Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

REACTION (FP7 248590)

D2-9 Updated requirements report

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Abstract	This deliverable contains the revised requirements taking into account the results of the watch reports and the *Lessons Learned* at the end of iteration cycle 3, and the current JIRA configuration and workflow management. The complete list of the requirements at the end of iteration cycle 3 is reported in a separate appendix.
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1 Executive Summary

Since its start the REACTION project has adopted a specification and design methodology based on an evolutionary requirements engineering procedure underpinned by a strong user-centric development process.

The methodology calls for comprehensive iterative requirements and stakeholder analysis based on initial requirements gathered from medical and clinical scenario thinking. The REACTION requirements encompass the needs and priorities of the users as well as the wider exploitability and scalability requirements taking into account the technical constraints as well as the safety, socioeconomic and legal acceptance and the capability of deploying the resulting REACTION platform in real Public Healthcare Systems.

Towards the end of each iterative cycle (corresponding to one calendar year) a prototype of the REACTION platform is assembled with a view to integrating as many of the existing components as are available at the time and in accordance with the detailed work plan. The components of the REACTION platform will undergo technical verification of their functionality. Then, system integration and verification will take place in each of the four iterative validation cycles in the research and development phase.

After the successful completion of a prototype cycle, each work package analyses and reports its development results and experiences in the development, integration, verification and validation work through Lessons Learned. In addition, Lessons Learned may result from the continual monitoring of developments in the clinical, technology, market and regulatory standards fields, as reported in three M24 Watch reports. Lessons Learned constitute both individual and organisational knowledge gained by experience; either negative or positive.

All results from validation and experiences gathered in the process lead to refined technical scenarios, revised requirements specifications, updated platform architecture and new prototype specifications.

This document describes the work performed on the iterative requirement engineering during the third iteration cycle describing the impact of the Lessons Learned in the REACTION requirements and explaining the change request and re-engineering produced in each work package. All changes in the requirements have been reported and in several cases a comparison with the situations at the end of the first and second iteration cycles has been shown as well.

Some refinements in the requirement management process have been reported and the main statistics about the requirements and their progresses to the implementation and validation have also been described in this document. The main actions foreseen for the fourth iteration cycle have been included as well. The complete list of the requirements at the end of the third iteration cycle has been reported in a separate appendix.

2 Introduction

2.1 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.

2.1.1 Background and Context

The background and context of the work performed and described in this deliverable follow from deliverable ID2-8-4 *"Change request and re-engineering report 3"* detailing the Lessons Learned, change requests and requirement re-engineering done in the third iteration cycle. The work performed in cooperation with the WP leaders for the finalization of the third requirement revision is documented in this deliverable.

2.1.2 Target Audience

The target audience of this deliverable is all REACTION partners and particularly the technical partners who will have to design appropriate technical solutions to address the remaining unresolved requirements and to react promptly to the agreed changes.

2.1.3 Purpose

The purpose of this deliverable is to describe both the procedure for the requirement revision and the changes performed in the requirements and in the requirement management.

2.1.4 Scope

The requirements and the entire REACTION 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 the next prototype. Thus, the requirement management is a dynamic on-going process that will continue throughout the project. The evolutionary approach is based on yearly iteration cycles. During each iteration cycle a refinement of the requirements, fully managed using appropriate requirement management tools, is performed in the context of a user centred design approach.

The scope of this deliverable is restricted to the requirement revision during the third iteration cycle.

2.2 Outline

The remaining document is structured as follows:

Section 3 describes the entire process from the sources for the collection of *Lessons Learned* to production of suggestions for changes and the implementation or rejection of such changes. In this section also the main implications for the requirements derived from the analysis of the watch reports and the RTD work are presented and some significant statistical information is provided. The most significant actions for the refinement of the requirement management are reported in this section as well.

In Section 4, the suggested changes are presented and the implemented changes are finally described showing the list of new requirements at the end of the third iteration cycle. Section 5 outlines the intended actions to ensure the necessary monitoring and management of requirements in the final iteration cycle.

In Section 6 the lists of all requirements per WP and component are shown and, finally, in Section 7 the main conclusions are reported.

The complete list of requirements is available in a separate appendix D2-9 *"Updated requirements report (appendix)"*.

3 Main Outcomes from the Third Iteration Cycle

In REACTION four full iteration cycles are planned throughout the lifetime of the project, and after the successful completion of a prototype cycle, each work package leader analyses and reports her/his RTD experiences, important outcomes and consequences of the development and integration work and other relevant knowledge gained during the development cycle.

Lessons are learned during project RTD work, including testing and integration, as well as validation of project prototypes and from continuous monitoring of clinical, technical, market and regulatory standards developments, as reported in the three watch reports submitted in M24.

More details about the *Lessons Learned* collected during the third iteration cycle can be found in ID2-8-4 *"Change request and re-engineering report 3"*.

A total of 58 *Lessons Learned* has been reported in the third iteration cycle. All *Lessons Learned* have been stored in a repository of the REACTION TWiki.

The analysis of the *Lessons Learned* produces requests for changes that, once examined, can be implemented or rejected. The whole process is summarized in Figure 1.

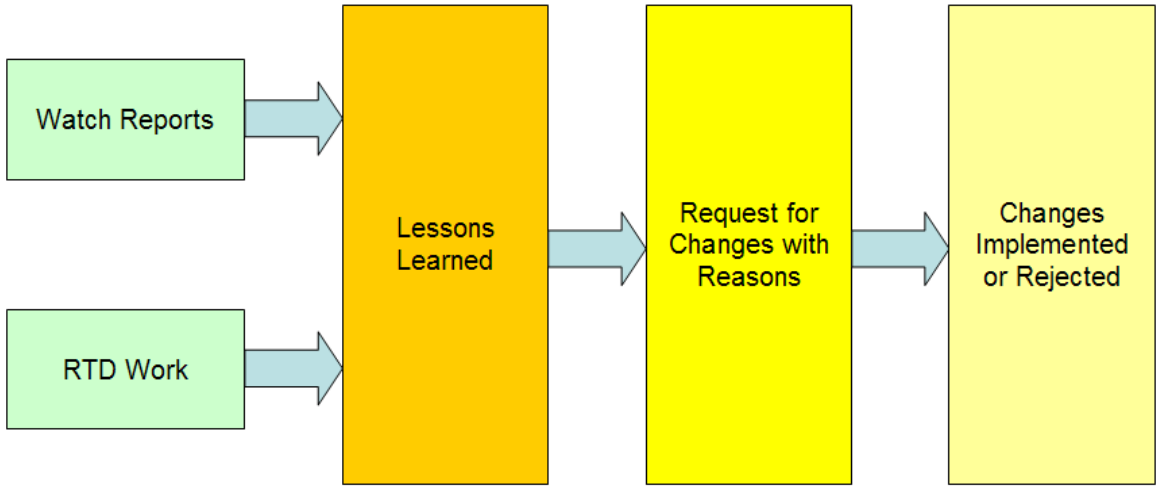

Figure 1: The requirement revision process at each iteration cycle

In this chapter we will analyze the main outcomes coming from both the watch reports and the RTD work while in the next chapter the request for changes and the implemented changes will be described.

3.1 Outcomes from the Watch Reports

At the end of the second iteration cycle three watch reports were produced and submitted in the context of the work performed in WP2: D2-2 *"Clinical watch report"*, D2-3 *"Technology Watch Report"* and D2-4 *"Market and Regulatory Standards Watch Report"*.

The main outcomes of the watch reports with potential impact on the project requirements can also be expressed in terms of *Lessons Learned*.

An analysis of the findings of the watch reports was included in ID2-9-2 *"Updated requirements report 2"*, but, as this deliverable is an internal document, the analysis is repeated here for the benefit of the readers of the present document.

3.1.1 Outcomes from the Clinical Watch Report

One of the most significant results of the clinical watch report has been the growing use of web technologies for the support of self-management in chronic diseases. When enhanced by proper e-

research strategies, the web-based interventions have achieved successful outcomes, but the approach based on short concentrated interventions (the one selected in REACTION primary care field trial) has the greatest overall impact.

Further significant issues emerging from this watch report are:

- Little evidence is found on employing and evaluating use of health IT technology with users not familiar with technology
- The use of mobile technology for diabetes management is generally reported as well received in the adolescent group, but there are many patients, though, who refuse to use mobile technology and there is no clear explanation or solution for this finding
- Studies demonstrate that self-management of blood glucose produces significant improvements in clinical outcomes, including significant reduction of HbA1c
- There is no clearly defined treatment regime for establishing glycaemic control of hospitalised patients
- The consensus panel of the American Diabetes Association concluded that hospitalised patients should have a target glycaemic pre-meal/fasting level of <140 mg/dL (7.8 mmol/L) and that insulin, whether administered intravenously or subcutaneously is the primary means of effective glycaemic control in the hospital setting
- Among various published protocols the basal bolus insulin treatment protocol currently represents the best practice to manage type 2 diabetic patients in non-intensive care beds
- Continuous Glucose Monitoring (CGM) will only be acceptable to the patient if it is convenient; the sensor is required to be comfortable in use and to be in place for as long as possible without pain, the biocompatibility is an important issue
- Systematic reviews demonstrate statistically significant benefits from the use of CGM over self-monitoring of blood glucose in terms of HbA1c reduction, speed of reduction and decrease in hypoglycaemic episodes
- Non-glucose based hypoglycaemia detection can provide significant help in diabetes management, but even if there is a link between hypoglycaemia and cardiovascular parameters there is no proof of the principle that hypoglycaemia can be detected from electrocardiographic data (no causal dependency), nor does the literature provide solid proof of the actual usability of these parameters in terms of sensitivity and specificity
- There are no developments in the basic technology of the insulin pen, and no manufacturers have reported pens capable of sending information
- Research in insulin pumps is going in the direction of making it less obtrusive, reducing size and increasing convenience
- Several efforts are currently made towards the development of patch pumps with a cradle (where the pump is inserted) semi-permanently attached to the patient's body through an adhesive pad
- In order to compensate for the delay in absorption of insulin when infused subcutaneously, which can result in a peak of blood glucose immediately postprandial, the best strategy is to deliver a bolus injection 15 minutes before the meal
- Two major pump-controlling algorithms are currently under investigation in closed-loop systems: the proportional integrative derivative (PID) algorithm and the model predictive control (MPC) algorithm
- In-silico evaluations of closed-loop control algorithms are likely to be prerequisites to clinical trials of the artificial pancreas
- Although intravenous or intra-peritoneal devices may deliver insulin more physiologically (i.e., without any delay between glucose sensing and insulin delivery) than subcutaneous devices, they entail risks associated with invasive procedures (e.g., infection)

- In order to reduce the hypoglycaemic episodes at night a successfully demonstrated approach is the suspension of insulin delivery either for a fixed period, or until blood glucose rises above a specified threshold
- Current approaches for the control of blood glucose are limited by the time lag experienced in the subcutaneous measurement of glucose and subcutaneous infusion of insulin and alternative fast measurement and fast delivery techniques are essential if high performance algorithms able to respond closely to meals and exercise are to be developed

3.1.2 Outcomes from the Technology Watch Report

One of the most significant results of the technology watch report has been the growing impact of Continua Alliance guidelines in the medical device field, even if the level of maturity of the standards is still not very high. All other conditions being equal, Continua compliant devices should be considered and preferred for use in the REACTION platform. That would also have a positive impact in the adoption of interoperability standards. However, there is also the necessity of supporting protocols not compliant with the Continua Alliance guidelines including ANT+ and other proprietary protocols (especially for environmental and fitness/wellness devices, and for a higher exploitation).

Further significant issues emerging from this watch report are:

- Intensive care unit time resources can be reduced by 20% by the usage of smart machine-to-machine (M2M) sensor systems for remote care of patients
- It is estimated that Remote Patient Monitoring (RPM) is already highly relevant in the treatment of chronic diseases but that it also will increase over the coming years
- In chronic disease management also the following parameters should be monitored: vital signs and symptoms, medication and side effects, diet and lifestyle, compliance information
- In addition, psychological-mental aspects may also be considered since stress, depression, education about the disease and coping with the disease influence the patient's outcomes, e.g., their compliance, and ultimately the success of diabetes management
- Environmental data to be considered are: position (GPS), ambient temperature, physical activity
- In the primary care environment the availability of a patient diary (reviewed by the clinicians at least at regular visits) may be very helpful even if it has to be clarified which data should be included in the diary and which methods have to be used in order to collect them without introducing unacceptable overload in the patient
- While several wireless medical devices exist for automatic measurements, monitoring lifestyle parameters is still not straightforward in the same way, and keeping a detailed daily log requires much efforts and manual input (these parameters are most commonly assessed using questionnaires and they may provide a good general view of a certain time period, but are usually not able to measure day-to-day details)
- The new approach is from compliance to concordance where concordance encompasses the idea that the doctor and the patient are equals, and that the patient makes informed decisions without the clinician giving up their power and authority but more about enabling the patient to share the power and authority to make treatment decisions
- Existing systems are based on glucose (including also HbA1c) and a few other parameters (contextualized carbohydrate and medication intake, physical exercise): integration of other parameters is a key for going beyond the state of the art
- Some existing systems have also the capability of sending reminders
- REACTION monitoring technology provided to the patient will have to co-exist and function together with an already existing network of devices in the home of patients; it is not likely that a separate infrastructure can be established in the homes of patients: REACTION will have to build on already existing infrastructures

- Event Management and Rule Engine technologies are highly relevant and interesting areas that can provide a competitive advantage in the overall application (decision support system)
- Self-management is important as most of the necessary actions and problems arise between visits in health centres
- More emphasis should be put on the patient's needs and technologies that help them self-manage their diseases
- In case of elderly users the platform should: be easy to use, use large fonts, consider voice support, provide user guidance and have customizable subjective disease-related queries
- Colourful interfaces are preferred for the display of the monitoring results

3.1.3 Outcomes from the Market and Regulatory Standards Watch Report

One of the most significant results of the market and regulatory standard watch report has been the entry into force in all member states of the Amendment 2007/47/EC to the Medical Device Directive (MDD) 93/42/EC and its implications for the product (including software as medical device) life cycle management.

