or through the RPM Created: 18/Jun/10 Updated: 06/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Outpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient can be monitored in the traditional way (manually).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.		

Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Franco Chiarugi [06/Jul/10 2:09 PM]
Main impact is on WP4

[REACTION-219] Safe Glycaemic Control (SGC) Created: 18/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Glucose Control Algorithm, Ontology/Terminology, Physiology Models, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:07 PM]
Main impact is on WP4
Comment by Peter Beck [09/Jul/10 10:25 AM]
This should be part of the electronic decision support system (eDSS) in the inpatient area.
Comment by Franco Chiarugi [09/Jul/10 11:51 AM]
Changed the rationale addressing Peter's comments

[REACTION-220] Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management) Created: 18/Jun/10 Updated: 26/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Data Management, Glucose Control Algorithm, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP5, WP4, WP10		
Rationale:	In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by clinicians and/or nurses		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:02 PM]
Type 1: most of them do their measurements themselves; Type 2: most measurements are done by the nurses (Lukas)
Comment by Franco Chiarugi [06/Jul/10 2:06 PM]
Changed the rationale in order to address Lukas's comments. Considering the main issue is the storage of measurements, this issue impacts mainly on WP5

[REACTION-222] Insulin evaluation in Inpatient environment Created: 18/Jun/10 Updated: 26/Jul/10

Status:	Open

Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Glucose Control Algorithm		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP6		
Rationale:	The data used for the insulin evaluation have to be contextualized before their usage and then passed to mathematical algorithms for the calculation of the required insulin doses. Results have to be fed to dedicated diabetes experts specialized in glycaemic control for verification and evaluation. Their appraisal have to be fed back to physicians and nurses at the point of care in the patient ward.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The glucose control algorithms have to evaluate the insulin based on the parameters described above.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-223] Basic workflow for insulin treatment in Inpatient environment Created: 18/Jun/10 Updated: 26/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Glucose Control Algorithm, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP8, WP6, WP4, WP10		
Rationale:	The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on additional parameters and insulin administration		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The basic workflow should be easily accessible in the REACTION Inpatient application		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:00 PM]
Main impact is on WP10 (but with significant efforts in WP4 and WP6)
Comment by Peter Beck [09/Jul/10 9:14 AM]
Without WP8 (MUG) this requirement cannot be fulfilled. Therefore I would suggest to add WP8! Further I would suggest that the main work on developing a electronic decision support for glucose administration (that's what this requirement is about?) should be done in the ward by MUG and MSG in WP6/WP8. WP10 would be responsible for implementation into the inpatient REACTION pilot application.
Comment by Franco Chiarugi [09/Jul/10 11:49 AM]
Added WP8 as suggested by Peter

[REACTION-224] Basic workflow is repeated 4 times a day in inpatient environment Created: 18/Jun/10 Updated: 26/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The first workflow is in the morning a little before breakfast time (administration of bolus insulin), the second is at midday before lunch time (administration of bolus insulin), the third is in the evening before dinner time (administration of bolus insulin), and finally the fourth is at bedtime (administration of basal insulin and correction of boluses, if necessary).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	These 4 loops should be easily identified in the Inpatient application		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:58 PM]
Main impact is on WP10

[REACTION-225] PoC device for blood glucose measurement will be used in the first-year prototype Created: 18/Jun/10 Updated: 08/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Communication, Interfaces with HIS/EPR, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP3, WP10		
Rationale:	The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the consortium sensors. Furthermore, before their regular use in hospital ward consortium sensors have to obtain special approval. Thus, in the Inpatient environment the devices currently used will continue to be used also in the first-year prototype.		
Source/Originator:	Inpatient workshop		
Fit Criterion:	The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. The acquired measurements through an appropriate HL7 interface will be retrieved and made available in the REACTION data management.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:58 PM]
Main impact is on WP10 (integration with HIS is part of WP10)

[REACTION-226] Electronic fever/sugar chart should be modelled in the data management system Created: 18/Jun/10 Updated: 26/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Backend Middleware, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:54 PM]
Main impact on WP10

[REACTION-227] Initialization of the fever/sugar chart Created: 18/Jun/10 Updated: 26/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be registered in the fever/sugar chart		

Source/Originator:	D2.1 and workshops
Fit Criterion:	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Franco Chiarugi [06/Jul/10 1:54 PM]
Main impact is on WP4

[REACTION-228] Blood glucose measurements have to be contextualized (e.g. before/after meal) Created: 18/Jun/10 Updated: 26/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	The availability of the blood glucose measurements shall be accompanied also by the context of the measurements		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Measurements before any usage have to be contextualized		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-229] Decision on therapy in Inpatient environment Created: 18/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history and associated parameters. It might imply changes in the therapy scheme.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the administration of carbohydrates is necessary (hypoglycaemic episode).		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:52 PM]
Main impact on WP4

[REACTION-230] Overall evaluation in Inpatient environment Created: 18/Jun/10 Updated: 26/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Supervision of glycaemia and according treatment is performed once a day. Adaptation of therapy or changes of medications have to be evaluated also consulting the physician on duty.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Every day an evaluation report has to be stored and available in the Inpatient application		
Customer Satisfaction:	Extremely Pleased		

Customer Dissatisfaction:	Extreme Unhappiness

Comment by Franco Chiarugi [06/Jul/10 1:51 PM]
Main impact on WP10

[REACTION-231] End of process for the diabetic patient in the inpatient environment Created: 18/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The workflows in the Inpatient glycaemic control management ends with the patient discharge from the department. However, there should be a transition of care (from inpatient to outpatient) which should be considered in the discharge management.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	At the patient discharge from the department, the workflow related to the patient has to be terminated		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:50 PM]
Main impact is on WP4
Comment by Franco Chiarugi [28/Jul/10 11:26 AM]
Changed the rationale in order to address Lukas's comments

[REACTION-232] Continua Manager emulation Created: 18/Jun/10 Updated: 18/Jun/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Matts Ahlsen	**Assignee:**	Peter Rosengren
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP4		
Rationale:	The integration of Continua devices requires a Continua Manager component as part of the architecture. In the absence of such a manager, the system should provide an emulation of the corresponding functionality.		
Source/Originator:	CNet WP4 architecture design meeting		
Fit Criterion:	A Continua Manager stub exists allowing simulated access to a Continua device.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-233] Insulin sensitivity and insulin resistance Created: 20/Jun/10 Updated: 26/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Glucose Control Algorithm, Ontology/Terminology, Physiology Models, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).		
Source/Originator:	Inpatient workshop		
Fit Criterion:	Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion shall be available		

Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Franco Chiarugi [06/Jul/10 1:49 PM]
Main impact is on WP6

[REACTION-234] Determination of health status in Inpatient environment Created: 20/Jun/10 Updated: 08/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or adapted to the status of the patient. In the second case a dose-finding procedure for the individual patient will be started associated with education in nutrition and therapy. Type of diabetes has to be registered.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:48 PM]
Main impact is on WP10

[REACTION-235] Therapy scheme in Inpatient environment registered immediately after the patient enrolment Created: 20/Jun/10 Updated: 26/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status and associated conditions (fasting, special diet, diarrhoea, vomiting, infection, fever), nutrition (snacks in between, diminished/absence of appetite), insulin sensitivity (diurnal changes, fever...), planned examinations/treatments (e.g. surgery, endoscopic examinations), interaction with other medication (e.g. glucocorticoids)		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:47 PM]
Main impact is on WP10

[REACTION-236] Blood glucose measurements in Inpatient environment Created: 20/Jun/10 Updated: 28/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	PAN/BAN, Portable Devices, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - Inpatient pilot application		

Workpackage:	WP3, WP5
Rationale:	PoC devices are currently used and will be used in Inpatient environment. The procedure is reliable and has been used since several years. Substitution of the used PoC devices with other devices (consortium sensors) in the daily practice can be done only after passing through a very severe procedure. This might not be foreseen (for the daily practice) in this project.
Source/Originator:	Inpatient workshop
Fit Criterion:	There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose sensors using a procedure which should be quite simple and user friendly.
Customer Satisfaction:	Interested
Customer Dissatisfaction:	Low Unhappiness

Comment by Jesper Thestrup [28/Jun/10 12:42 PM]
Check for potential overlap with issue 225 /Helene
Comment by Franco Chiarugi [02/Jul/10 3:23 PM]
Comment: as an alternative the finger prick method was discussed, to be performed by the patient himself or a clinician and subsequent entering the data into the REACTION-platform, so this requirement might be connected to REACTION-215 and -243 (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 1:44 PM]
This requirement is beyond the first-year prototype (in the first-year prototype the currently used sensors will continue to be used). For the next prototypes suitable sensors with the necessary approvals have to be provided, otherwise PoC devices will necessarily continue to be used.
Comment by Franco Chiarugi [06/Jul/10 1:46 PM]
Main impact is on WP3
Comment by Franco Chiarugi [28/Jul/10 9:40 AM]
Changed the fit criterion in order to address Lukas's comments

[REACTION-237] Annotation of blood glucose values, especially in inpatient environment Created: 20/Jun/10 Updated: 23/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Interfaces with HIS/EPR, Ontology/Terminology, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP3, WP4, WP10		
Rationale:	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:39 PM]
Main impact on WP4 (context and annotations)

[REACTION-238] Update and entering of drug administration (OAD and/or insulin) data Created: 20/Jun/10 Updated: 26/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Drug administration (time, type, dosage and other relevant information) has to be immediately annotated in the fever chart by the administering nurse.		