Further significant issues emerging from this watch report are:

- Existing barriers to the market remain, such as the lack of real interest in adopting standards
- Focus on user friendliness and user acceptance
- Creation of an improvement compared to the current diabetes (self)-management
- Broad management of diabetes is about the maintenance of a healthy glucose level, avoiding hyperglycaemic and hypoglycaemic events and includes insulin-dependent patients (focus is on glucose measurement and insulin administration) and non insulin-dependent patients (focus has to be on lifestyle management)
- Flexibility versus the different national healthcare systems across Europe with different actors for running healthcare services and different reimbursement schemes (the main difference between the healthcare systems is related to the financing of the systems, which in turn influences how healthcare provisioning is organised)
- For the patient the obvious benefits, or value objects, of self-management and tele-monitoring are that it can be done at any time and any place allowing the patient to live a practically normal life, ensuring continuity of disease management, preventing serious complications, and reducing hospital stays
- Healthcare professionals can benefit from the REACTION platform by targeting those patients that need priority help, having a decision support system (DSS) that will assist them in the decisions related to the therapy, saving time and reducing paperwork
- Policy makers announce every year more steps to limit healthcare spending to a level that states are prepared to finance as well as promoting ICT adoption for managing chronic diseases and treating patients outside the hospital environment
- Strategic health authorities (where present) and/or large health insurance groups can act as a leverage in promoting the adoption of telemedicine at a national (rather than regional) level creating the foundation for an easier exploitation of the REACTION platform
- Compliance with the highest safety standards (sensors and the overall platform) is a must and a prerequisite for any exploitation
- Compliance with standards for patients' security, data protection and privacy
- Necessity of interoperability capabilities across different environments and existing technologies to be obtained through the adoption of selected interoperability standards

- The design, development and entire life cycle of medical devices (including software as medical device) have to follow the medical device directive (MDD) 93/42/EC and its Amendment 2007/47/EC entered into force in all member states in March 2010
- Depending on their classification according to the MDD, medical devices should be verified by a Certificate of Conformity issued by a Notified Body; certified medical devices should also have the CE mark
- Selection of proper standards for informed consent and authorization for the data transmission
- Selection of the applicable standards on quality management and on risk management
- Necessity of a product life cycle management, better if in accordance with relevant standards

3.1.4 Implications for the Requirements

The impact of the issues of the watch report on the requirements is always indirect and is done through specific *Lessons Learned* that eventually emerged from these issues.

Some main issues coming from the watch reports were considered and used as *Lessons Learned* immediately at the end of the second iteration cycle. The five *Lessons Learned* reported in WP8 summarized the main issues arisen in the clinical watch report (glucose management in the hospital ward and its margins for improvements once the entire procedure is electronically controlled). Three *Lessons Learned* collected in WP4 and one in WP5 were specifically referring to Continua Alliance guidelines and the recommended standards which were main issues of the technology watch report but also of the market and regulatory standards watch report. Two *Lessons Learned* collected in WP10 and one in WP2 were specifically referred to the product life cycle management and to the requirement management as a part of the product life cycle management which were main issues of the market and regulatory standards watch reports. For more details about these *Lessons Learned*, the reader can refer to ID2-9-2 *"Updated requirements report 2"*.

During the third iteration cycle other *Lessons Learned* have been collected per each WP and many of them are strictly related to main issues coming from the watch reports. Following some outcomes of the technology watch and the market and regulatory standards watch reports, one *Lesson Learned* in WP4 states that, even if the adoption of Continua standards should be the main road, the general adoption of Continua by the global medical device market is very slow and adopters have difficulties in working with the very few certified devices and to integrate concepts. Furthermore, another *Lesson Learned* in WP4 states that often end customers in the healthcare sector already have devices or have preferences about which devices to buy. This means that a software platform distributor cannot dictate a single device communication protocol to support. Any gateway solution designed to run in the home of the patient must provide multiprotocol support in terms of data interoperability and communication interoperability at least till when, in a bright future, a single communication protocol will be fully adopted by the international medical device market.

WP5 reported three *Lessons Learned* related to the SMS service which is a basic component for the support of sending reminders and any other notification to the end user, an advanced functionality available in some existing system according to the technology watch report and introduced also in the REACTION platform. The flexibility versus the different national healthcare systems across Europe with different actors for running healthcare services and different reimbursement schemes, stated in the market and regulatory standards watch reports was summarized in two *Lessons Learned* in WP9 and two in WP10.

Also the need of high and easy usability for people with low ICT literacy and elderly, but also for the generic diabetic patients was clearly affirmed in the watch reports and reported directly or indirectly in several *Lessons Learned*: one in WP4 related to the user interfaces for the context information, two in WP8 and related to the first results of the validation phase in the primary care environment where improvement in device connectivity and user manuals were necessary, and four in WP10 where an improvement in the cross-platform compatibility of the patient portal and an improvement of the user manual and of the UI described there were required. The majority of these problems have been solved in the third-year prototypes released for the field trials.

Finally, no or minimal overload is required for all stakeholders during the use of the system and that has been reported directly or indirectly in several *Lessons Learned*: one in WP7 related to the modification of the user profiles by the administrators that should be done in an easier way, since

administrators are not developers, one in WP8 related to the questionnaire for the paper-based REACTION algorithm for the in-hospital environment (the electronic version of the decision support has solved this issue) and three in WP10 related to the glucometer to be used in the in-hospital environment, to the installation time required for the multiprotocol home gateway and to the necessity of avoiding duplicate inputs (error-prone and time-consuming) as much as possible.

Other main outcomes from the watch reports had already been considered in the REACTION requirements like, for example, the generic need of promoting the self-management or producing an effective improvement of self-management with the help of technology. The entire specifications of the primary care environment were defined with the objective of the self-management very clearly in focus.

It is likely that some outcomes from the watch reports, in conjunction with the collected RTD experience, will produce additional *Lessons Learned* in the fourth iteration cycle which will impact on the existing requirements.

3.2 Outcomes from the RTD Work

Lessons have been learned mainly in the technical work packages (WP3, WP4, WP5, WP6, WP7 and WP10), but also the non-technical work packages (i.e. WP1, WP2, WP8, WP9 and WP12) generated several *Lessons Learned*.

Different *Lessons Learned* were collected in the various work packages and most of them did not have any impact on the requirements established at the start of the third iteration cycle.

Generally the impact on the requirements was due not only to the explicit *Lessons Learned* reported in the various work packages but also to the implicit *Lessons Learned* collected in the activities performed in the third year iteration where several cross checks between the technical people and the clinical people were performed in order to test and improve very frequently the prototypes in all phases of their design, implementation and testing since their deployment in the clinical sites for the field trials. Moreover, the first results of the trials produced a better knowledge and an impact on the requirements. In several cases this allowed us to determine that some requirements were not in the scope of the REACTION project. Other requirements were deleted during the third year of REACTION, but not in all cases as a result of specific and explicit Lessons Learned entered in the TWiki repository.

More details about the explicit *Lessons Learned* collected in the third iteration cycle can be found in the detailed analysis contained in ID2-8-4 *"Change request and re-engineering report 3"*. Below a few significant examples have been reported.

A *Lesson Learned* in WP1 refers to proper management of situations in which a component, application or subsystem was developed by more than one partner creating consequently a case of joint ownership that should be properly and fairly clarified by the consortium, based on the consortium agreement, before any exploitation can be made.

Another Lessons Learned in WP2 refers to the use of the JIRA tool to manage requirements that is still not fully exploited. For this reason several follow-up telcos have taken place in the second half of the third iteration cycle.

Some other *Lessons Learned* in WP3 refer to the results of the first tests in the developed sensors with the problems of bubble formation and the difficulties of calibrating and compensating the signal drift due to thermal or differential heating in the IMM sensor.

Another *Lesson Learned* in WP4 refers to the lack of a service layer on top of the application specific REACTION database used for the primary care prototype which has slowed down the joint component development in the project.

A *Lesson Learned* in WP5 refers to the need of a common set of events at system level in order to set up an efficient event driven architecture with loose interaction of all components.

A couple of *Lessons Learned* in WP6 refer to the difficulties of performing a proper validation of the long-term risk models since the large dataset used (DCCT Study) might use some clinical parameters that are not in use in the validation site and the retrospective validation needs to collect a sufficient number of cases to provide statistical significance, with further complications arising from the presence of censored data.

In WP8 the *Lessons Learned* are mainly related to the first outcomes of the field trials and two of them indicate some problems due to too strict inclusion criteria which delayed the patient recruitment for the in-hospital environment and the need of more than 4 glucose measurements per day in order to assess the efficacy of the paper-based algorithm in the in-hospital environment.

In WP9 two *Lessons Learned* were focused on the difference in liability regimes for product and medical liability in the EU member states and on the right of patients to erase and block their health data.

In WP10 an important *Lesson Learned* is focused on the deployment procedure which has to be tested accurately and case-by-case in order to avoid component incompatibility and interruption of service for the end users. A possible solution is provided by another *Lesson Learned* describing the need for component versioning that can be displayed when the component has a user interface (UI).

3.2.1 Implications for the Requirements

All the validated *Lessons Learned* have been listed per WP and for each WP the impact of the collected *Lessons Learned* on the existing requirements has been accurately evaluated. In chapter 4 the impact of the *Lessons Learned* on the requirements in each WP will be described.

3.3 Refinement of the Requirement Management and Statistics

Before analyzing the status of the requirements at the end of the third year and the related statistics, it is necessary to resume the main activities that were performed in the JIRA administration. These activities consisted in the addition of two new attributes to the Volere template used in the first two years of the project (more details can be found in D2-5 *"Initial requirements report")* and in a more strict management and monitoring of the progress performed with telcos involving all REACTION partners and more frequent reminders. However, it is definitely useful to mention some changes that were performed during the second iteration cycle (more details can be found in ID2-9-2 *"Updated requirements report 2"*) and more specifically the optimization of the requirement workflow and the changes in the component list in order to better reflect the changes in the platform architecture.

3.3.1 Optimization of the Requirement Workflow

During the second year the default workflow mechanism of JIRA (see Figure 2) was changed.

The basic ideas on which the new workflow was built were:

- Execute only targeted changes to the statuses of the default workflow, focused on improved adaptation to the needs of the REACTION project.
- Change the transitions available in the default workflow in order to make them simpler and clearer.
- Use the resolution field (as suggested by JIRA) only to explain the reason why a requirement was resolved. Thus, all requirements will retain resolution “UNRESOLVED” until they are transitioned into the “Resolved” status.
- Customize adequately the set of the available resolutions for resolving the requirements.

The new workflow is shown in Figure 3, where the transitions are presented in italics and the resolutions in bold. Only the transitions terminating with a circle change the resolution. The transitions terminating with a black circle will set a resolution (possible resolutions are marked in bold) for the requirement, while the transitions terminating with a white circle will reset the resolution to “UNRESOLVED”.

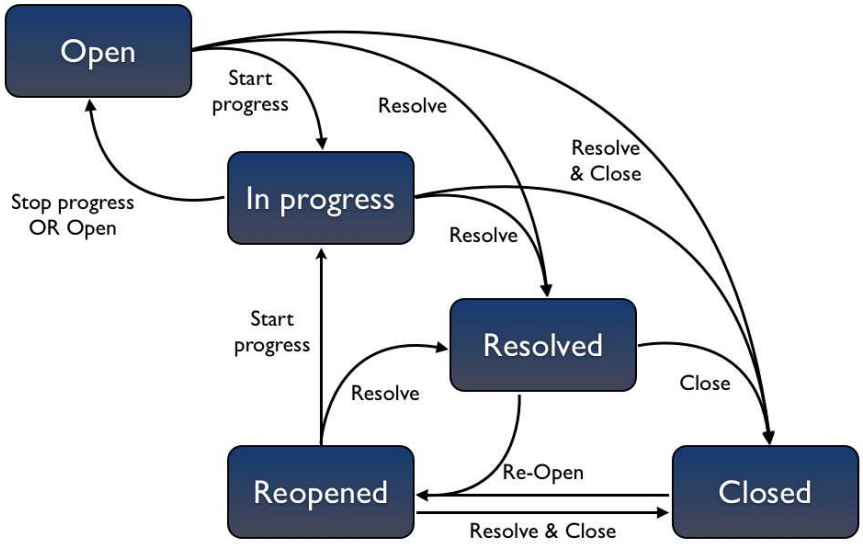

Figure 2: Default workflow scheme

In practice, a new status “Part of Specification” was introduced where any requirement will be moved after the initial quality check, if not resolved as “Out of scope”, “Duplicate”, “Nonsense” or “Conflicting”.

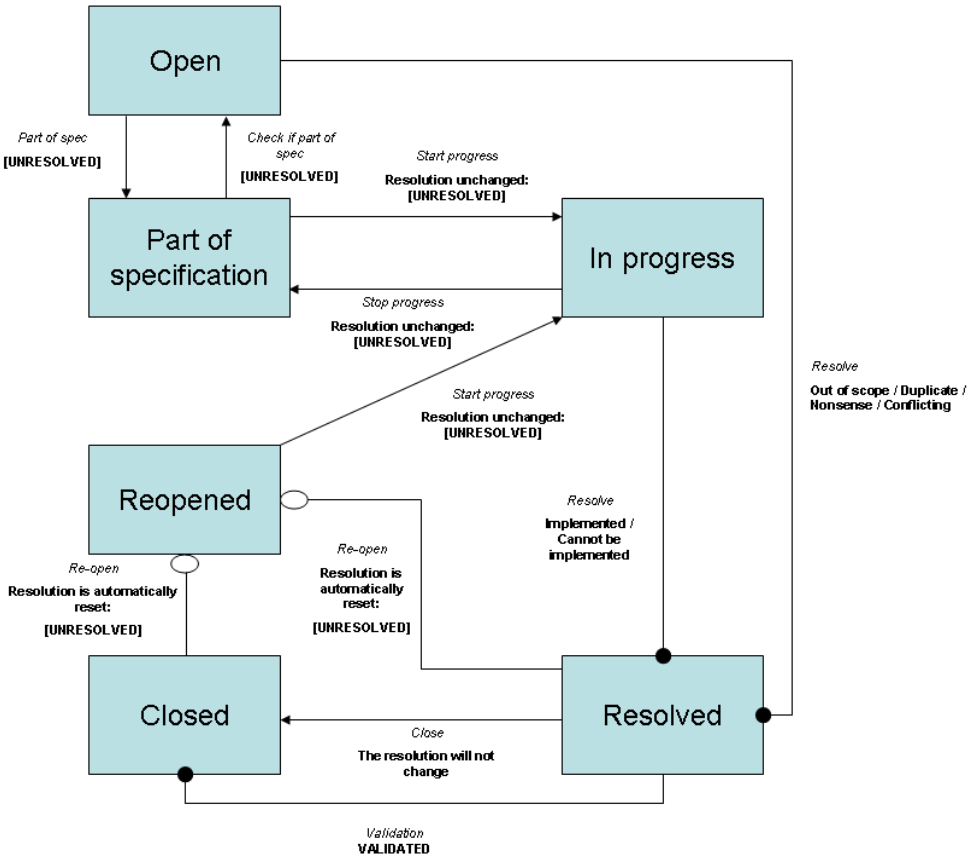

Figure 3: The new workflow

New resolutions were also added to the default ones in order to allow a better specification of the reasons for resolving a requirement. The list of all resolutions is provided in Table 1.

Conflicting	The requirement is in conflict with another requirement
Nonsense	This requirement makes no sense
Out of scope	The requirement is outside the scope of the project
Duplicate	The problem is a duplicate of an existing requirement
Implemented	The requirement has been implemented
Validated	Testing confirms that the requirement has been satisfied
Cannot be implemented	This requirement cannot be implemented
Cannot Reproduce	This issue cannot be reproduced

Table 1: List of resolutions

Resolution “Cannot Reproduce” is more suitable for bug reporting and should not be used for requirement management, but substituted with more suitable resolutions.

Finally, it has to be noticed that in the requirement life cycle the Reporter is the person who initially created the requirement, while the Assignee is the person in charge of implementing the requirement once it has been agreed this requirement is “Part of specification”. Reporter will also have the responsibility of verifying that the requirement was properly implemented and consequently closing it. In this case the Reporter will operate the Validation transition from the “Resolved” status to the “Closed” status with resolution = “Validated” (more details can be found in D2-8 *“The requirement engineering process”*).

3.3.2 Changes in the Platform Architecture and Impact on the Requirements

At the beginning of the project the platform architecture was not defined but there was just a first idea about the logical or physical components (not necessarily software) and their logical interaction. During the first and the second iteration cycles and mainly after the production of the detailed specifications for the in-hospital and primary care prototypes several architectural schemas were proposed and further refined. Based on the detailed specifications of the two environments, which have to be addressed by the REACTION platform, it was possible to define the final design of the platform architecture and to identify the resulting set of components.

The list of components at the end of the first iteration cycle was:

- 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 In-hospital or Primary care 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)

After careful consultation among the partners a new list of components was proposed:

- Application development kit (ADK) (the tools and software for developers in order to facilitate the application development)
- Data management (the storage and structuring of all the data in the platform)
- Health professional sphere (the software, devices and interfaces for the interaction of the health professional with the platform)
- Internal communication (all sort of communications between the various parts of the platform)
- Medical and environmental devices (all medical and environmental devices commercially available or developed by the consortium for the contextualized monitoring of the patient)
- Network management (the tools and software for the daily management of the network infrastructure)
- Patient sphere (the software, hub, feedback devices and interfaces for the interaction of the patients and informal carers with the platform)
- Security and safety management (all tools for the proper management of security and safety issues)
- Service orchestration (the orchestration mechanism of the different services)
- Third-party system interfaces (all interfaces with third-party systems like HIS, EPR, etc.)

During the second year all requirements were re-assigned to the components or building blocks of the redefined architecture. A further effort was also made in order to assign each requirement to only one component of the new list. That was considered necessary in order to clarify better the allocation of work necessary to satisfy the requirement and the consequent responsibilities.

3.3.3 Changes in the Volere Template

During the third iteration cycle the various high-level versions for the prototypes foreseen for the REACTION project where defined. A new field "Affects Version/s" was added to the Volere template together with a "Due Date" in order to allow planning the resolution of each requirement after linking it to a specific version of the prototypes (more details about the Volere template can be found in D2-5 *"Initial requirements report"*).

The various versions are listed in Figure 4:

Versions

REACTION Platform	General REACTION platform
Basic Primary care prototype	First prototype developed for use in Primary care
Extended Primary care prototype	Final prototype developed for use in Primary care
Basic In-hospital prototype	First prototype developed for use in general wards in hospitals
Extended In-hospital prototype	Final prototype developed for use in general wards in hospitals
Automatic Glucose Control prototype	Final Closed-loop prototype
Peripherals	For requirements not belonging to other categories, typically device-related
Documentation	Used for requirements relating to documentation and similar non-sw requirements

Figure 4: The various versions

The final shape of the “modified” Volere template used in the “REACTION requirements” JIRA project is shown in Figure 5.

Requirement #	Requirement Type	Due Date
Description/Summary		
Priority		
Affect version/s	Component/s	Workpackage
Source/Originator		
Rational		Fit criterion
Customer satisfaction		Customer dissatisfaction
Dependencies		Conflicts
Comments		Reporter
		Assignee

Figure 5: The "modified" Volere template

Then the technical manager, together with the WP2 leader, the other WP leaders and the involved consortium partners, mediated (through various telcos) and finally established the assignment of each requirement to a specific version with a specific Due Date in accordance with the foreseen times for the release of the various versions. After that, frequent reminders were issued and contacts with specific partners taken to solicit the completion of work for unresolved requirements nearing or past their due date.

3.3.4 Requirement Statistics and Progress

At the end of the third iteration cycle, the REACTION requirements registered in JIRA were 461 (they were 281 at the end of year 1 and 437 at the end of year 2). From the statistics in Figure 6 it can be seen that 16% of the requirements are “In progress” (they were 36% at the end of year 2), while only 1 requirement is still “Open” (they were 6% at the end of year 2). 5% of the requirements are in the “Part of specification” status (they were 21% at the end of year 2), thus they have passed the initial quality check and are ready to be worked on. 25% of requirements are closed while 53% are resolved (they were 21% and 16% at the end of year 2, respectively).

The progress compared to the end of the second year is substantial. In fact, despite a small increment in the number of requirements (5% compared to the second year), the number of requirements resolved or closed is 78% (it was 14% in year 1 and 37% in year 2). A similar progress can be also observed in the reduced number of requirements on which no work has started yet (5%, while it was 27% in year 2 and 49% in year 1).

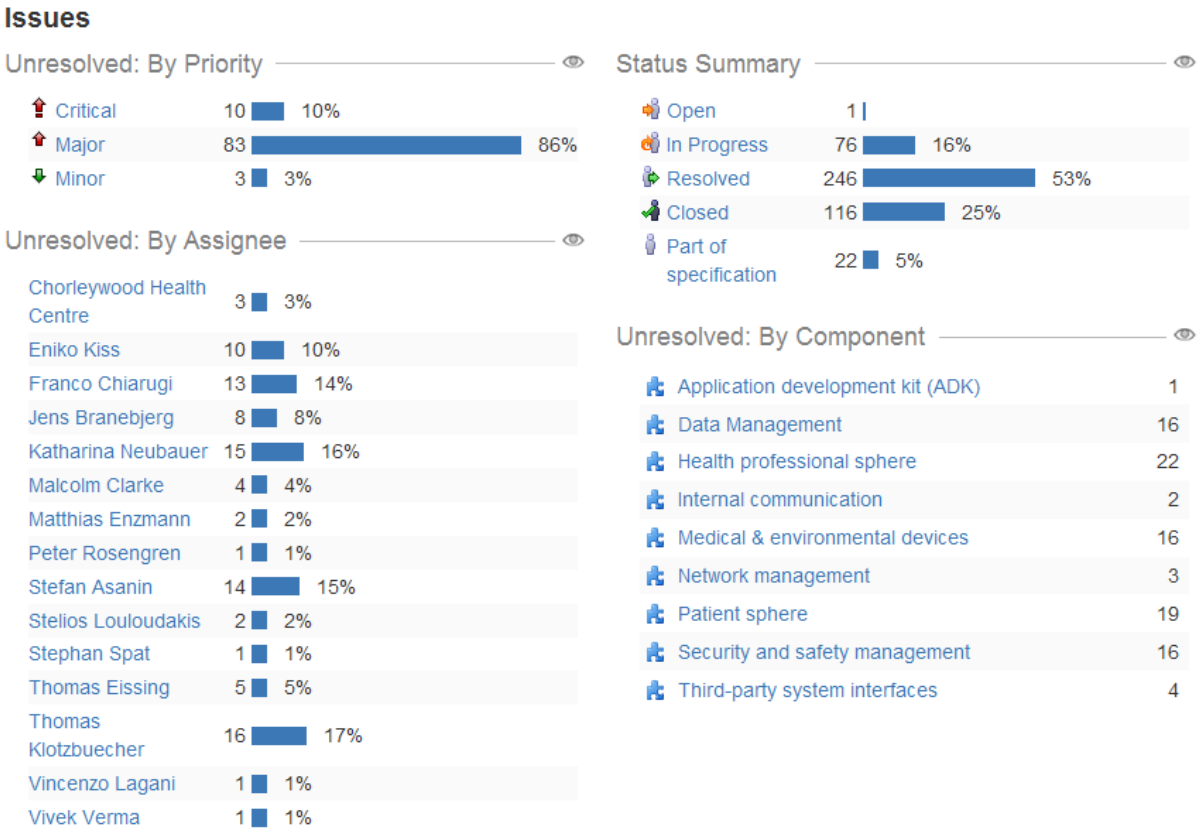

Figure 6: The requirements in the JIRA requirements project

The JIRA requirements can be either Volere requirements or sub-tasks. At the end of the third year there are 450 Volere requirements and 11 sub-tasks. In the rest of this section the analysis will be focused on the Volere requirements since sub-tasks mostly specify how some Volere requirements can be implemented rather than introduce new stakeholder requirements. Volere requirements are classified as functional, non-functional or constraints as reported in D2-5 *“Initial requirements report”*. In Figure 7 the classification according to the requirement type is shown. One can see most requirements are functional, while very few requirements are constraints.

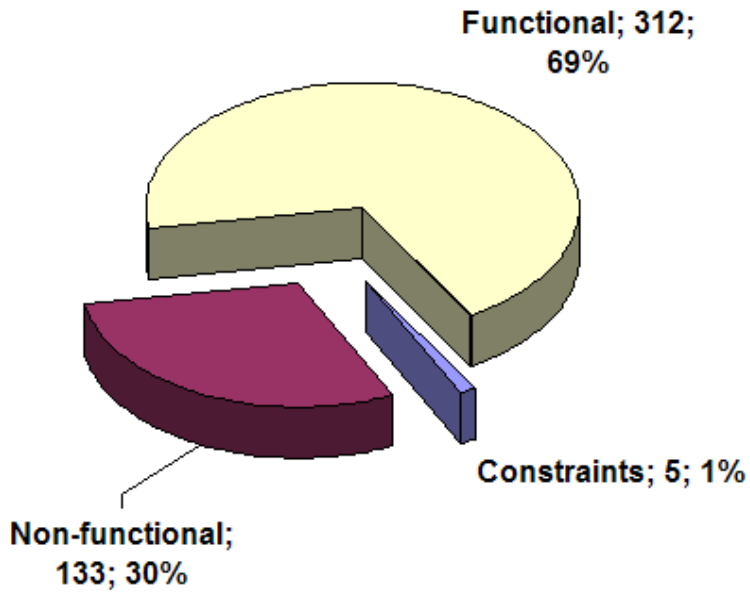

Figure 7: The REACTION requirements classified by requirement type

The classification of functional requirements based on their subtype is shown in Figure 8.

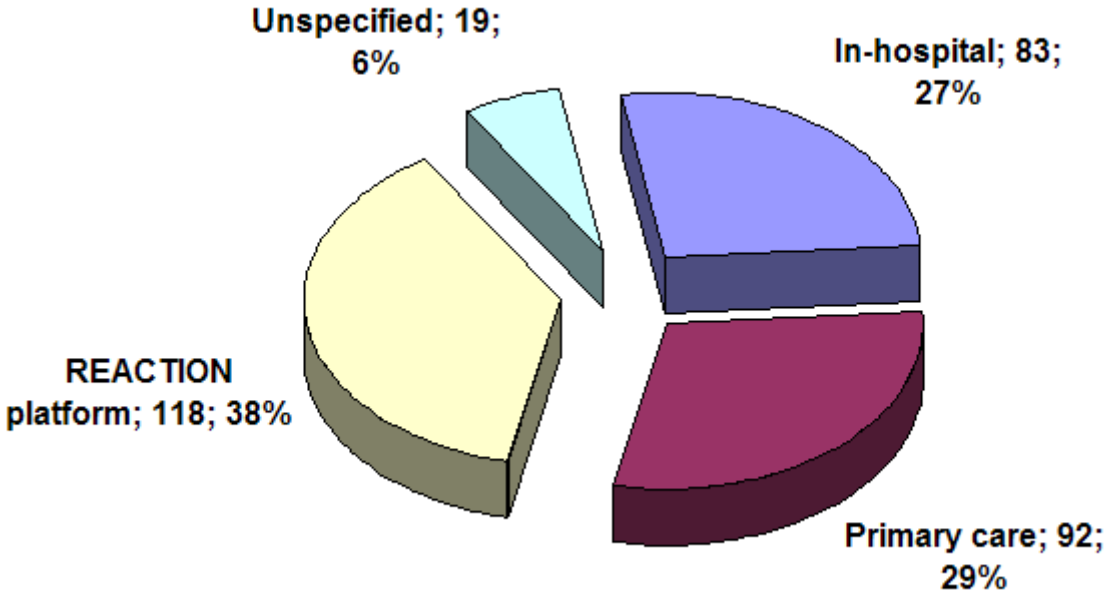

Figure 8: The REACTION functional requirements classified by requirement subtype

The classification of non-functional requirements based on their subtype is shown in Figure 9. One can see that also in this third iteration the major focus has been given to usability, security and legal aspects since specific partners of the consortium are focused on these issues and more specifically clinical partners (MUG and CHC) for the usability, FHG-SIT for the security and VUB for the legal aspects.