Source/Originator:	D2.1 and workshops
Fit Criterion:	The nurse through an appropriate user interface can check the last drug administration and insert the relevant data related to the drug administration she has just performed.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Franco Chiarugi [05/Jul/10 2:40 PM]

Main impact on WP4

[REACTION-239] Special examinations/treatments to be registered in fever chart Created: 20/Jun/10 Updated: 26/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases the treatment is adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). A problem for the patient may arise if the patient has to wait longer than expected due to unexpected delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). Therefore, the dose of insulin and/or OADs will be adapted, the patient will get some food which he can eat in case of hypoglycaemia and the patient will get insulin which will be injected in case of hyperglycaemia.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the therapy scheme.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 2:38 PM]

Main impact in WP4

[REACTION-240] Intravenous insulin Created: 20/Jun/10 Updated: 26/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP8, WP4, WP10		
Rationale:	In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The insulin administration shall allow also the IV way in the user interface		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Low Unhappiness		

Comment by Matts Ahlsen [22/Jun/10 3:32 PM]

Unclear to WP4, maybe more a requirement on clinical WF & user interface. If wp4: Please specify the data/service management requirement, i.e. what is required to be stored.

Comment by Franco Chiarugi [05/Jul/10 2:38 PM]

Main impact is on WP10 (user interface)

[REACTION-241] Management of hypoglycaemic episodes in Inpatient environment Created: 21/Jun/10 Updated: 26/Jul/10

Status:	In Progress
Project:	REACTION requirements

Component/s:	Alarm & Alert Subsystem, Data Management, Glucose Control Algorithm, Ontology/Terminology, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP8, WP6, WP4, WP10		
Rationale:	The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose measurement (under a certain threshold). In case of episode the reasons for hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 2:35 PM]
Main impact on WP10
Comment by Peter Beck [09/Jul/10 9:08 AM]
The details for this requirement (especially which parameters are relevant) have to be identified together with WP8 (clinicians), because they influence the organizational work at the ward.
Comment by Franco Chiarugi [09/Jul/10 11:47 AM]
Added WP8 in order to address Peter's comments

[REACTION-242] Management of hyperglycaemic episodes in Inpatient environment Created: 21/Jun/10 Updated: 26/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem, Data Management, Glucose Control Algorithm, Ontology/Terminology, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered and the changes in treatment have to be documented as well.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 2:34 PM]
Main impact on WP10

[REACTION-243] Nutrition has to be taken into account in the calculation of the drug dosage Created: 21/Jun/10 Updated: 26/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Glucose Control Algorithm, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The data management and the user interface shall allow the insertion of time and composition of nutrition		

	accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness
Dependencies:	REACTION-215

Comment by Franco Chiarugi [02/Jul/10 4:28 PM]
Main impact is in WP6
Comment by Peter Beck [09/Jul/10 9:37 AM]
Due to lot of organizational work for suggest nutrition recording and how food is administered on the ward we cannot proceed from the assumption that all parameters will be filled in. Considering the required fields from the rationale in the REACTION platform is OK.
Comment by Franco Chiarugi [09/Jul/10 11:44 AM]
Changed (lowered) customer satisfaction and customer dissatisfaction in order to address Peter's comments
Comment by Franco Chiarugi [20/Jul/10 5:15 PM]
#215 is a duplicate of this requirement

[REACTION-244] The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs. Created: 21/Jun/10 Updated: 26/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Glucose Control Algorithm, Ontology/Terminology, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 2:34 PM]
Main impact is on WP6 (insulin dosage evaluation)

[REACTION-245] Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation Created: 21/Jun/10 Updated: 26/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Glucose Control Algorithm, Ontology/Terminology, Risk Assessment, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP6, WP10		
Rationale:	Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:06 PM]

Blood gas analysis is more appropriate than keton bodies in urine (Lukas)
Comment by Franco Chiarugi [05/Jul/10 2:31 PM]
Changed the rationale in order to address Lukas's comment
Comment by Franco Chiarugi [05/Jul/10 2:32 PM]
Main impact is on WP10 (user interface)

[REACTION-246] Multi-user availability and display of the fever chart Created: 21/Jun/10 Updated: 26/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	The fever chart shall be considered as a central document and collects all the information about the patient stay in the hospital ward (blood glucose level, temperature, vital signs, information about the actual status of the patients, drug administration, nutrition, relevant events, etc.)		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 2:27 PM]
Main impact on WP4

[REACTION-247] Mobile access point in wards of Inpatient environment Created: 21/Jun/10 Updated: 21/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Architecture, Backend Middleware, Communication, Data Management, Networking, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication, ease of operation.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matts Ahlsen [01/Jul/10 1:45 PM]
WP4: not specifically a WP4 requirement. More likely WP10 only.
Comment by Franco Chiarugi [05/Jul/10 2:27 PM]
Main impact is on WP10

[REACTION-248] Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events Created: 21/Jun/10 Updated: 26/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Data Management, Ontology/Terminology		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen

Requirement Type:	Functional - Inpatient pilot application
Workpackage:	WP4
Rationale:	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.
Source/Originator:	D2.1 and workshops
Fit Criterion:	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

[REACTION-250] Different contextualization of the patient clinical information Created: 21/Jun/10 Updated: 06/Jul/10

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	Different modes of visualisation with different relevant parameters for decision support shall be foresee. The relevant data have to be displayed contextualized. The relevant values have to be highlighted.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The possibility of configure the display of the patient clinical data (mainly the fever chart) has to be present.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 2:25 PM]
Main impact is on WP10

[REACTION-251] Creation of electronic decision support rules shall be supported Created: 21/Jun/10 Updated: 06/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Glucose Control Algorithm, Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	An electronic decision support system with standardised instructions and decisions (e.g. evidence based medicine, support identification of "patients at risk") shall be present. There have to be "guidelines" on how to titrate insulin. An active alarm system would remind the staff to perform measurements/injections.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Suggestions on treatments shall be available in order to facilitate the clinical decision. An available protocol from literature (e.g. RABBIT II trial) should be implemented and improved. Alerts for next insulin administration should be provided together with a support for calculation of insulin amount depending on known (acquired or estimated/evaluated) parameters.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-252] When some measurements are missing the system shall remind it through an active alarm reminder Created: 21/Jun/10 Updated: 06/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Alarm & Alert Subsystem		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Stelios Louloudakis
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP5		

Rationale:	Sometimes nurses forget to perform measurements. An active alarm system shall remind to perform the missing measurements. Regular measurements are necessary in order to have an optimal clinical decision and to minimize adverse events.
Source/Originator:	D2.1 and workshops
Fit Criterion:	When a configurable time after the expected measurement acquisition time is elapsed, the system should send (at regular intervals) an alert to the nurse(s) in duty in order to perform the missing measurements.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

[REACTION-253] Data entry shall be facilitated as much as possible Created: 21/Jun/10 Updated: 06/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Portable User Interface, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Lukas Schaupp
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP8, WP4, WP3, WP10		
Rationale:	Data entry in any information system is an additional task for patients and formal/informal carers. This additional workload has not to be burdensome in order to facilitate the adoption of the platform in the clinical sites.		
Source/Originator:	Workshops		
Fit Criterion:	Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work they have to do and how much this additional work (if any) is useful.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Matts Ahlsen [01/Jul/10 12:00 PM]
WP4: not a specific WP4 requirement, more likely WP10 or 8
Comment by Franco Chiarugi [02/Jul/10 3:22 PM]
Requirement? (Thomas, IMM)
Comment by Franco Chiarugi [05/Jul/10 2:23 PM]
Main impact is on WP8 (verification of easy data entry is a task of WP8)

[REACTION-255] Management of missing data Created: 21/Jun/10 Updated: 09/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Peter Beck
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP10, WP6		
Rationale:	The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour...).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In case of missing data, the Inpatient application shall ask for them or make a good guess on default values based on context. For critical medical parameters (e.g. blood glucose, lab values) instead of offering automatic default values, it would be probably better to show past values and the user has to choose the appropriate one.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Matts Ahlsen [01/Jul/10 11:53 AM]
WP4: Suggest this requirement to be attributed to WP10 only.
Comment by Franco Chiarugi [05/Jul/10 1:47 PM]
Probably parameter estimation is a task of WP6. WP10 cannot make an estimation of the missing value but simply ask WP6 for the "best value" to assign to the field. I propose to change WP4 with WP6 but main impact will be on WP6.
Comment by Peter Beck [09/Jul/10 9:00 AM]
I depends very much on the parameters whether parameter estimation is suitable or not. For critical medical parameters like blood glucose or lab values I would not suggest to offer automatic default values as input parameters by the system (e.g. for decision support). A better way would be to show past values and the user has to choose the appropriate one.