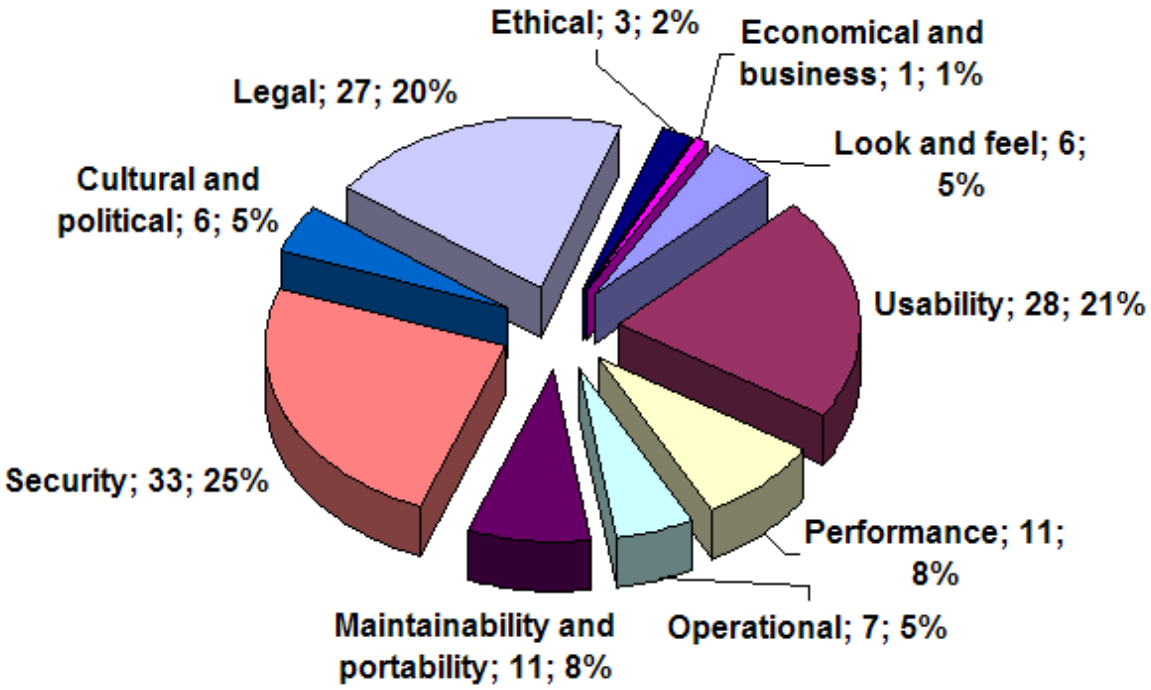

Figure 9: The REACTION non-functional requirements classified by requirement subtype

Finally, in Figure 10 the classification of constraints based on their subtype is shown.

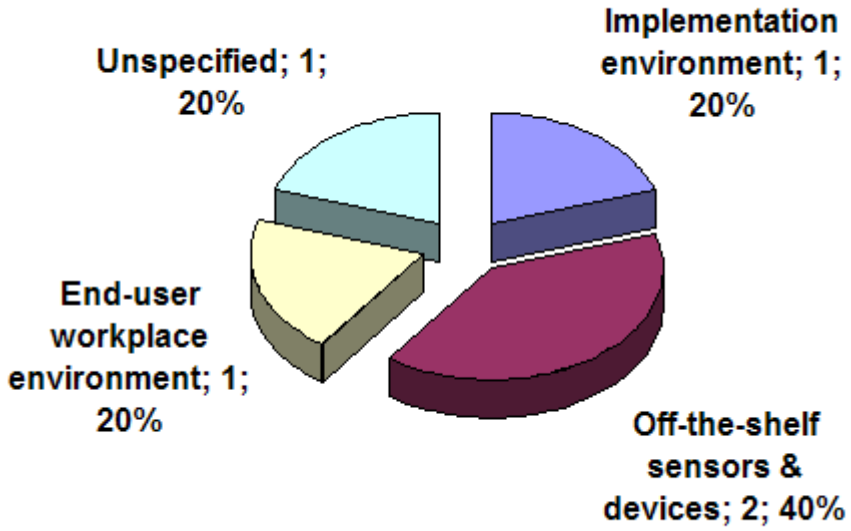

Figure 10: The REACTION constraints classified by their subtype

Requirements follow the workflow associated with the REACTION requirements project in JIRA as they evolve through the various stages.

The status and resolution of each requirement provide indications of its advancement towards completion.

In Figure 11 the status of all REACTION requirements is presented:

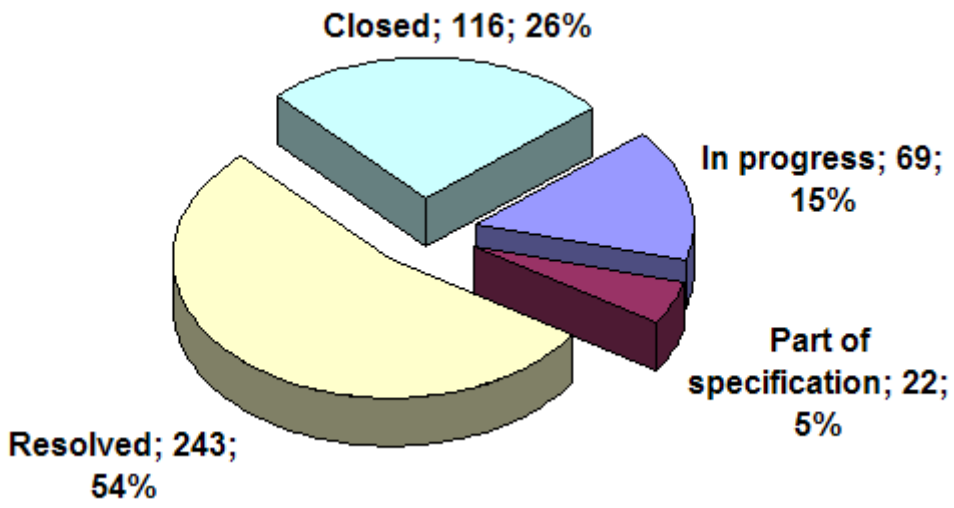

Figure 11: The status of all REACTION requirements at the end of the third iteration cycle

Most requirements are “Resolved” or “Closed” and no requirement is still in the “Open” (or “Reopened”) status. Few requirements (5%) are in the “Part of specification” status and a small percentage (15%) is “In progress”. The development activities of REACTION during the last iteration cycle will be focused on these requirements.

The 22 “Part of specification” requirements are grouped by components in Figure 12 and by partners in Figure 13. The majority of these requirements belong to the health professional sphere and to the data management, while partners more heavily charged are MUG and ALL.

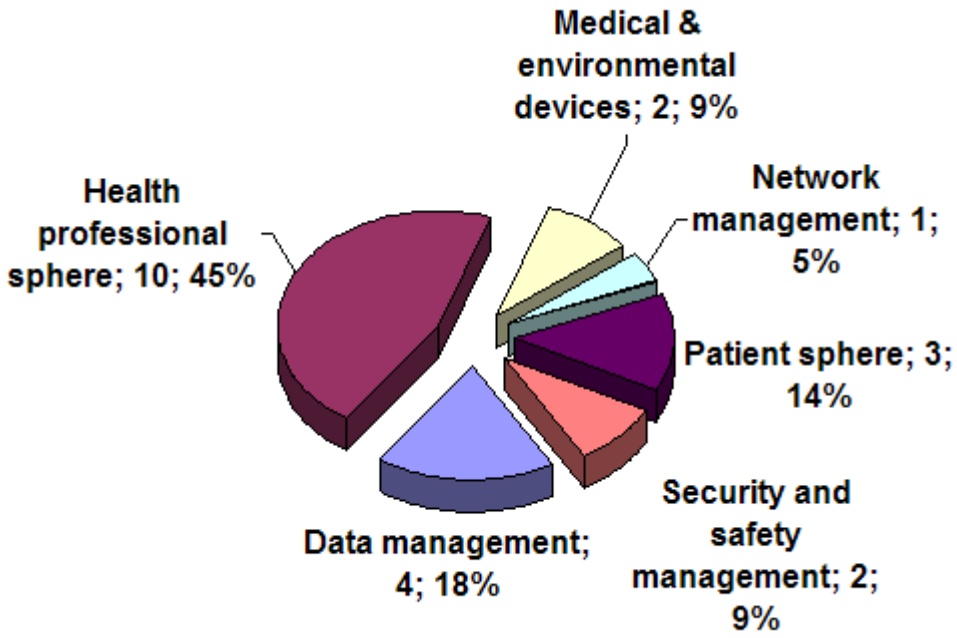

Figure 12: The “Part of specification” requirements grouped by components at the end of the third cycle

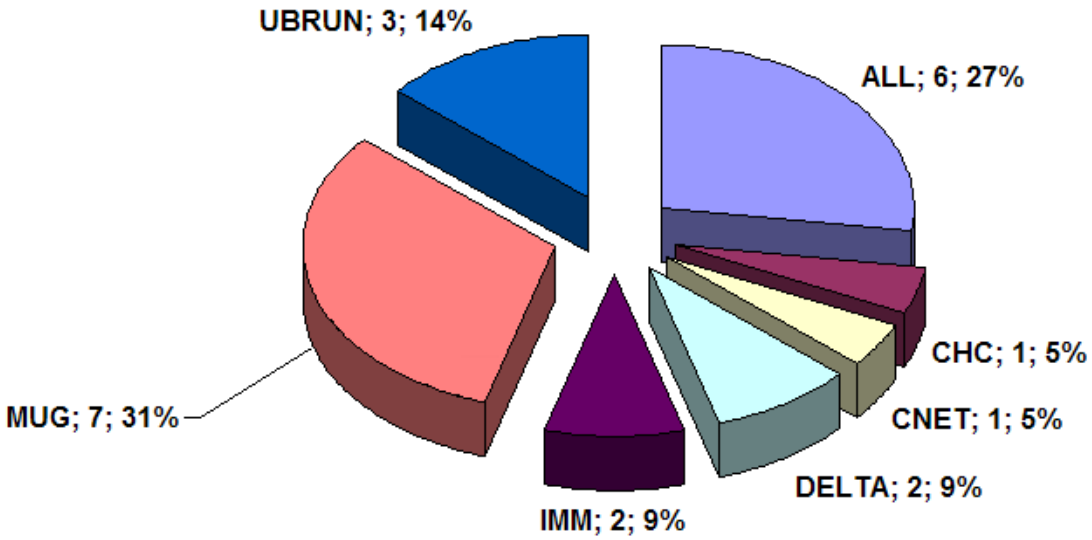

Figure 13: The "Part of specification" requirements grouped by partners at the end of the third cycle

69 requirements (~15%) are “In progress” and, in Figure 14 and Figure 15 respectively, the distribution of these requirements per component and per partner is shown. This depicts a fairly high level of activity across all types of components with main efforts on the security and safety management, the medical and environmental devices, the patient and health professional spheres and the data management (see Figure 14). Consortium partners more active in this phase of implementation are IMM, FORTH and CNET as can be seen in Figure 15.

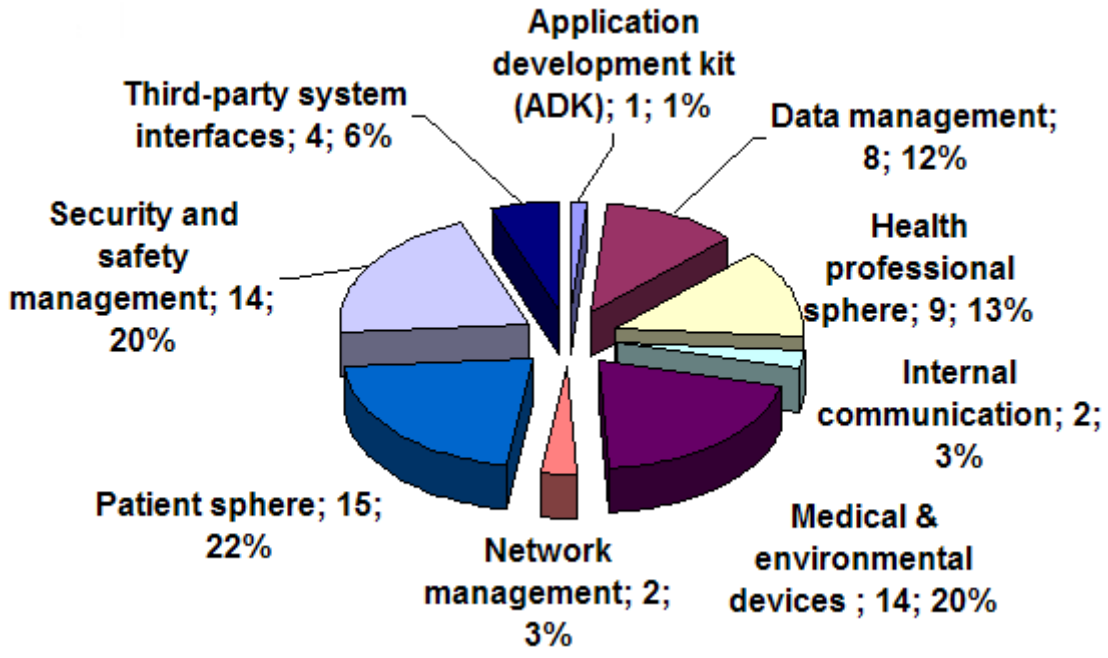

Figure 14: The components to which the “In progress” requirements are associated at the end of the third cycle

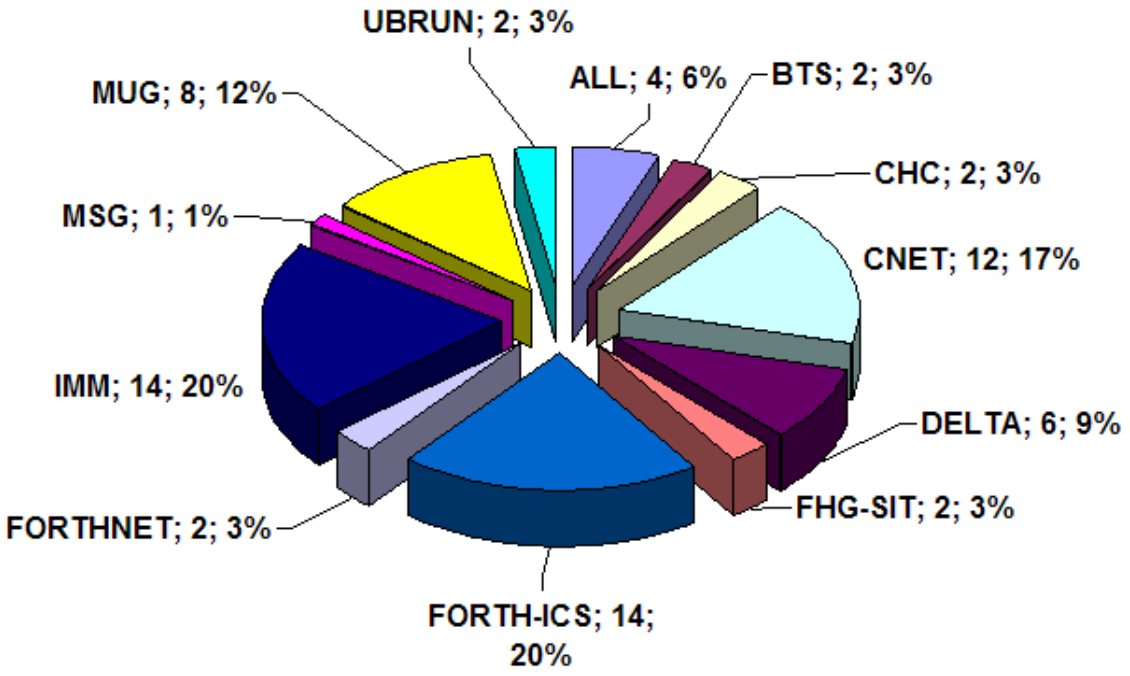

Figure 15: The partners to which the “In progress” requirements are assigned

There are 359 “Resolved” or “Closed” requirements (~80%) of which 62 have been resolved as duplicates and 38 as out of scope. In Figure 16 the resolutions associated to the “Resolved” or “Closed” requirements are shown.