Comment by Franco Chiarugi [09/Jul/10 11:42 AM]
Changed the fit criterion in order to address Peter's comments

[REACTION-257] Automated transfer of measured and relevant data to the patient's record Created: 21/Jun/10 Updated: 23/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Data Management, Interfaces with HIS/EPR, PAN/BAN, Portable Devices, Portable User Interface, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP3, WP4, WP5		
Rationale:	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matts Ahlsen [01/Jul/10 11:43 AM]
WP4: suggest this to be attributed to WP4 only. The Fit criterion: what is the meaning of transcription here ?
Comment by Franco Chiarugi [05/Jul/10 1:09 PM]
The meaning of transcription is that currently the nurses write the blood glucose values in the paper form (even if these values have been electronically acquired and stored in the HIS). Thus, this manual writing (transcription) can be prone of errors and in REACTION the writing of the blood glucose values should be made automatically by the PLATFORM (no operation is required to nurses). I have changed the word transcription with store in the fit criterion
Comment by Franco Chiarugi [06/Jul/10 3:12 PM]
Main impact is on WP4

[REACTION-258] Automated transfer of patient related data from the hospital information system Created: 21/Jun/10 Updated: 23/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Interfaces with HIS/EPR, Ontology/Terminology, Web User Interface		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4, WP10		
Rationale:	At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred from the HIS to the platform (when a HIS/EPR is present in the clinical site). This procedure reduces transcription errors and save doctors/nurses time for manual data entry. This procedure must be flexible enough to interface different HIS/EPR HL7-based including the one used at the clinical site.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:10 PM]
This has to be adapted to the current status in the hospital (Lukas)
Comment by Franco Chiarugi [05/Jul/10 1:04 PM]
Changed the rationale trying to address Lukas comments
Comment by Franco Chiarugi [06/Jul/10 3:11 PM]
Main impact is on WP10

[REACTION-259] Automated patient identification Created: 21/Jun/10 Updated: 21/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture, Security		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matthias Enzmann
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP7		
Rationale:	Automated patient identification to avoid identification mistakes. Risks of wrong patient identification have to be negligible. The REACTION identification system must be flexible enough to integrate existing identification methods employed on site, e.g., wards in a hospital.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	An effective, proper and easy-to-use way for automated patient identification, when mobile device is close to the patient (RFID, NFC?) has to be present. For example, each patient might wear wristband with a barcode which identifies the patient. This is standard in many hospitals and in some wards of the inpatient clinical site these wristbands are in use. This way shall reduce errors in patient identification and speed-up the patient management.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Dependencies:	REACTION-176		

Comment by Jesper Thestrup [28/Jun/10 3:04 PM]
Identification should be related to the patient, not the bed /Helene
Comment by Franco Chiarugi [01/Jul/10 4:11 PM]
This has to be adapted to the current status in the hospital. My idea was that each patient should wear wristband with a barcode which identifies the patient. This is standard in many hospitals. In some of our wards we have already these wristbands. However it is the decision of the hospital management which wards will have which kind of identification (optical - barcode, name, RFID, ...). Therefore we have to adapt the identification system to the system which will be defined by the hospital management. Therefore the REACTION platform should be flexible enough to cover different systems! (Lukas).
Comment by Franco Chiarugi [02/Jul/10 10:30 AM]
We should add something to the rationale like: "The REACTION identification system must be flexible enough to integrate existing identification methods employed on site, e.g., wards in a hospital" (Matthias).
Comment by Franco Chiarugi [05/Jul/10 12:57 PM]
Tried to address comments from Helene, Lukas and Matthias, changing the rationale and the fit criterion.
Comment by Franco Chiarugi [20/Jul/10 5:16 PM]
#176 is a duplicate of this requirement

[REACTION-261] The platform shall not generate additional workload for the clinical staff Created: 21/Jun/10 Updated: 06/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Usability		
Workpackage:	WP8, WP4, WP10		
Rationale:	Additional workflow shall be avoided or allowed only when the advantages produced by this workflow overcome the disadvantages		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the filed trials evaluation additional workflow shall be assessed by questionnaire or quantitative measurements and its advantages/disadvantages properly evaluated		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Matts Ahlsen [01/Jul/10 11:32 AM]
Requirement not directly related to WP4. Suggest to assign to WP8 only.
Comment by Franco Chiarugi [05/Jul/10 12:47 PM]
Probably main impact is on WP8 (but proper design is necessary in WP4 & WP10, proper definition of the evaluation plan in WP2 and performing of the evaluation in WP8)

[REACTION-262] Improve productivity and efficiency, reducing cost Created: 21/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Performance		
Workpackage:	WP8, WP4, WP10		
Rationale:	The platform shall improve productivity and efficiency and at the same time shall reduce the cost of the diabetic patient workflow and management		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Qualitative or quantitative measurements of productivity, efficiency and cost shall be foreseen in the field trials in order to make a proper comparison between the performances before the introduction of the REACTION platform and after the introduction of the REACTION platform. Assessment in field trial will be based on questionnaire for evaluating productivity and efficiency and on cost-benefit analysis estimating the different performances before the introduction of the REACTION platform and after the introduction of the REACTION platform.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Matts Ahlsen [01/Jul/10 11:30 AM]
This requirement is not directly attributed to WP4. Propose to assign is to WP8 only. Fit crit: inital assessment procedures should be indicated
Comment by Franco Chiarugi [05/Jul/10 12:41 PM]
Modified the fit criterion trying to address Matts's comment. Probably main impact is on WP8 (but proper design is necessary in WP4 & WP10, proper definition of the evaluation plan in WP2 and performing of the evaluation in WP8)

[REACTION-263] Improve documentation quality and streamlined access to information Created: 21/Jun/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	The registration of all measurements, additional information, decision on treatments, drug administration will improve the quality of documentation. The reduction of the number of missing information and an efficient access to all information related to the patient will improve the quality of care.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The platform shall allow the registration of all relevant information and its contextualized retrieval. In the questionnaires used in the evaluation procedures specific questions should be included in order to verify the user satisfaction about the improvement in the documentation and in the streamlined access to information.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Matts Ahlsen [23/Jun/10 4:14 PM]
WP4: The fit criterion must be detailed in order to be measurable. The requirement can be broken down into multiple ones in order to achieve this.
Comment by Franco Chiarugi [05/Jul/10 12:36 PM]
Changed the fit criterion trying to address Matts's comment. In the questionnaire associated to the evaluation plan, end-users will be asked to evaluate the improvement in documentation and streamlined access to information

[REACTION-264] Increase accuracy and reduce errors Created: 21/Jun/10 Updated: 06/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Architecture		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Non-functional - Performance		

Workpackage:	WP4
Rationale:	The registration of all relevant data (vital sign and environmental measurements, nutrition and lifestyle, drugs/insulin administration, adverse events) shall allow a reduction in the errors committed in the current workflows and an improvement in the accuracy of the diabetic patient management
Source/Originator:	D2.1 and workshops
Fit Criterion:	Qualitative and quantitative criteria shall be present in the field trial evaluations in order to measure the reduction of errors compared to the existing workflows before the installation of the REACTION platform and a quality improvement in the clinical decision.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Matts Ahlsen [22/Jun/10 3:45 PM]
Need refinement: specify the "relevant data" as far as possible. Also the fit criterion should be quantified.
Comment by Franco Chiarugi [05/Jul/10 12:28 PM]
Matts's comment has been addressed in the reviewed version of this requirement

[REACTION-265] The clinical parameters to be measured must be specified Created: 22/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	For sensor development the type of clinical parameter must be specified to adapt sensor properties to the specific parameter.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Clinical parameters given by the clinicians, but also parameters that are necessary for running the physiological model		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:20 PM]
For this requirement the physicians in the project should specify what they would like to have and also Bayer should say what say need for their algorithms (Thomas, IMM)

[REACTION-266] Type of sensor/signal should be specified Created: 22/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	Type of sensor/signal, whether chemical, electrical, optical, etc. is important for integration in e-patch and sensor platform and for the possibility to build an online sensor.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Type of sensor specified by the sensor manufacturers.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

[REACTION-267] Accuracy/precision of sensors should be specified Created: 22/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher

Requirement Type:	Functional - REACTION platform
Workpackage:	WP3
Rationale:	For all types of sensors the accuracy/precision has to be known. In some sensors a high accuracy can be required, as, for example, for online monitoring of glucose where a high precision is required, especially in the hypoglycaemic regime.
Source/Originator:	Lukas Schaupp
Fit Criterion:	The accuracy/precision should be specified by the sensor manufacturers.
Customer Satisfaction:	Uninterested
Customer Dissatisfaction:	Very Low Unhappiness

Comment by Franco Chiarugi [02/Jul/10 3:20 PM]
Is correlated to REACTION-180 (interference, specificity) and REACTION-183 (accuracy in the lower concentration range) (Thomas, IMM)
Comment by Franco Chiarugi [05/Jul/10 12:26 PM]
This is a generic requirement which addresses all sensors used in the REACTION platform while #180 & #183 refer to the blood glucose sensors

[REACTION-268] Response time and drift of the sensors should be specified Created: 22/Jun/10 Updated: 02/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	Response time of the sensor is important for online monitoring and it may not be too long, drift could influence the accuracy and could require regular calibrations.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Response time and drift should be specified by the sensor manufacturers.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:19 PM]
Is correlated with REACTION-267 since drift could influence the accuracy (Thomas, IMM)

[REACTION-269] Working range of sensors should be specified (linearity and detection limit) Created: 22/Jun/10 Updated: 22/Jun/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	The working range of the sensors should cover the required ranges as defined by the clinicians and ideally should be linear, the detection limit should be well below the minimal relevant measured variable.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Working range of the different sensors should be specified by the sensor manufacturers.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

[REACTION-270] Operating temperature of sensors should be specified Created: 22/Jun/10 Updated: 05/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher

Requirement Type:	Functional - REACTION platform
Workpackage:	WP3
Rationale:	The temperature might influence the result of the measurement and its accuracy.
Source/Originator:	Lukas Schaupp
Fit Criterion:	Either sensor manufacturers should specify the operating temperature of the sensors or the device should be able to adjust the measurement based on the temperature value (in this case a temperature sensor has to be integrated in the device)
Customer Satisfaction:	Uninterested
Customer Dissatisfaction:	Very Low Unhappiness

Comment by Franco Chiarugi [02/Jul/10 3:18 PM]
Is correlated to REACTION-29 although less specific (Thomas, IMM)

[REACTION-271] The calibration of the sensors should be specified (strategy, intervals, reference, algorithms) Created: 22/Jun/10 Updated: 02/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	The sensor must be calibrated before usage and might be re-calibrated after a certain time, also might the calibration required to be individual for a single patient.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Calibration routines of the sensors should be specified by the sensor manufacturers.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:18 PM]
Calibration is correlated to REACTION-268, since drift could require regular calibrations! (Thomas, IMM)

[REACTION-272] The body interface of the sensors should be specified Created: 22/Jun/10 Updated: 06/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3, WP8		
Rationale:	The body interface of the sensors determines whether it is invasive or non-invasive, it probably influences the accuracy and operating time of the sensors.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	The body interface should be specified by the sensor manufacturers.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:13 PM]
It impacts also in WP8 (Lukas)
Comment by Franco Chiarugi [02/Jul/10 3:16 PM]
Is connected to REACTION-267 (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 3:07 PM]
Main impact is on WP3

[REACTION-273] The sensor safety should follow the device directive 93/42/EEC and subsequent amending directives like the directive 2007/47/EC Created: 22/Jun/10 Updated: 28/Jul/10

Status:	Open

Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	The safety directive is essential for sensors being operated on patients. The off-the-shelf sensors/devices and the consortium-designed sensors/devices must comply with the device directives in force. In addition document history files among other quality assurance documents must be available to be submitted to the local authorities when conducting clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Sensors should be designed in a way that the directive 93/42/EEC is fulfilled.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Jesper Thestrup [28/Jun/10 11:49 AM]
Issue 273 and 281 are the same or overlap /Helene
Comment by Franco Chiarugi [01/Jul/10 4:14 PM]
is the same as N281 (Lukas)
Comment by Franco Chiarugi [02/Jul/10 3:15 PM]
is the same as REACTION-281 (Thomas, IMM)
Comment by Franco Chiarugi [05/Jul/10 12:00 PM]
Impact only on WP3. The off-the-shelf sensors/devices and the consortium-designed sensors/devices must comply with the device directives in force.
Comment by Franco Chiarugi [28/Jul/10 10:16 AM]
Changed the rationale in order to address Lukas's comments

[REACTION-274] The cost of the sensor should be specified Created: 22/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Functional - REACTION platform		
Workpackage:	WP3		
Rationale:	The cost of the sensor determines its later potential for a certain application (outpatient or inpatient use) and is influenced by its production effort.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	The cost of the sensor should be specified by the sensor manufacturers and be as low as possible.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:15 PM]
Costs are difficult to estimate unless not a real supplier is known. E.g. if IMM produces the sensors they might be much more expensive (Thomas, IMM)

[REACTION-275] Clinical trials, formal application Created: 22/Jun/10 Updated: 22/Jun/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Legal		
Workpackage:	WP8		
Rationale:	A formal application is required for clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Formal application must be made before clinical trials.		

Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

[REACTION-276] Clinical trials, patient's information sheet including informed consent Created: 22/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Legal		
Workpackage:	WP8		
Rationale:	Patient's information sheet including informed consent is needed for clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Patient's information sheet including informed consent must be given before clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-277] Clinical trials study protocol Created: 22/Jun/10 Updated: 08/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Legal		
Workpackage:	WP8		
Rationale:	A study protocol must be written during clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Study protocol must be available after clinical trials. The protocol should fulfil EN ISO 14155-1 and EN ISO 14155-2		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-278] Clinical trials case report form Created: 22/Jun/10 Updated: 22/Jun/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Legal		
Workpackage:	WP8		
Rationale:	For clinical trials a case report form has to be generated.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Case report form was generated for clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-279] Clinical trials investigators brochure Created: 22/Jun/10 Updated: 05/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Risk Assessment, Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Legal		

Workpackage:	WP3, WP8
Rationale:	It is important to create an investigators brochure (sensor development) for clinical trials.
Source/Originator:	Lukas Schaupp
Fit Criterion:	Investigators brochure present for clinical trials.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Franco Chiarugi [01/Jul/10 4:16 PM]
It impacts also in WP3 (Lukas)
Comment by Franco Chiarugi [05/Jul/10 12:07 PM]
Main impact on WP8

[REACTION-280] Device manual for clinical trials Created: 22/Jun/10 Updated: 06/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Thomas Klotzbuecher
Requirement Type:	Non-functional - Legal		
Workpackage:	WP3, WP8		
Rationale:	For clinical trials a sensor device manual must be available.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Manual available for clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:16 PM]
It impacts also in WP3 (Lukas)
Comment by Franco Chiarugi [05/Jul/10 12:04 PM]
Main impact is on WP3.

[REACTION-281] Clinical trials CE- certification OR certification that the device fulfils the MDD 93/42/EEC and subsequent amending directives like the directive 2007/47/EC Created: 22/Jun/10 Updated: 08/Jul/10

Status:	Open		
Project:	REACTION requirements		
Component/s:	Sensors		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Legal		
Workpackage:	WP8		
Rationale:	For clinical trials applied sensors or devices must fulfil the medical device directive (MDD). The clinical sites have to check the requirements (also on sensors/devices which will be used) for starting the clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Sensors applied in clinical trials fulfil the MDD.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:16 PM]
It impacts also in WP3 (Lukas)
Comment by Franco Chiarugi [02/Jul/10 3:13 PM]
Is the same as REACTION-273 (Thomas, IMM)
Comment by Franco Chiarugi [05/Jul/10 11:58 AM]
Main impact is on WP8. The clinical sites have to check the requirements for starting the clinical trials.