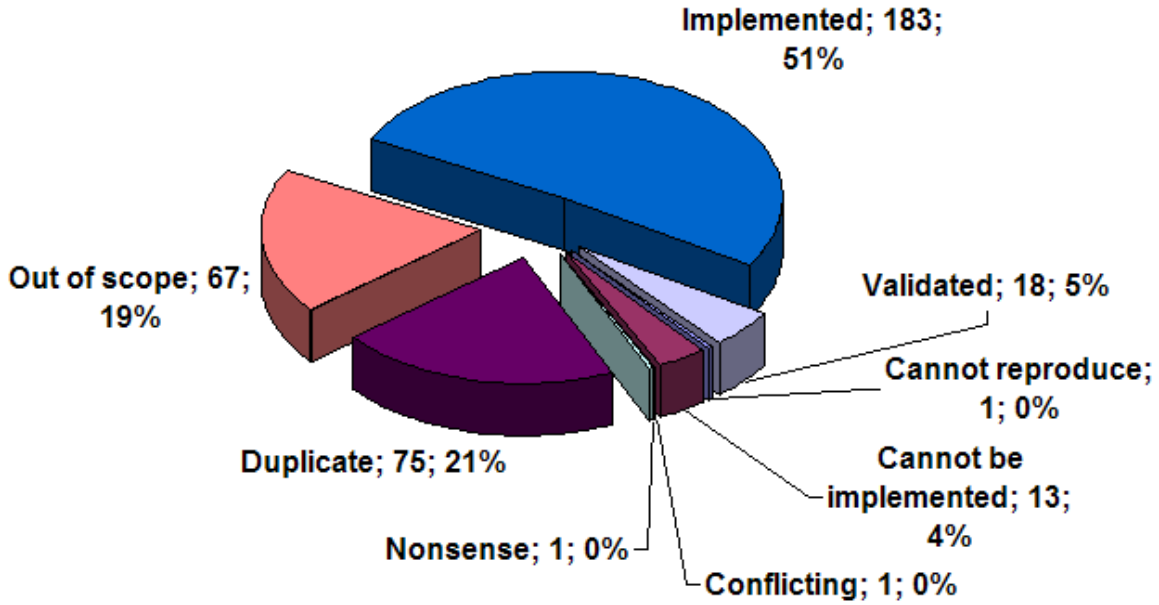

Figure 16: The resolutions of all the "Resolved" or “Closed” requirements at the end of the third iteration cycle

A total of 201 requirements (~69% of the effective requirements) have been implemented at the end of the second year, but 183 are still waiting for user validation, while 18 have already been validated and then closed. It is worth noting that there has been a significant increase in the resolved requirements compared to the first year (only 7%) and to the second year (only 16%). This has been mainly due to the successful finalization of the in-hospital and primary care prototypes with their subsequent deployment in the clinical sites for the start of the field trials.

The version released for the in-hospital field trial (started in November 2012) is the “basic in-hospital prototype”. 51 requirements were specifically assigned to this version and 45 have been resolved (4 of

them have already been validated). The other 6 requirements refer to the clinical trials and the validation phase that has to be performed with the “basic in-hospital prototype” and for this reason they are still unresolved.

The version released for the primary care field trial (started in January 2013) is the “basic primary care prototype”. 46 requirements were specifically assigned to this version and 44 have been resolved (2 of them have already been validated, while 1 was resolved as “Out of scope” and another as “Duplicate”). About the other two requirements, one of them was actually resolved but the status not yet updated by the “Assignee” in JIRA, while the other was referred to a component not really used for the basic primary care prototype, but foreseen for the extended primary care prototype. This last requirement should be reassigned to the right version.

4 Impact of the Lessons Learned on the Requirements of Each WP

Each *Lesson Learned* reported in cycle 3 has been collected and associated to a specific WP. Then, for each WP, the impact of the *Lessons Learned* on the requirements existing at the beginning of the iteration cycle has been accurately evaluated and the consequent requirement changes have been reported.

The collected *Lessons Learned* have produced changes in many technical work packages (i.e., WP3, WP4, WP5, WP6, WP7 and WP10) and also in one non-technical work package (WP9). The *Lesson Learned* in WP1, the two in WP2 and the one in WP12 did not produce any changes in the requirements and for this reason their impact is not analyzed in this section. The eight *Lessons Learned* in WP8 produced only one update in a sub-task and, since the focus of this document is only on stakeholders' requirements which are Volere requirements, the impact of the WP8 LLs is not analyzed in this section. Furthermore, WP11 and WP13 have reported no *Lessons Learned* in the third iteration cycle.

The implications of the *Lessons Learned* for the requirements resulted in 14 proposed new requirements, 5 requirements proposed for update and 27 requirements proposed for deletion.

After an accurate evaluation of the proposed changes finally 13 new requirements were inserted (the remaining one was inserted but resolved as "Out of scope"), 5 requirements were updated and no requirement was deleted, but 51 resolved as out of scope, duplicate, nonsense, conflicting, cannot be implemented or cannot reproduce.

The change request and re-engineering originated from each WP is reported in the following sections only for the WPs where the LLs produced some change requests or had some impact in the resolution of some requirements as Out of Scope or Duplicate.

It is worth noting that the strict interaction with the end users during the third year of the project, and also some pre-trial phases run in the clinical sites with small subsets of end users, allowed a better understanding of the real needs of the end users and in some cases led to the identification of some Out of Scope requirements which are not necessarily connected to any specific *Lesson Learned* during the second year. For this reason, these requirements are not explicitly mentioned in any change request table of the various WPs but simply listed under the "deleted requirements" section as requirements that were resolved as Out of Scope.

More details about the explicit *Lessons Learned* in each WP can be found in the detailed analysis contained in ID2-8-4 *"Change request and re-engineering report 3"*.

4.1 Change Request and Re-Engineering Originating from WP3

All *Lessons Learned* (nine *Lessons Learned* in WP3) collected in WP3 were analyzed. LL WP3-2 refers to the problems related to the extrapolation of the in-silico results for the insulin-glucose model and the glucose control algorithms (GCA) in case of in-vivo outliers. There is a need for improving the robustness of the model and the algorithms through new public data and new clinical trials. LL WP3-4 refers to the need of being able to fix the continuous glucose sensors either to the right or to the left arm. LL WP3-5, WP3-6 and WP3-7 refer to the drift problems and the calibration procedure of the IMM glucose sensor. LL WP3-8 reports better results obtained with a new catheter compared to the one initially used and suggests the definite adoption of the new one. LL WP3-9 finally signals the problem with bubbles in the IMM sensor that has been experienced during the first trials causing reduced accuracy and need for recalibration.

The impact of these *Lessons Learned* on the requirements related to WP3 has been summarized in the following table.

Key	Summary	Priority	Suggestions for Changes
	Continuously improve robustness properties of the GCA, train model kernels on new data from the public domain and if possible in new clinical trials	Major	6 new requirements containing the specification of a Glucose Control Suite (in Matlab) for the clinical validation of the closed-loop glucose control algorithms including personalization, initialization, semi-automatic

			management and optimization tools
REACTION-78	Identify a series of steps for the improvement of the GCA and the model kernels	Major	The reviewed various phases of the validation have to be reported in sub-tasks instead of being described in the rationale, thus allowing a more accurate monitor of the progresses

As a consequence it has been suggested that:

- Six new requirements have been proposed.
- One requirement should be updated, changing its rationale and introducing four sub-tasks for monitoring more accurately the implementation progress.
- No requirements have to be deleted.

4.1.1 New Requirements

Six new requirements have been inserted.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-481	Functional – REACTION platform	Major	Glucose Control Suite (GCS) – Matlab GUI	Implementation of a Matlab based GUI for the clinical validation of the closed loop glucose control algorithm	Operable Interface on a laptop within a patients room in the clinic
REACTION-482	Functional – REACTION platform	Major	GCS – Interface to create individual model file	Interface to create Individual specifying: Race, Gender, Age, Weight and Height	A new individual model file is created. The model initialization is initiated.
REACTION-483	Functional – REACTION platform	Major	GCS – Interface for Model Initialization	Second Component of the GCS - Interface for the Initialization (Individualization) of the PBPK/PD model during Observation Phase, allows: - Input scheduling (IV Glucose, IV Insulin) - Measurement Data Entry (Plasma Glucose) - Visualization of Best Model Fits	Matlab GUI fitting rationale described above

REACTION-484	Functional – REACTION platform	Major	GCS – Interface for semi-automatic online glucose control	Third Component of the GCS - Interface for the calculation of insulin infusion rates based on glucose measurements, allows:
				- Input scheduling (SC Insulin infusion rate, IV insulin, Meal, Oral Glucose)
				- Measurement data entry (Plasma Glucose)
				- Visualization of:
				  - Plasma glucose
				  - Plasma insulin
				  - Applied rate of insulin
				- Confirm (update) inputs
				- Apply calculated or anter dose Insulin manually
					Matlab GUI as described in rationale

REACTION-485	Functional – REACTION platform	Major	GCS – Interface for online model optimization	2nd part of the third Component of the GCS - Interface for the further individualization of the GIM model based on past glucose measurements, allows:
				- Visualization of:
				  - Plasma and interstitial glucose
				  - Plasma and interstitial insulin
					Matlab GUI as defined in rationale

				- Values of optimized parameters - Values of penalty function components (met constraints) - Level of manual interaction to be defined	
REACTION-501	Functional – REACTION platform	Major	Second Prototype of the Glucose Control Algorithm (GCA 2) – Matlab GUI	Second Prototype of the Glucose Control Algorithm (GCA 2, formerly known as Glucose Control Suite, GCS): Implementation of a Matlab based GUI for the clinical valdiation of the closed loop glucose control algorithm	Operable Interface on a laptop within a patients room in the clinic

4.1.2 Updated Requirements

One requirement has been updated. This requirement is now linked to four new sub-tasks which allow easier monitoring of the progress towards its implementation.

Details of this modified requirement are shown in the table below.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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.	Mechanistic physiology-based models are available within the REACTION platform

4.1.3 Deleted Requirements

No requirements have been deleted.

4.1.4 Requirements Resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce

No requirements have been resolved with any of the above resolutions.

4.2 Change Request and Re-Engineering Originating from WP4

All *Lessons Learned* (six *Lessons Learned* in WP4) collected in WP4 were analyzed.

LL WP4-1 deals with the slow adoption of the Continua guidelines by the international market and with the under development of the technology enabling the Continua guidelines making hard for the adopters to integrate the Continua concepts. LL WP4-4 also refers to device protocols and recommends the implementation of multiprotocol interoperable solutions taking into account also ANT+.

LL WP4-2 concerns the relevance of context data (i.e. nutrition) and the necessity of providing the end users with easy input modalities in order to facilitate the data input.

LL WP4-3 describes the advent of the 'Device-as-a-service' concept and the need to take into account service interoperability with a consequent impact in the REACTION SDK.

LL WP4-5 deals with the need of having in the REACTION platform a service layer to be used by the applications for accessing domain information in order to allow a greater modularity of the platform and facilitate the exploitation of the platform beyond the project trials.

Finally, LL WP4-6 signals the lack of current market where emergency centres consume and manage responses on remote monitoring data. This might be exploited as competitive advantage of the REACTION platform after project end time.

There is no impact of these *Lessons Learned* on the requirements related to WP4 and:

- No new requirements are proposed.

- No requirements need to be updated.
- No requirements have to be deleted.

4.2.1 New/Updated/Deleted Requirements

No requirements have been inserted, updated or deleted.

4.2.2 Requirements Resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce

REACTION-175, REACTION-212, REACTION-357, REACTION-369, REACTION-378, REACTION-386, REACTION-393, REACTION-396, REACTION-433, REACTION-434, REACTION-457 and REACTION-458 have been resolved as being Out of scope.

REACTION-195, REACTION-211, REACTION-389, REACTION-424, REACTION-430 and REACTION-445 have been resolved as being Duplicate.

REACTION-213 has been resolved as being Nonsense.

REACTION-333 has been resolved as Conflicting.

REACTION-361 and REACTION-410 have been resolved as “Cannot be implemented”.

REACTION-39, resolved as “Cannot reproduce” during the second iteration cycle, was reopened and resolved more appropriately as “Cannot be implemented”, since “Cannot reproduce” is more suitable for bugs than for requirement management.

4.3 Change Request and Re-Engineering Originating from WP5

All *Lessons Learned* (six *Lessons Learned* in WP5) collected in WP5 were analyzed.

LL WP5-1 refers to the optimization of the development work, since there was a change in the plan and the network management system was not included in the basic primary care prototype but only in the extended primary care prototype.

LL WP5-2, LL WP5-3 and LL WP5-4 concern the SMS service and the necessity of shaping it as web service, including communication encryption for security reason and improving reliability issues with message deliveries (also with support of "message delivery notifications").

LL WP5-5 deals with the need of component developers to agree on common event types that all components should understand in order have an event driven architecture able to provide an extensible and flexible way for loosely coupled components interaction.

LL WP5-6 deals with REACTION SDK that, after being tested in several applications and environments, provides a stable and flexible way of integrating medical devices in several different scenarios and can be easily extended to meet new domain requirements.

There is no impact of these *Lessons Learned* on the requirements related to WP5 and:

- No new requirements are proposed.
- No requirements need to be updated.
- No requirements have to be deleted.

4.3.1 New/Updated/Deleted Requirements

No requirements have been inserted, updated or deleted.