[REACTION-282] Insurance for clinical trials must be made Created: 22/Jun/10 Updated: 22/Jun/10

Status:	Open

Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Legal		
Workpackage:	WP8		
Rationale:	Insurance is required for clinical trials otherwise it can not be performed.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Insurance made before clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-283] Qualification of the investigator for clinical trials Created: 22/Jun/10 Updated: 22/Jun/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Risk Assessment		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Thomas Klotzbuecher	**Assignee:**	Lukas Schaupp
Requirement Type:	Non-functional - Legal		
Workpackage:	WP8		
Rationale:	Qualification of investigator must be given for clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Qualification of investigator given in advance of clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-284] Clinical data to be stored in the Inpatient environment Created: 05/Jul/10 Updated: 28/Jul/10			
Status:	Open		
Project:	REACTION requirements		
Component/s:	Context Management, Data Management		
Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Matts Ahlsen
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP4		
Rationale:	The data management shall be design in order to allow the storage of the clinical data to be registered at the patient enrolment and other clinical parameters which have to be acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, comorbidities, therapy scheme. Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, estimation of insulin sensitivity and resistance. The possibility of adding further parameters should be foreseen in the design.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The data management shall allow the insertion and the update of all the listed clinical parameters.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Dependencies:	REACTION-254		

Comment by Franco Chiarugi [28/Jul/10 10:49 AM]
Changed the rationale in order to address Lukas's comments

[REACTION-285] User interface for the clinical data stored in the inpatient environment Created: 05/Jul/10 Updated: 28/Jul/10			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Web User Interface		

Type:	Volere Requirement	**Priority:**	Major
Reporter:	Franco Chiarugi	**Assignee:**	Franco Chiarugi
Requirement Type:	Functional - Inpatient pilot application		
Workpackage:	WP10		
Rationale:	The user interface shall allow the insertion, modification and visualization of the clinical data registered at the patient enrolment and of the clinical data acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, comorbidities, therapy scheme. Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, estimation of insulin sensitivity and resistance. The possibility of adding further parameters should be foreseen in the design.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	There shall be a user interface which allows the insertion and the update of all the listed parameters.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Dependencies:	REACTION-254		

Comment by Franco Chiarugi [28/Jul/10 10:50 AM]
Changed the rationale in order to address Lukas's comments

Appendix A JIRA User Guide for REACTION Requirements

A.1: Logging into JIRA

Accessing the JIRA web site in a browser, the **Login** panel will display (see fig. 4). In this panel it is possible to:

1. **Log into JIRA:** To login to JIRA, the **'Username'** and **'Password'** have to be entered and then the user has to click the **'Log In'** button.
2. **Get the user login details:** Click the **'Can't access your account?'** link. User is then asked for the login data to be retrieved (user name or password) and an email is sent with all the required data.

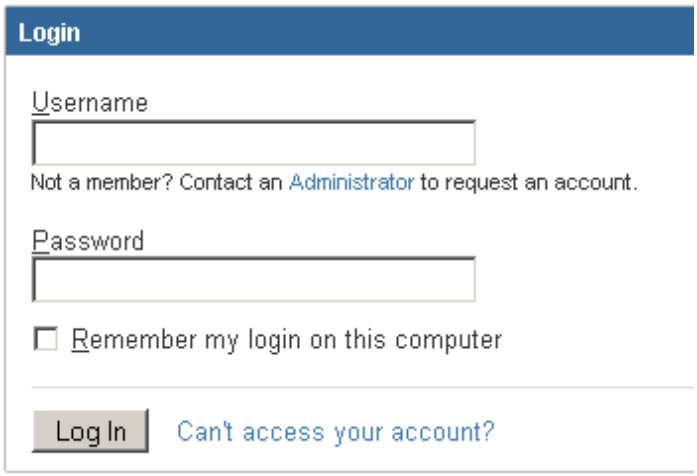

Figure 4: The Login panel of JIRA

A.2: Creating an Issue

Once accessed JIRA, to create a new **JIRA issue**:

1. Click the '**Create Issue**' link at the top of the screen.
2. The '**Choose the project and issue type**' popup will be displayed (see fig. 5). Select the relevant **project** and **issue type**, and then click the '**Create**' button.

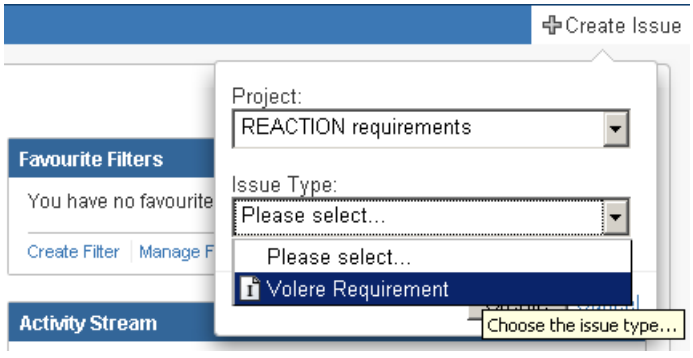

Figure 5: Choose the project and issue type

3. The '**Enter the details of the issue**' screen (see fig. 6) will be displayed. Complete any mandatory field, whose description is in italic and marked by an asterisk.

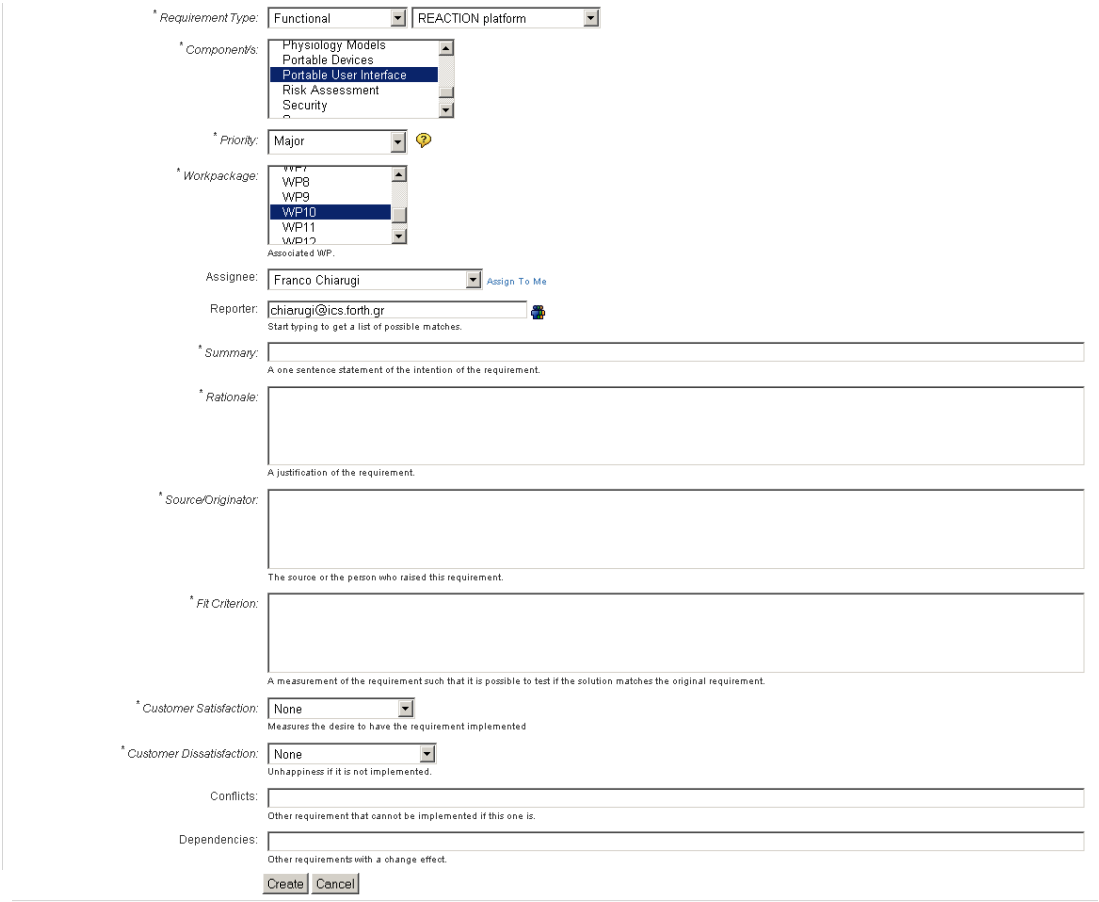

Figure 6: Enter the details of the issue

4. Click the '**Create**' button at the bottom of the page. The new issue will be created and added to the database. With the notification mechanism enabled, the user will also receive an email containing the issue details and a link to the inserted issue.

A.3: Viewing an Issue

The '**View Issue**' screen (see fig. 7) presents all the information about the issue and allows user making changes and watching the progress of the issue. It is divided into the *Details*, *Activity*, *People* and *Dates* sections.

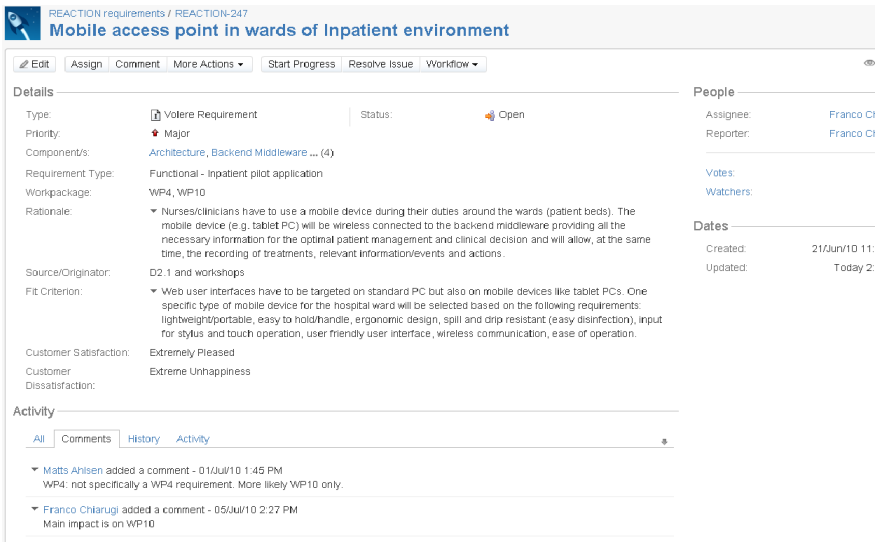

Figure 7: View of an issue

A.4: Edit Issue

To edit the issue click **'Edit'** button in the 'Operations Bar' of the *Details* section. The same screen that is displayed when creating an issue appears. The user can then update the fields.

A.5: Assign Issue

The issue can be assigned to a different person by clicking the '**Assign**' button in the 'Operations Bar'. The following screen (see fig. 8) is displayed where the assignee can be selected:

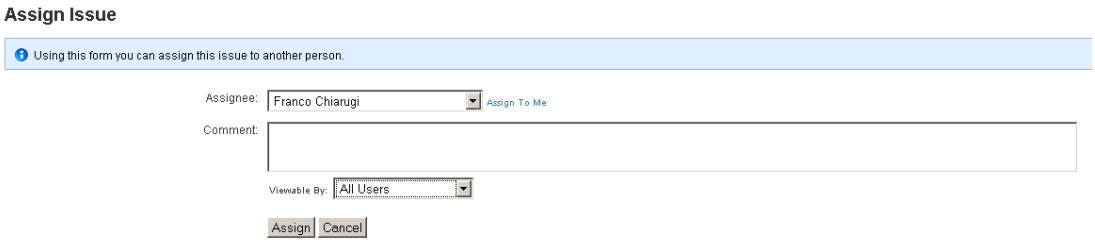

Figure 8: Assignment of an issue

A.6: Adding comments

It is possible to add a comment to an issue by clicking the **'Comment'** button in the **'Operations Bar'** of the Details section. This opens the comment text box (see fig. 9):

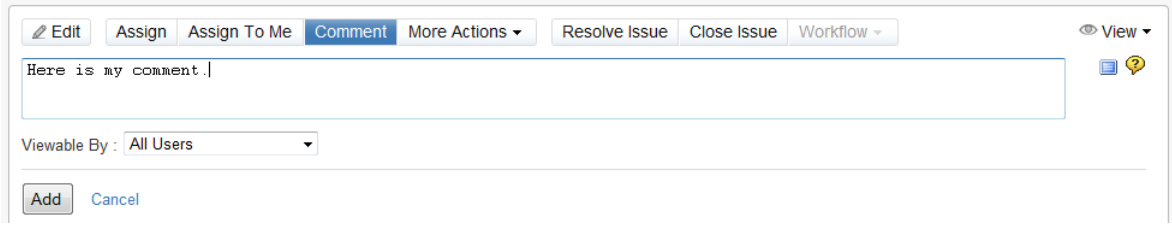

Figure 9: Comment text box

A.7: Attaching files

It is possible to attach a file to an issue. From **'More Actions'** menu, select **'Attach File'**. The **'Attach Files'** page (see fig. 10) will appear:

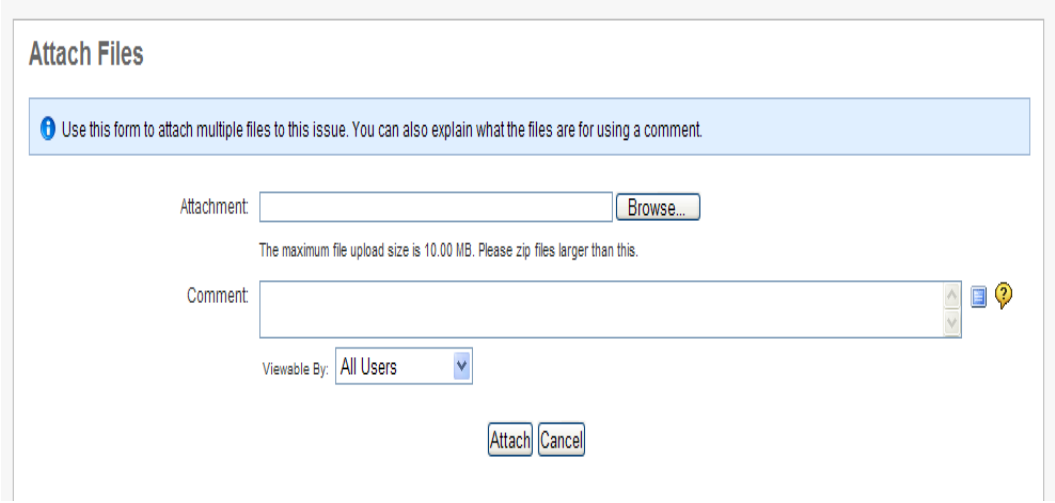

Figure 10: Attach files to an issue

Click the **'Browse'** button to select the files and then click the **'Attach'** button.

A.8: Vote and Watch an Issue

In the People section the Assigner and the Reporter are shown. Also the user can vote on an issue or edit the list of the watchers. JIRA allows the user to vote for a particular issue — "voicing" the preference for

that issue to be resolved or completed. JIRA also allows the user to watch a particular issue, signing up for notifications of any updates relating to that issue.

The user can also view the voter and watcher lists for an issue and, having the correct permission, the user can manage the watcher list — that is, add other people to the watcher list. This is useful if the user needs to draw someone's attention to a particular issue.

The voter and watcher lists are shown in at the right of the screen when viewing an issue. More specifically the user can:

- Click the '**Vote**' icon ( ) to instantly vote for the issue.
- Click the word '**Votes**' to view the list of people who have voted for the issue.
- Click the '**Watcher**' icon ( ) to instantly become a watcher of the issue.
- Click the word '**Watchers**' to view and edit the list of people who are watching the issue. The 'Manage Watch List' form will appear (see fig. 11). The user can type the required username(s) into the field provided, or click the 'user-picker' icon to select the username(s) from a list.

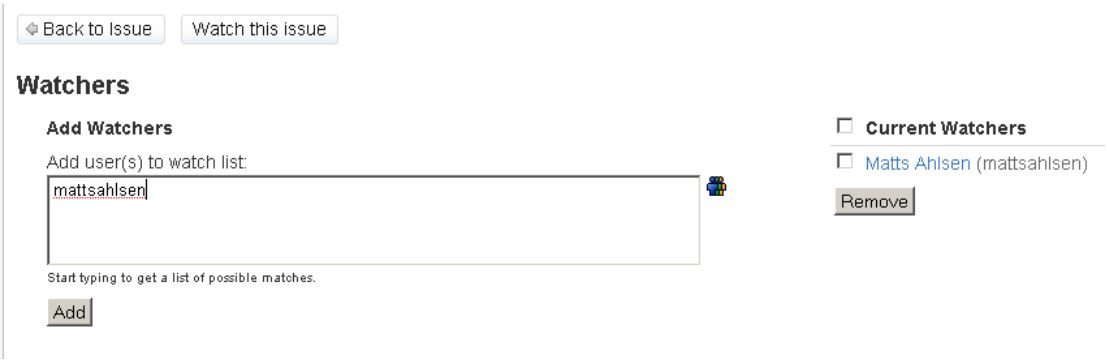

Figure 11: Manage watch list

A.9: Edit Comments

The Activity section (shown at the down left of the screen when viewing an issue) (see fig. 12) presents all the changes and comments that have been applied to the issue. To edit a comment, after selecting the tab **'Comments'**, browse to the comment to be edited and click the Edit link, located on the comment.