4.3.2 Requirements Resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce

REACTION-473 has been resolved as “Cannot be implemented”.

4.4 Change Request and Re-Engineering Originating from WP6

All *Lessons Learned* (four *Lessons Learned* in WP6) collected in WP6 were analyzed.

LL WP6-1 addresses the upgrade of the models and the revalidation process which took more time than expected and schedule more time for any future upgrade.

LL WP6-2 puts into evidence problems in the harmonization of clinical and medical data coming from diverse sources and specifically the learning set (DCCT study) and the testing set (patients in CHC).

LL WP6-3 focuses on the necessity of a close collaboration among statistical experts and clinicians in order to optimally design a sound retrospective validation for the long-term risk models.

LL WP6-4 deals with the processes of bug fixing and change requests under the influence of the MDD which is very work intensive and time consuming due to the documentation needs. It is necessary to allocate more efforts for testing before starting the clinical trials.

There is no impact of these *Lessons Learned* on the requirements related to WP6 and:

- No new requirements are proposed.
- No requirements need to be updated.
- No requirements have to be deleted.

4.4.1 New/Updated/Deleted Requirements

No requirements have been inserted, updated or deleted.

4.4.2 Requirements Resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce

REACTION-97, REACTION-101, REACTION-184, REACTION-192, REACTION-200, REACTION-243, REACTION-244 and REACTION-360 have been resolved as being Out of scope.

REACTION-479, initially proposed as new requirement, has been also resolved as being Out of scope.

4.5 Change Request and Re-Engineering Originating from WP7

All *Lessons Learned* (two *Lessons Learned* in WP7) collected in WP7 were analyzed.

LL WP7-1 deals with the issue of the role-based access control (RBAC) which does not allow expressing dynamic constraints. In such case, access control should take into account also context information.

LL WP7-2 deals with the need of administrators to add or modify existing user profiles in a user-friendly way.

The impact of these *Lessons Learned* on the requirements related to WP7 has been summarized in the following table.

Key	Summary	Priority	Suggestions for Changes
	Access control rules stated in terms of standard RBAC (Role-Based Access Control) do not allow expressing dynamic constraints like context information	Major	A new requirement specifying that REACTION's current RBAC language constructs need to be extended and modules for dynamic constraints need to be developed in order to be able to process context information.
	Administrators must be able to add or modify existing profiles of users in a user-friendly way	Major	A new requirement specifying that administrators of the Profile Management System cannot be assumed to have the same skills as developers. Therefore, administrators must be given

			'productivity tools' allowing them to effectively manage the users' data and respond to their requests.

As a consequence it has been suggested that:

- Two new requirements have been proposed.
- No requirements need to be updated.
- No requirements have to be deleted.

4.5.1 New Requirements

Two new requirements have been inserted.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-480	Non-functional - Security	Major	Access control mechanisms should be able to process context information	It may not be sufficient to make access control decisions based only on the role(s) owned by a user. In some use cases, access restrictions depend on context information like time, location, and access history, etc. For example, a physician should only be able to treat patients that are assigned to her own ward. Therefore, access control mechanisms applied in REACTION should be able to process access rules that rely on context constraints.	Availability of a control mechanism which decides whether a requested action may be granted or denied based on context information.
REACTION-497	Functional - In-hospital pilot application	Major	Management Functionality for the Identities used in the In-Hospital-Scenario	Administrators must be able to add or modify existing profiles of users. This should be possible in a user-friendly way, i.e., by a management application designed for user management tasks.	Availability of a management application

4.5.2 Updated Requirements

No requirements have been updated.

4.5.3 Deleted Requirements

No requirements have been deleted.

4.5.4 Requirements Resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce

REACTION-324 has been resolved as being Duplicate.

4.6 Change Request and Re-Engineering Originating from WP9

All *Lessons Learned* (four *Lessons Learned* in WP9) collected in WP9 were analyzed.

LL WP9-1 refers to the use of focus groups external to the REACTION consortium in order to collect unbiased requirements in view of a large-scale exploitation at EU level.

LL WP9-2 is about the liability regimes for product and medical liability which may differ (not completely harmonized) in the various EU member states and must be known very well before proceeding to any exploitation of the REACTION solutions.

LL WP9-3 illustrates that the REACTION platform is intended for use in different cultural and social settings with different expectations and needs of the end users. For this reason, configurability of the REACTION applications is fundamental.

LL WP9-4 deals with the mistakes that end users can make during the data entering and processing. Thus, it must be possible to rectify data and, additionally, patients have the right to erase and block their sensitive data.

The impact of these Lessons Learned on the requirements related to WP9 has been summarized in the following table.

Key	Summary	Priority	Suggestions for Changes
	In view of the exploitation of the REACTION platform in the various EU states, it is important to take into account the different cultural and social settings with different expectations and needs of the end-users.	Major	Two new requirements specifying the need of being able to configure the main REACTION applications.
	End users can make mistakes during the data entering and processing.	Major	A new requirement specifying that it must be possible to rectify data and, additionally, patients must have the right to erase and block their sensitive data.

As a consequence it has bees been suggested that:

- Three new requirements have been proposed.
- No requirements need to be updated.
- No requirements have to be deleted.

4.6.1 New Requirements

The *Lessons Learned* in the third cycle have resulted in the insertion of three new requirements.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-493	Non-functional - Legal	Major	The user must be able to correct, rectify, block or erase personal data that has been disclosed - In-Hospital	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. This is strengthened in the new proposal on a data protection framework of the EC.	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?

REACTION-494	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings - Patient Portal.	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-495	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings - Clinician portal.	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?

4.6.2 Updated Requirements

No requirements have been updated.

4.6.3 Deleted Requirements

No requirements have been deleted.

4.6.4 Requirements Resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce

REACTION-148, REACTION-149 and REACTION-150 have been resolved as being Out of scope.

REACTION-142, REACTION-143, REACTION-144 and REACTION-147 have been resolved as being Duplicate.

REACTION-474, REACTION-476 and REACTION-477 have been resolved as "Cannot be implemented".

4.7 Change Request and Re-Engineering Originating from WP10

All *Lessons Learned* (fifteen *Lessons Learned* in WP10) collected in WP10 were analyzed.

LL WP10-1 refers to the browser compatibility in patients' homes (but also for the mobile patient) which has to be quite wide in order to cover the majority of browsers and operating systems.

LL WP10-2 and LL WP10-6 refer to some problems faced during the initial tests with a small subset of real patients. These problems were due to changes in the database schema or generically to the use of different and incompatible versions of applications or components.

LL WP10-3 refers to the need of having more accurate manuals for the user and the technical people.

LL WP10-4 refers to the differences in practices and culture of national health systems which have to be taken into account before exploiting a remote management system in different countries. Some issues have already been taken into account (languages and user preferences) while others will be considered after the successful validation in the clinical trials in order to extend the configurability and flexibility of the developed prototypes.

LL WP10-5 shares the same concerns as LL WP10-2 and in some way goes beyond, since the existing procedures for the common development have to be understood and put into practice in the same way by all involved partners. It states that it is necessary to have the procedures written (as the consortium has) but also to monitor continuously the situation in order to avoid or at least minimize any problem.

LL WP10-7 and LL WP10-8 refer to the first results of the in-hospital clinical trials and reveal that end users like to work with their well-known PoC devices and do not use the electronic fever chart.

LL WP10-9 is related to LL WP10-4 and states that components should be flexible in order to match the different national requirements, policies, guidelines or provisions.

LL WP10-10 is related to LL WP10-3 and states that all user interfaces in all front end applications must be accurately described in order to facilitate the end users.

LL WP10-11 describes the complexity of the installation phase in different patient homes and addresses the need to reduce the installation time or, even better, the capability to make the end user capable of performing the installation by himself.

LL from WP10-12 to WP10-15 addresses issues in the glucose management in general ward and in the primary care environment which led to the resolution of three requirements as out of scope.

The impact of these Lessons Learned on the requirements related to WP10 has been summarized in the following table.

Key	Summary	Priority	Suggestions for Changes
REACTION-68	Use of different versions of applications and/or components in different test sites	Major	Inclusion of the version number (and an easy way for checking it)

			in all components and applications
REACTION-225	Users in in-hospital pilot site are well-trained and fully satisfied with the use of the PoC device	Major	The manual procedure for the insertion of the glucose measurements is fully satisfactory for the end-users and ensure quick response of the decision support system (otherwise not attainable through agents interfacing the LIS)
REACTION-238	Fever chart management is not a main requirement for the glucose management system in the in-hospital environment	Major	The update and entering of drug administration has nothing to do with the fever chart
REACTION-250	Fever chart management is not a main requirement for the glucose management system in the in-hospital environment	Major	The configuration for the display of the patient clinical data has nothing to do with the fever chart
	Need for the REACTION components to be flexible in order to match the different national Requirements, policies, guidelines and provisions.	Major	A new requirement specifying that components should reflect national requirements, policies, guidelines and provisions.
	Need for having all user interfaces in all frontend applications accurately described for the primary care environment.	Major	A new requirement specifying that there should be a more detailed description of user interfaces for the primary care environment.

As a consequence it has bees been suggested that:

- Two new requirements have been proposed.
- Four requirements are to be updated.
- No requirements have to be deleted.

4.7.1 New Requirements

The *Lessons Learned* in the third cycle have resulted in the insertion of two new requirements.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-492	Functional - REACTION platform	Major	Components should reflect national requirements, policies, guidelines or provisions.	National organisations can provide specific requirements, policies and guidelines for health care systems. They may also make national provision for health care services ans IT that are required to be used. Components should be flexible to be substituted to match these national requirements. An example is the SMS messaging service provided by NHS on its secure network.	Components
REACTION-496	Non-functional - Usability	Major	Documentation of user interfaces - primary care prototype	Documentation for User Interface of all frontend applications.	User manual for all frontend applications

4.7.2 Updated Requirements

Four requirements have been updated. Requirement REACTION-68 specifies clearly the need of having the version number (and an easy way for checking it) in all components and/or applications. REACTION-225 states that in the in-hospital environment the manual procedure for the insertion of the glucose measurements is fully satisfactory for the end users and ensures quick response of the decision support system that could be attained through agents interfacing the LIS. REACTION-238 and REACTION-250 are now totally unrelated to the fever chart.

Details of the modified requirements are shown in the table below.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-68	Functional - REACTION platform	Major	Component Versioning	In order to facilitate the software development cycle (especially the testing phase) all components and mainly the applications should contain the version number (e.g. in the about menu). In this way we should be able to reduce misunderstandings in setting up varios testing configurations at different partners' premises and minimize signalling of "false bugs".	The test facility will take into account also the version of components including in the feedback to the developers (test reports) also the version number of the various applications/components.
REACTION-225	Functional - In-hospital pilot application	Major	PoC device for blood glucose measurement will be used by the in-hospital glucose management system.	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.	a) The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. b) The acquired measurements will be manually inserted using the front-end in the tablet PC and stored in the REACTION data management.
REACTION-238	Functional - In-hospital 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 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-250	Functional - In-hospital pilot application	Major	Different contextualization of the patient clinical information	Different modes of visualisation with different relevant parameters for decision support shall be foreseen. 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 sugar chart) has to be present.

4.7.3 Deleted Requirements

No requirements have been deleted.

4.7.4 Requirements Resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce

REACTION-15, REACTION-185, REACTION-194, REACTION-196, REACTION-216 and REACTION-240 have been resolved as being Out of Scope.

REACTION-191 has been resolved as being Duplicate.

4.8 Change Request and Re-Engineering Originating from the Other WPs

No requirements were inserted, updated or deleted as a consequence of the work performed in the other WPs (WP1, WP2, WP8, WP11, WP12 and WP13).

Moreover, no requirement was resolved as Out of Scope, Duplicate, Nonsense, Conflicting, “Cannot be implemented” or “Cannot reproduce” during the third iteration cycle in the course of the work performed for the other WPs and without any strict connection to any specific *Lesson Learned*.

4.9 List of Consolidated Requirements

This section deals with the 14 Volere requirements (REACTION-479 to REACTION-501) added to the JIRA REACTION requirements project in the course of the third iteration cycle. The lists below focused on the 13 new Volere requirements which have not been resolved after the quality check as Out of scope, Duplicate or "Cannot be implemented". These new "active" requirements have been grouped in constraints and non-functional requirements (5 in all), functional requirements of the REACTION platform (7 in all), and functional requirements of the in-hospital pilot application (1 in all), while no new functional requirement has been created for the primary care pilot application.

The first list below contains all constraints and non-functional requirements (5 in all).

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-480	Non-functional - Security	Major	Access control mechanisms should be able to process context information	It may not be sufficient to make access control decisions based only on the role(s) owned by a user. In some use cases, access restrictions depend on context information like time, location, and access history, etc. For example, a physician should only be able to treat patients that are assigned to her own ward. Therefore, access control mechanisms applied in REACTION should be able to process access rules that rely on context constraints.	Availability of a control mechanism which decides whether a requested action may be granted or denied based on context information.
REACTION-493	Non-functional - Legal	Major	The user must be able to correct, rectify, block or erase personal data that has been disclosed - In-Hospital	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. This is strengthened in the new proposal on a data protection framework of the EC.	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?
REACTION-494	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings - Patient Portal.	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-495	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings - Clinician portal.	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-496	Non-functional - Usability	Major	Documentation of user interfaces - primary care prototype	Documentation for User Interface of all frontend applications.	User manual for all frontend applications

In the list below all new functional requirements of the REACTION platform are listed (7 in all).

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-481	Functional – REACTION platform	Major	Glucose Control Suite (GCS) – Matlab GUI	Implementation of a Matlab based GUI for the clinical validation of the closed loop glucose control algorithm	Operable Interface on a laptop within a patients room in the clinic
REACTION-482	Functional – REACTION platform	Major	GCS – Interface to create individual model file	Interface to create Individual specifying: Race, Gender, Age, Weight and Height	A new individual model file is created. The model initialization is initiated.
REACTION-483	Functional – REACTION platform	Major	GCS – Interface for Model Initialization	Second Component of the GCS - Interface for the Initialization (Individualization) of the PBPK/PD model during Observation Phase, allows: - Input scheduling (IV Glucose, IV Insulin) - Measurement Data Entry	Matlab GUI fitting rationale described above

				(Plasma Glucose) - Visualization of Best Model Fits	
REACTION-484	Functional – REACTION platform	Major	GCS – Interface for semi-automatic online glucose control	Third Component of the GCS - Interface for the calculation of insulin infusion rates based on glucose measurements, allows: - Input scheduling (SC Insulin infusion rate, IV insulin, Meal, Oral Glucose) - Measurement data entry (Plasma Glucose) - Visualization of: - Plasma glucose - Plasma insulin - Applied rate of insulin - Confirm (update) inputs - Apply calculated or anter dose Insulin manually	Matlab GUI as described in rationale
REACTION-485	Functional – REACTION platform	Major	GCS – Interface for online model optimization	2nd part of the third Component of the GCS - Interface for the further individualization of the GIM model based on past glucose measurements, allows: - Visualization of: - Plasma and interstitial glucose - Plasma and interstitial insulin - Values of optimized parameters - Values of penalty function components (met constraints) - Level of manual interaction to be defined	Matlab GUI as defined in rationale
REACTION-492	Functional - REACTION platform	Major	Components should reflect national requirements, policies, guidelines or provisions.	National organisations can provide specific requirements, policies and guidelines for health care systems. They may also make national provision for health care services ans IT that are required to be used. Components should be flexible to be substituted to match these national requirements. An example is the SMS messaging service provided by NHS on its secure network.	Components
REACTION-501	Functional – REACTION platform	Major	Second Prototype of the Glucose Control Algorithm (GCA 2) – Matlab GUI	Second Prototype of the Glucose Control Algorithm (GCA 2, formerly known as Glucose Control Suite, GCS): Implementation of a Matlab based GUI for the clinical valdiation of the closed loop glucose control algorithm	Operable Interface on a laptop within a patients room in the clinic

The list below contains all new functional requirements which refer to the in-hospital pilot application (1 in all).

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-497	Functional - In-hospital pilot application	Major	Management Functionality for the Identities used in the In-Hospital-Scenario	Administrators must be able to add or modify existing profiles of users. This should be possible in a user-friendly way, i.e., by a management application designed for user management tasks.	Availability of a management application

5 The Next Iteration Cycle

Requirement monitoring and management will continue during the final iteration cycle. Special attention will be dedicated to requirements close to their Due Date, and specific reminders will be sent to the Assignees to solicit the completion of the necessary implementations. Whenever necessary, telcos will be organized with the participation of the WP2 leader, the technical manager, the project coordinator and the involved partners in order to mediate conflicts, to clarify issues and to guarantee a smooth continuation of the technical work.

No specific actions are foreseen for the next iteration cycle from the point of view of JIRA administration. The main work will be focused on the ordinary user administration and support.

6 The Requirements of the REACTION Platform after the Third Year Revision

In this chapter the requirements of the REACTION platform after the third year revision are reported per WP and per component showing only the major fields like priority, summary, rationale and fit criterion. Requirements in the “Resolved” or “Closed” statuses with resolution “Duplicate”, “Out of scope”, “Nonsense”, “Conflicting”, “Cannot be implemented” or “Cannot reproduce” have not been listed. The focus is only on all requirements that at the end of the third iteration cycle are still “Unresolved” or “Implemented” or “Validated”. A complete list of the requirements (with resolution “Unresolved”, “Implemented” or “Validated”) after the third year revision, which includes all the requirement fields and their current status in the selected JIRA workflow, is provided in a separate appendix.

It should be noted that, in the default workflow initially used, each requirement had an impact on more than a single WP and on more than a single component. Ideally each requirement should be assigned only to one component and to one WP, but the complexity of the project did not make that possible during the first iteration cycle. With the introduction of the new workflow and components in the second iteration cycle, each requirement was assigned only to one component, and for each requirement a WP of major impact was identified. It is a task of the Assignee to coordinate the work during the life cycle of the REACTION project among different WPs in order to assure the requirement will be properly resolved.

In order to give an effective view of the requirements and to avoid an excessive length for this deliverable, each requirement has been listed only in the WP on which it has major impact. Furthermore, for the same reasons, only the requirements which have had some changes in the third iteration cycle are listed in their entirety and in bold, while for all the other requirements only the first four lines of their summary, rationale and fit criterion are reported and suspension points have been added. In case suspension points have been added and text suppressed, the text in the field has been displayed in italic. For these requirements the reader can find all the details in the appendix of this document containing the complete list of the requirements of the REACTION platform at the end of the third iteration cycle.

In the tables below all requirements that have already been implemented or, even better, validated are shown with a light green background. The requirements which are in the “In progress” status are shown with a light yellow background, while the requirements with the standard white background have been simply opened or identified as “Part of specifications”, but work has not yet started on them.

The main purpose of the tables shown below is to give each WP leader a quick overview of the status and progress of the requirements of her/his WP.

6.1 Requirements of WP2 – User Centric Requirements Engineering and Validation

6.1.1 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-397	Functional - Primary care pilot application	Major	The patient shall be registered to the sytem manually and all patient monitorered data will be followed. .	The patient shall be registered by her/his care giver and having ability to send data to the caregiver due to evaluate.	No fit Criterion identifed.

6.2 Requirements of WP3 – Sensors Monitoring and Contextualisation

6.2.1 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

6.2.2 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-481	**Functional – REACTION platform**	**Major**	**Glucose Control Suite (GCS) - Matlab GUI**	**Implementation of a Matlab based GUI for the clinical valdiation of the closed loop glucose control algorithm**	**Operable Interface on a laptop within a patients room in the clinic**
REACTION-482	**Functional – REACTION platform**	**Major**	**GCS - Interface to create individual model file**	**Interface to create Individual specifying: Race, Gender, Age, Weight and Height**	**A new individual model file is created. The model initialization is initiated.**
REACTION-483	**Functional – REACTION platform**	**Major**	**GCS - Interface for Model Initialization**	**Second Component of the GCS - Interface for the Initialization (Individualization) of the PBPK/PD model during Observation Phase, allows: - Input scheduling (IV Glucose, IV Insulin) - Measurement Data Entry (Plasma Glucose) - Visualization of Best Model Fits**	**Matlab GUI fitting rationale described above**
REACTION-484	**Functional – REACTION platform**	**Major**	**GCS - Interface for semi-automatic online glucose control**	**Third Component of the GCS - Interface for the calculation of insulin infusion rates based on glucose measurements, allows: - Input scheduling (SC Insulin infusion rate, IV insulin, Meal, Oral Glucose) - Measurement data entry (Plasma Glucose) - Visualization of:**	**Matlab GUI as decribed in rationale**

				- Plasma glucose - Plasma insulin - Applied rate of insulin - Confirm (update) inputs - Apply calculated or anter dose Insulin manually	
REACTION-485	**Functional – REACTION platform**	**Major**	**GCS - Interface for online model optimization**	**2nd part of the third Component of the GCS - Interface for the further individualization of the GIM model based on past glucose measurements, allows: - Visualization of: - Plasma and interstitial glucose - Plasma and interstitial insulin - Values of optimized parameters - Values of penalty function components (met constraints) - Level of manual interaction to be defined**	**Matlab GUI as defined in rationale**
REACTION-501	**Functional – REACTION platform**	**Major**	**Second Prototype of the Glucose Control Algorithm (GCA 2) - Matlab GUI.**	**Second Prototype of the Glucose Control Algorithm (GCA 2, formerly known as Glucose Control Suite, GCS): Implementation of a Matlab based GUI for the clinical valdiation of the closed loop glucose control algorithm**	**Operable Interface on a laptop within a patients room in the clinic**

6.2.3 Internal 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…*	*To guarantee the operation of the portable devices under any circumstances. Consortium developed…*	*Multiple trials in a real life environment (not only in the fully controlled environment of the laboratory) using…*

6.2.4 Medical & environmental 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-180	Functional - REACTION platform	Major	*Measurement of glucose should be specific and the glucose sensor should be able to monitor glucose in…*	*If the glucose monitoring is not specific, detection could be disturbed by other components of the ISF or…*	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…*	*For AGC the accuracy should be +/-5% of the measured value in the specified range. For a closed loop sensor…*	Performance of reference measurements on defined samples.
REACTION-186	Functional - Primary care pilot application	Major	*The sensor platform should be robust and simple to be used, enabling the device to be operated by the patient…*	Sensor platform has to be worn for several days and should not hinder the patient in his normal activities.	Simplicity and reliability in patient trials is to be demonstrated.
REACTION-204	Functional - REACTION platform	Critical	ePatch	*The ePatch is the preferred device and technology used to attached and connect sensors to the body…*	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 …*	Hardware fabricated.
REACTION-207	Functional	Major	ePatch communication	*The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance…*	*The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration…*
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…*	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…*	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…*	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…*	Activity parameter sensors must be integrated into the REACTION e-patch.

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…*	*Clinical parameters given by the clinicians, but also parameters that are necessary for running the…*
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 …*	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 …*	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…*	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 …*	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 and kept on equal level for the IR GM sensor reference …*	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 …*
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…*	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…*	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…*	*The safety directive is essential for sensors being operated on patients. The off-the-shelf sensors/devices …*	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)…*	*The cost of the sensor should be specified by the sensor manufacturers and be as low as possible. The cost of …*
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.
REACTION-472	Functional - REACTION platform	Major	A portable sensor patch should have as reduced visibility as is technically feasible	*The lower the visibility of such equipment the less the chance that an individual's condition might become …*	Equipment should have as low a level of visibility as is technically possible.
REACTION-478	Functional	Major	The recovery for microdialysis	*Due to sensor fouling effects*	Recovery detection

			based glucose sensors should be monitored to avoid recalibration	*the recovery of a microdialysis catheter may change as a function of time, requiring …*	implemented

6.2.5 Patient sphere

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 …*	*All devices, those used in the field of testing and those that will eventually be selected, must comply with this …*
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 …*	*All devices, those used in the field of testing and those that will eventually be selected, must comply with this …*
REACTION-51	Functional - Primary care 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…*	*It is likely that outside the home, the user will not have access to a wireless network. In such a case the mobile …*	*All devices, those used in the field of testing and those that will eventually be selected, must comply with this …*
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…*	*If no wireless network is available at the user's home environment, then he/she must be given the …*	*Creation of a service for the home gateway that upon USB connection with the portable device, the service will…*
REACTION-53	Non-functional - Usability	Major	**The portable touch device must have at least the following connectivity options: WiFi (802.11g or 802.11n), …*	*The device must support the latest and most widespread communication protocols. The presence of specialized…*	*All devices, those used in the field of testing and those that will eventually be selected, must comply with this …*
REACTION-55	Non-functional - Usability	Major	*The portable touch device must have a display of sufficient screen size & resolution (more than a …*	*A device with smaller screen estate will compromise its usability, and will make the interaction with user an …*	*All devices, those used in the field of testing and those that will eventually be selected, must comply with this …*
REACTION-56	Non-functional - Usability	Major	*The portable touch device must have a satisfactory operational time. The battery must be able to support the …*	*The portable device will have to be operated continuously. The small size and weight of the device allows the user …*	*All devices, those used in the field of testing and those that will eventually be selected, must comply with this …*
REACTION-80	Non-functional - Usability	Major	*Only one or max two categories of different mobile operating systems will be considered for the portable …*	*The large spread of existing operating systems will not make affordable a development effort on a …*	*Internal test and field trials will be performed only using portable devices with one of the selected operating …*
REACTION-126	Functional - REACTION platform	Major	*Portable device should allow patients to complete the acquired data set with questionnaire or additional …*	*The necessity to provide a context for the acquired measurements implies that non-directly measurable …*	*Verify that the additional non-directly measurable data can be collected by the patient herself with the portable …*
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 …*	*The portable user interface should be used also for displaying the clinician feedback to patients, …*

6.2.6 Third-party system interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-236	Functional - In-hospital pilot application	Major	Blood glucose measurements in In-hospital environment	*PoC devices are currently used and will be used in In-hospital environment. The procedure is reliable and …*	*There should be in the platform an alternative way for acquiring blood glucose measurements from other …*

6.3 Requirements of WP4 – Data Management and Service Orchestration

6.3.1 Application development kit (ADK)

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 …*	*Developers can develop better applications faster. The platform thus could also provide easy access to …*	*Writing sufficient documentation for the technical interfaces and also by providing examples and …*
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 …*	A Continua Manager stub exists allowing simulated access to a Continua device.

6.3.2 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-3	Functional - REACTION platform	Major	Support for IEEE 11073 medical device standards	*To support a wide variety of medical devices, the selected subsets of the IEEE 11073 medical device standards …*	Show that REACTION device proxies can be developed for at least 2 different devices from different manufacturers.
REACTION-6	Functional - REACTION platform	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 - REACTION platform	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-68	**Functional - REACTION platform**	**Major**	**Component Versioning**	**In order to facilitate the software development cycle (especially the testing phase) all components and mainly the applications should contain the version number (e.g. in the about menu). In this way we should be able to reduce misunderstandings in setting up varios testing configurations at different partners' premises and minimize signalling of "false bugs".**	**The test facility will take into account also the version of components including in the feedback to the developers (test reports) also the version number of the various applications/components.**

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…*	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 …*	Specific test has to be done on each component
REACTION-156	Functional - In-hospital pilot application	Major	The system should provide a regular backup of data	Inpatient pilot application offers data backup mechanism	Regular backup of data
REACTION-228	Functional - In-hospital 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-231	Functional - In-hospital pilot application	Major	End of process for the diabetic patient in the In-hospital environment	*The workflows in the In-hospital glycaemic control management ends with the patient discharge from the …*	At the patient discharge from the department, the workflow related to the patient has to be terminated
REACTION-284	Functional - In-hospital pilot application	Major	Clinical data to be stored in the In-hospital environment	*The data management shall be design in order to allow the storage of the clinical data to be registered at the patient …*	The data management shall allow the insertion and the update of all the listed clinical parameters.
REACTION-340	Functional - REACTION platform	Major	Storage of insulin administration	*Insulin administrated to patient has to be stored with time, dosage (units), type of insulin and modality of …*	*Specific fields have to be foreseen in data management, ontologies and user interfaces (also …*
REACTION-348	Functional - REACTION platform	Major	High-level data fusion	*Besides low-level data fusion on the client side a high-level data fusion should be available for the …*	High-level data fusion functionality will be available for the REACTION hosting server.
REACTION-351	Functional - Primary care pilot application	Major	Telemonitoring data should be visualized to patients and professionals in a flexible and performant way	*GPs and nurses as well as patients and their carers use the telemonitoring data to get an impression of the …*	Data can be visualized flexibly and with good performance to professionals
REACTION-371	Functional - REACTION platform	Critical	Use of activity patterns for context annotations	*Context has to be expressed synthetically in some way. A possible and common option is through activity patterns …*	*Collect measurements about physical activity, environmental data, additional information and evaluate …*
REACTION-372	Functional - REACTION platform	Major	Context of observations	The middleware of the REACTION platform should support context management for observed values.	The REACTION platform supports context management on the client side.
REACTION-374	Functional - Primary care pilot application	Major	Annual clinical checks	*The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, …*	Specific fields have to be present in ontologies and data management.