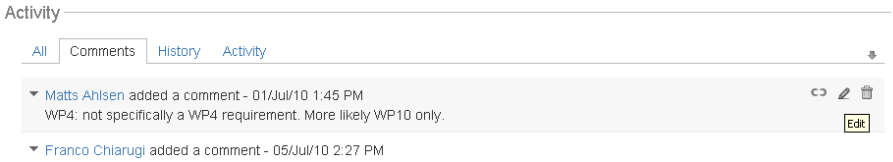

Figure 12: List of comments

Edit the comment's textbox and '**Viewable By**' list and Click the **'Save'** button (see fig. 13).

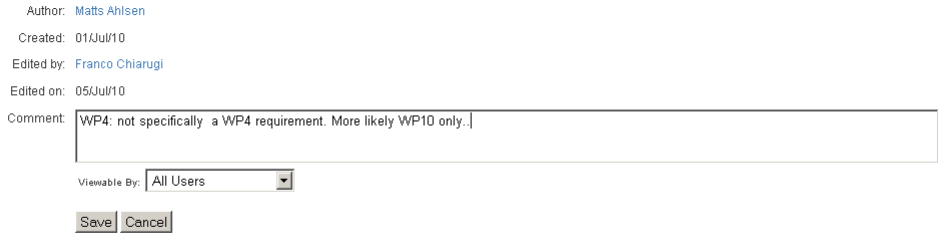

Figure 13: Edit a comment

A.10: View History

An issue *history* is a record of changes made to an issue, including:

- changes to an **issue field**

- attachment of a **file**
- deletion of a **comment**
- deletion of a **worklog**
- creation or deletion of an **issue link**

For each change, the following information is recorded:

- the person who made the change
- the time at which the change was made
- if an **issue field** was changed, the new and old values of the field

To view an issue change history:

1. Open the relevant issue in JIRA.
2. Click the '**History**' tab in the '**Activity**' section.
3. The list of changes to the issue will display (see fig. 14).

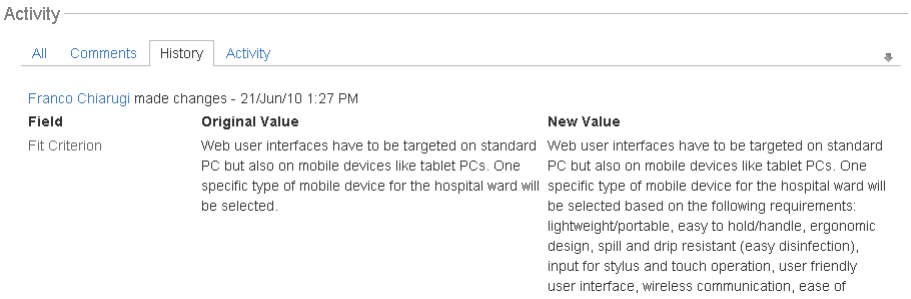

Figure 14: History of an issue

A.11: Search for Issues

JIRA provides a powerful issue search facility. Because of the large number of issues, it is important to know how to search for the issues the user is interested to. The search screen is under **Search for issues** item of the **Issues** menu (see fig. 15).

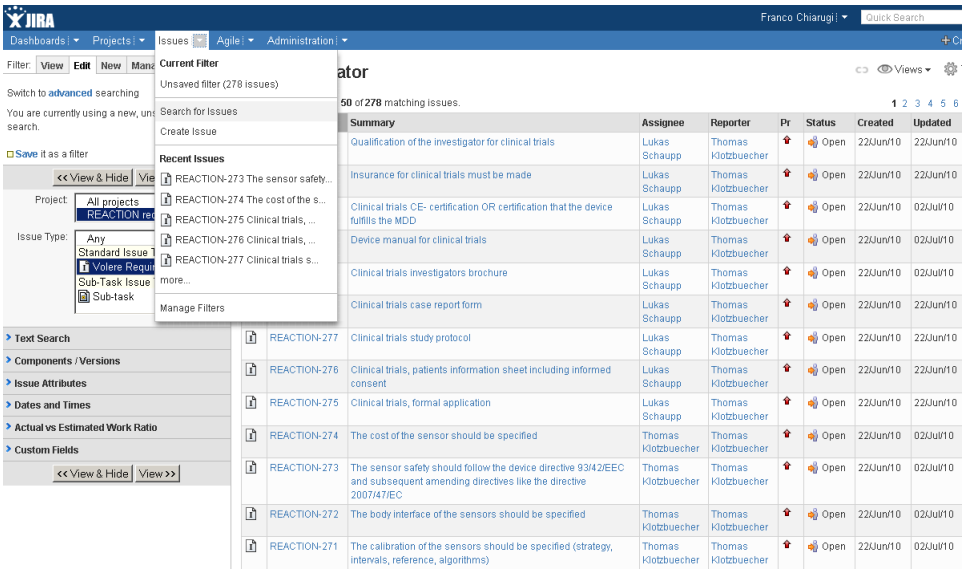

Figure 15: Search for issues

The user can search for issues across projects, versions and components using a range of search criteria described below. JIRA will display all the results that match the combination of the search criteria selected by the user.

Search by Project and Issue Type

A list of the available projects and issue types is displayed (see fig. 16) where the user can select any of them as a search criterion.

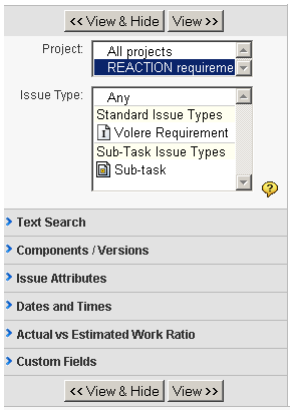

Figure 16: Search by project and issue type

By Component/s

The user can select as many components as he wants (see fig. 17) and all the issues related to these components will be listed in the search results.

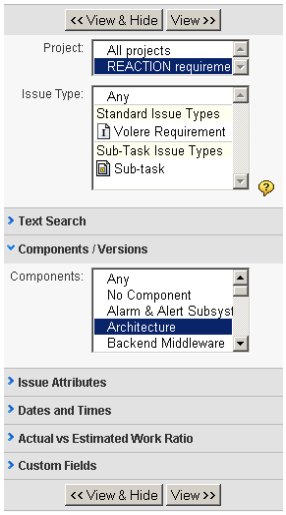

Figure 17: Search by component/s

Search by Issue Attributes

Reporter, assignee, status and priority can be selected as search criteria from lists of available values for each attribute (see fig. 18).

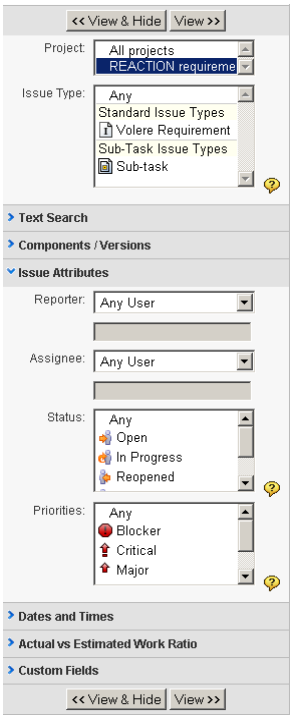

Figure 18: Search by issue attributes

Search by Dates and Times

Issues can be searched based on the date and time created, updated or resolved. Users can insert one or more of these values and the results matching this combination of values will be displayed in the search results (see fig. 19).

Figure 19: Search by dates and times

Search by Custom Fields

All the fields the user is asked to fill during the creation of an issue can be used as search filters (see fig. 20). The issues matching the combination of values the user enters will be displayed in the results.

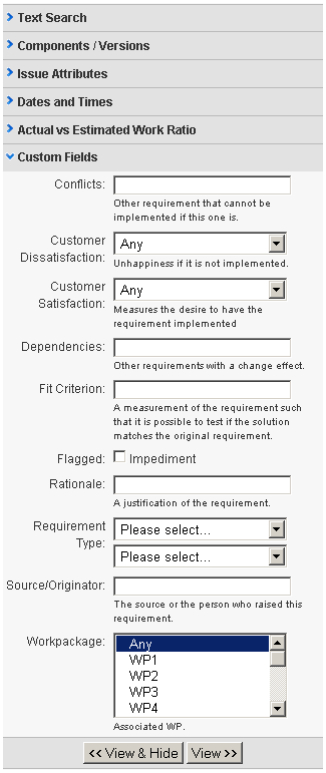

Figure 20: Search by custom fields

A.12: Sub-Tasks

Sub-task issues are generally used to split up a parent issue into a number of tasks which can be assigned, tracked and edited separately. Splitting issues into smaller tasks provides better organisation of the issue and a better picture of the progress on the issue, makes more clear what the issue includes and what has to be done, and allows to assign the issue to different persons where each person is responsible in resolving a particular part of the issue. Sub-tasks include the same set of fields as the standard issues. The only difference is that they have a different set of issue types.

Creating a Sub-Task

In the view screen of the issue which is the parent issue of the sub-tasks the user is going to create, select 'Create sub-task' from the 'More Actions' drop-down menu (see fig. 21).

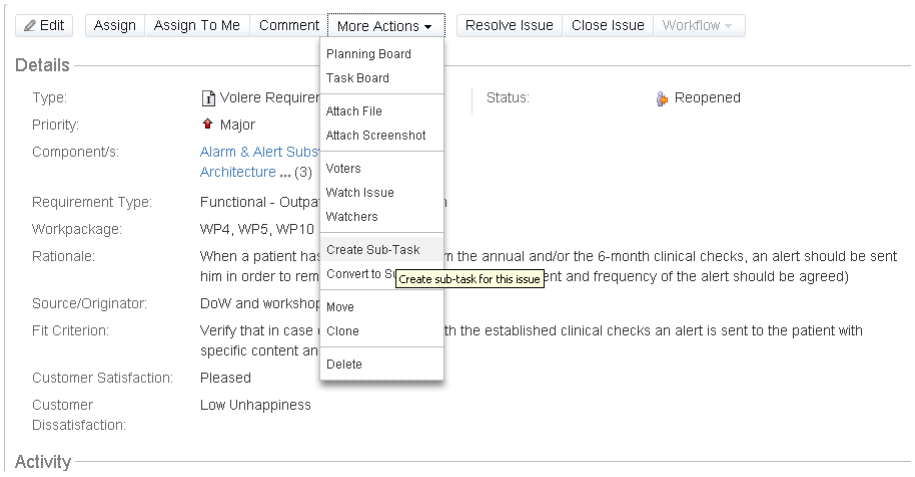

Figure 21: Start the creation of sub-task

Then a screen similar to the one of creating a standard issue appears (see fig. 22). The only difference is that issue type is *Sub-task* instead of *Volere Requirement*.

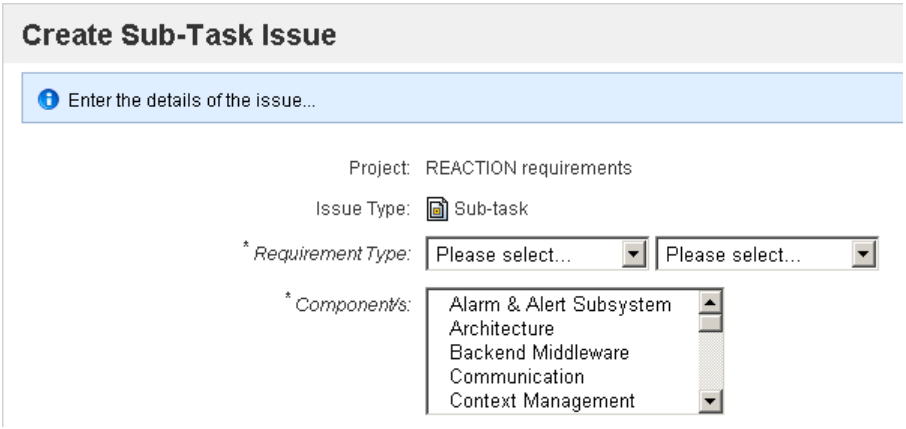

Figure 22: Create sub-task issue

Working with Sub-Tasks

If an issue has sub-tasks, a list of these sub-tasks is shown in the issue screen (see fig. 23). The **Sub-Tasks** section has two tabs: **All** and **Open**. The *All* view lists all sub-tasks, regardless of status, while the *Open* view only shows sub-tasks that have not been resolved.

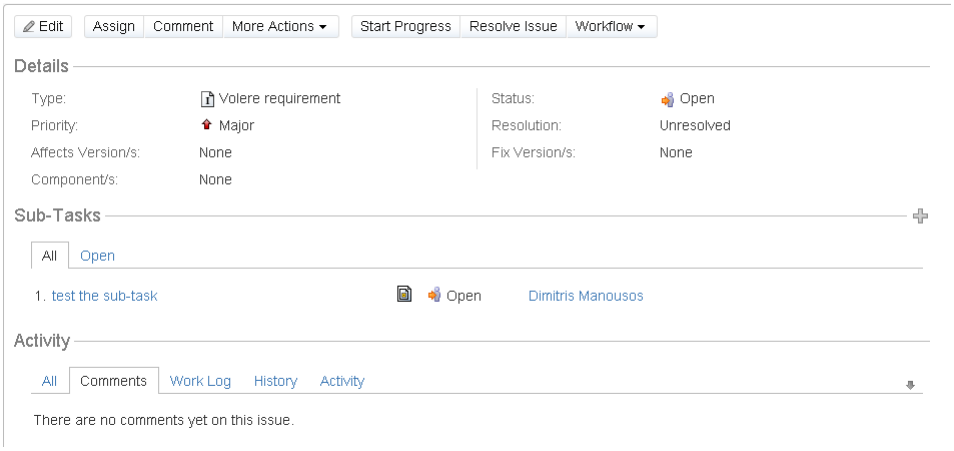

Figure 23: Issue with sub-tasks

The user can hover the sub-task in order to appear the **Actions** drop-down menu in the right of the sub-tasks area (see fig. 24).

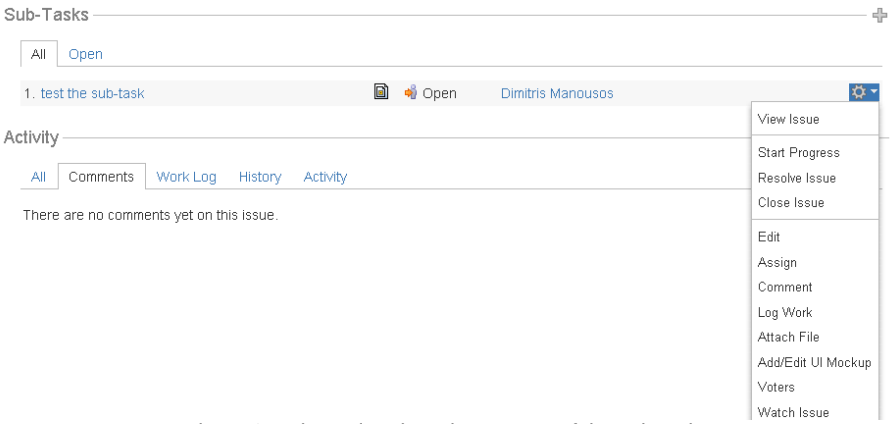

Figure 24: The action drop-down menu of the sub-tasks

This menu shows the actions that can be performed on the sub-task (e.g. Edit Issue, Assign Issue, Resolve Issue, Close Issue, Reopen Issue, Attach File).

Searching for Sub-Tasks

In the issue type drop-down list of the search for issue form there are two more choices named **Sub-Task Issue Types** and **Sub-task** (see fig. 25). The user has to select one of them in order to apply the search filters only to sub-tasks.

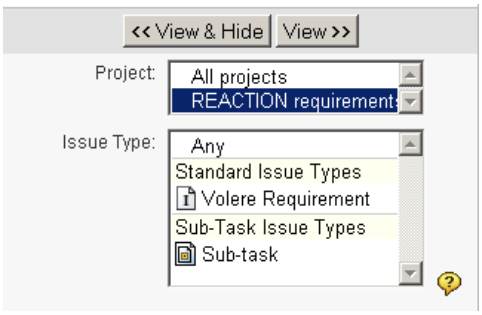

Figure 25: Using issue type for searching sub-tasks

If no entries are selected from the 'Issue Type' drop-down then the search will return all the standard issues and sub-task issues that meet the rest of the search criteria. The search results indicate sub-task issues by displaying the parent issue's issue key above the sub-task's summary, as shown in fig. 26.

T	Key	Summary	Assignee	Reporter	Pr	Status	Res	Created	Updated	Due	
	TP-11	TP-10 test the sub-task	Dimitris Manousos	Dimitris Manousos		Open	UNRESOLVED	07/Jul/10	07/Jul/10		

Figure 26: Results of a search with sub-tasks