REACTION-381	Functional - REACTION platform	Minor	Definition of a common ontology to refer to data, metadata, interfaces and models	*A common ontology facilitates components integration and maintain a common language among the technical …*	*All logical entities in software components should correspond to terms from the ontology (or to a published …*
REACTION-423	Non-functional - Operational	Major	Sensor quality parameters	*The REACTION data management model should consider data storage for sensor quality parameters …*	Data fields for sensor quality parameters are available in the data management model.
REACTION-442	Functional - Primary care pilot application	Major	Management of complications	*Apart from the diabetic management, the other managements for diabetic patients will be around the …*	*Data management should include the necessary structures for assuring the storage of all necessary …*
REACTION-444	Functional - Primary care 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 …*	Specific fields (entries) have to be foreseen in ontologies and data management.
REACTION-455	Functional - REACTION platform	Major	REACTION data storage	*The REACTION platform should provide a storage module (database). Data gathered within …*	*The REACTION platform provides a persistence layer for data storage with emphasis on data security …*
REACTION-456	Functional - In-hospital pilot application	Major	Nutrition information has to be stored in the data management	*Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation …*	*The data management shall allow the insertion of time and composition of nutrition accompanied also by …*
REACTION-459	Functional - In-hospital pilot application	Major	*Ontologies and data management designed for the storage and multi-user availability of all relevant …*	*Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all …*	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.
REACTION-460	Functional - REACTION platform	Major	Measurements of HbA1c	*The risk of developing diabetic complications is strongly affected by HbA1c. This parameter has to be …*	Specific fields have to be foreseen in data management.
REACTION-463	Functional - In-hospital pilot application	Major	Context management for clinical (lab) values.	*Contextualization of measured values (e.g. blood glucose values) is important in order to support …*	The data management model support context management functionality for the inpatient prototype application.
REACTION-467	Functional - REACTION platform	Major	Semantics based data management	The monitoring and other data need to be properly annotated with ontological descriptions.	Relevant entries in the REACTION's databases are annotated with semantic concepts.

6.3.3 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-155	Functional - In-hospital pilot application	Major	The System should keep an electronic paperless data record of the data relevant for	*Currently all actions are recorded on a paper chart/record. Because of data*	The inpatient pilot application stores data records/charts

			Glucose Management	*privacy protection and …*	
REACTION-161	Functional - In-hospital pilot application	Major	The system should remind caregivers to perform measurements.	*Measurements are required to allow the algorithm to function accurately and safely. A decision was taken not…*	*Reminder to perform measurements is available within the inpatient platform. This could be an "open …*
REACTION-219	Functional - In-hospital 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…*	*Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) …*
REACTION-227	Functional - In-hospital pilot application	Major	Initialization of the fever/sugar chart	*Immediately after the patient enrolment, the relevant information about medical history, general health …*	*The initialization of the fever/sugar chart is a pre-requisite for the daily management of the…*
REACTION-229	Functional - In-hospital pilot application	Major	Decision on therapy in In-hospital environment	*Decision on therapy has to be performed immediately after performing any measurements based also…*	*Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific …*
REACTION-238	**Functional - In-hospital 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 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-246	Functional - In-hospital pilot application	Major	Multi-user availability and display of the fever chart	*The fever/sugar chart shall be considered as a central document and collects all the information about the …*	*Clinical decision is often taken based on this document which has to be available (multi-user) and continuously…*
REACTION-251	Functional - In-hospital 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 …*	*Suggestions on treatments shall be available in order to facilitate the clinical decision. An available protocol from …*
REACTION-367	Functional - Primary care pilot application	Major	Insertion of baseline physiological measurements at the first visit	*At the first visit, baseline physiological measurements (the exact set has to be clearly defined) have to be …*	*The data management shall foresee the possibility of introducing the baseline physiological …*
REACTION-375	Functional - In-hospital pilot application	Major	Therapy scheme in In-hospital environment	Decision on therapy has to be performed immediately after performing any measurements based also …	The pharmaceutical and non-pharmaceutical treatment (or therapy scheme) has to be stored in the data …
REACTION-388	Functional - REACTION platform	Major	Insulin sensitivity and insulin resistance	*Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these ...*	The data management has to allow for the insertion and subsequent modifications of these values by clinicians.
REACTION-391	Constraint	Major	Data fields for the In-hospital glucose control prototype (eDSS).	*Following data fields should be provided:* *- administrative data (patient name, address, PID, ward, …*	Required data fields will be provided by data structure.

REACTION-399	Functional - Primary care pilot application	Major	Ongoing management	*Ongoing management follows investigative stage. This stage is used to: support patients with difficulties in managing …*	Specific fields have to be present in ontologies and data management
REACTION-402	Functional - In-hospital pilot application	Major	Measurements of blood glucose and insulin injections in In-hospital environment	*In In-hospital environment, the blood glucose level measurements are, in most cases, performed by …*	*Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses …*
REACTION-408	Functional - REACTION platform	Major	Non-pharmacological and/or pharmacological treatment	*Non-pharmacological (diet, lifestyle, education) and pharmacological (OAD, insulin and interfering drugs) …*	*In the ontologies and data management there should be the possibility of registering the different types of …*
REACTION-426	Functional - REACTION platform	Major	Comorbidities have to be registered	*Co-morbidities are almost always present in diabetic patient and their presence can affect the overall …*	*In the design of data management and ontologies the possibility of registering the co-morbidities with a …*
REACTION-428	Functional - In-hospital pilot application	Major	Drug administration data (OAD and/or insulin)	*Drug administration (time, insulin type, administration type -IV or SC-, dosage and other relevant information) …*	*Data on drugs administered have to be stored in the data management where they can be also retrieved as part of …*
REACTION-432	Functional - In-hospital 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 …*	*These events (special examination/treatments) have to be registered in the data management where they …*
REACTION-435	Functional - Primary care pilot application	Major	Outcomes of regular visits at primary healthcare centres	Outcomes of monitoring should be recorded in the Clinical Portal.	*Outcomes of the monitoring will be stored in a notes section on the clinical portal. This notes section should …*
REACTION-449	Functional - Primary care pilot application	Major	Personalized care plan	*A personalized care plan must be defined (and updated if necessary) for each patient. It includes disease …*	Care plan can be personalized.
REACTION-462	Functional - In-hospital pilot application	Major	Interface for user inputs from portable computer in order to store data in In-hospital data storage	For the In-hospital prototype user input should be possible. The user data should be stored in the data storage.	User input can be stored in the In-hospital prototype storage for further processing.
REACTION-465	Functional - In-hospital pilot application	Major	Clinical evaluation report	*Supervision of glycaemia and associated treatment is performed once a day. The clinical evaluation report …*	A daily clinical evaluation report has to be stored and available in the Inpatient application.
REACTION-466	Functional - In-hospital pilot application	Major	(Web) Service to present decision support for glucose control to clinicians	*After processing of data by the glucose prediction algorithm, the results should be presented by the …*	A service will be available to support physician with glucose control of patients.
REACTION-468	Functional - REACTION platform	Major	Provide regular update of data model for Health Care profil	*Most application depends on current clinical data (e.g. blood glucose). A mechanism for regular data updates …*	The Data Model for REACTION should provide a regular update mechanism for personal health care profiles.

6.3.4 Internal communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 …*	A log file will be available for each component, containing data which will be defined by the design process.
REACTION-32	Constraint	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-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-345	Functional - REACTION platform	Major	Two-way communication between REACTION server and client	*There is a need for two-way communication between server and client e.g.for remote configuration of the ...*	*Two way communication between Client and Server will be available for the REACTION platform in …*
REACTION-365	Functional - Primary care pilot application	Critical	*Data should be stored in proper way in order to be easily transmitted over mobile networks in case that …*	*In the event that the hosting client is not connected through a broadband connection, the patient will …*	Functional test uploading data over slow mobile networks.
REACTION-448	Functional - REACTION platform	Major	Alert / notification messages should be short enough in order to be delivered as SMS messages if necessary	*User's terminal mobile device will likely be used as a GSM mobile phone. Considering the advantages of Short …*	functional tests when user is away from broadband connection.
REACTION-451	Functional - REACTION platform	Major	In-hospital prototype communication with REACTION platform	*The current design of the In-hospital prototype and the Primary care prototype does not consider the …*	Communication and transfer of data between In-hospital and Primary care prototypes are possible.
REACTION-453	Functional - REACTION platform	Major	Communication interface between REACTION Client and REACTION Server	*A communication standard between REACTION client and server should be established …*	Communication interface between REACTION Client and REACTION Server will be available.
REACTION-454	Functional - REACTION platform	Major	Content formatter	A formatter for converting the acquired data to useful information for the patient shall be available.	Use a standard format or a verification mechanism.

6.3.5 Medical & environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-237	Functional - In-hospital pilot application	Major	Annotation of blood glucose values, especially in In-hospital environment	*In the hospital with associated laboratories there exists the possibility that specially trained nurses …*	*The blood glucose values have to be annotated specifying if collected with PoC devices or by …*

REACTION-334	Functional - Primary care pilot application	Major	Devices should be able to operate anywhere in the home	To make a system that is ubiquitous and fits patient lifestyle	Device specification
REACTION-401	Non-functional - Operational	Critical	Device specialization	*Based on the necessary information to be monitored from the patient, a complete list of IEEE 11073 device …*	For each device the supported standard has to be specified (or the company documentation).

6.3.6 Network management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 …*
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 …*
REACTION-134	Non-functional - Performance	Major	*Any interface between an end-user and the platform shall have a reasonable maximum response time in …*	*Response time should be quick enough except for reasons independent from the technical design of the …*	*The platform when the public network is perfectly working at the max speed shall respond in less than 5 sec in 90% of …*
REACTION-358	Functional - REACTION platform	Major	Network manager for hosting client	*TODO (Peter Rosengren) incl. security mechanism ("the Network Manager would be configured to encrypt the …*	TODO (Peter Rosengren)
REACTION-439	Functional - REACTION platform	Major	Information should be cashed in local storage to prevent loss in case of a node or communication failure.	*In case of network error the client application should be able to store temporary data. This will a) allow user to …*	The functional test should include specific tests in order to ensure that there is no data loss in case of network failure.

6.3.7 Patient sphere

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 …*	At least one external service is supported.
REACTION-160	Functional - Primary care 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 …*	*Verify that in case of not compliance with the established clinical checks an alert is sent to the patient …*
REACTION-338	Non-functional - Security	Critical	All data entered must be checked for format, consistency and validity	*Unintended user actions should not harm data integrity and the overall functioning of*	The functional test should include specific tests in order to verify such circumstances.

				the platform. In case of …	
REACTION-342	Functional - REACTION platform	Major	Low-level data fusion	*The REACTION platform should support low-level data fusion in order to interpret measurements occurring in …*	Low-level data fusion will be available for the REACTION platform (middleware).
REACTION-344	Non-functional - Look and feel	Major	Display of acquired measurements (values, time, context (if available))	Provide immediate and consistent (if possible also contextualized) information to the patient.	The user interface on the mobile device shall have this functionality.
REACTION-347	Non-functional - Operational	Major	Continuous blood glucose monitoring	*Using the acquired values, the mobile device must be able to analyze the glycaemic variability and to generate …*	This functionality can be tested using the device simulator and simulated sequences of values-
REACTION-349	Non-functional - Usability	Major	*Patient questionnaires (lifestyle, physio-psychological conditiond, checking medication compliance, …*	*Questionnaire for patients in order to collect qualitative (or quantitative but not directly measurable) information …*	The mobile device shall have user interfaces allowing completion of these questionnaires.
REACTION-356	Non-functional - Usability	Major	Manual data insertion	*In case of no connectivity with the sensor or medical device or use of a non-interoperable medical device, the mobile …*	Check that measurements can be inserted manually using the mobile device .
REACTION-383	Functional - Primary care pilot application	Major	Self-management and lifestyle support	*Support of the patients' self-management by lifestyle (diet, exercise etc.) advices, therapy advices, health …*	Self-management is supported.

6.3.8 Security and safety management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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, …*	Availability of a mechanism for ensuring data confidentiality
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, …*	*Qualitative and quantitative criteria shall be present in the field trial evaluations in order to measure the reduction of …*
REACTION-376	Non-functional - Security	Critical	Integrity check 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-387	Functional - REACTION platform	Critical	Information related to informed consent stored in the platform	*An ethical approved declaration of informed consent has to be signed (either digitally or in paper …*	*The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned …*

6.3.9 Service orchestration

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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-17	Functional	Major	Configurable data transfer frequency	*Possibility to configure the periodical transfer of the collected sensor data to external services such as …*	Lowest periodical transfer is once per day.
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 …*	Platform flexibly supports processing of data from multiple sources
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 gro…*	*A maximum number of simultaneous users has to be fixed. These numbers are very reasonable c…*	*The platform will be tested with the max number of simultaneous users verifying that the response time for …*
REACTION-202	Functional - Primary care pilot application	Major	Set up 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 …*	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-217	Functional - Primary care 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…*	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-380	Functional - REACTION platform	Major	Set of alerts and reminders	*A set of possible alerts and reminders. These can be thought as "prototypes". Action rules can define …*	Alerts and reminders can be defined and stored.
REACTION-404	Functional - REACTION platform	Major	Service Orchestration Manager	It should be possible to express execution of a set of services in combinations and sequences	Sercice orchestrations can be defined and stored
REACTION-419	Functional - REACTION platform	Major	Set of event rules	*Event rules define the criterions of different events. Events are detected based on these rules …*	Event rules can be defined and stored.
REACTION-425	Functional - REACTION platform	Major	Set of action rules	Action rules define what should be done if an event occurs, e.g. who should be notified and how.	Action rules can be defined and stored.
REACTION-441	Functional - In-hospital pilot application	Major	Basic workflow in In-hospital environment	*The basic workflow is based on measurement of blood glucose and evaluation of the necessary insulin (bolus or …*	*There should be the possibility of acquiring, storing and retrieving all the information generated …*

6.3.10 Third-party system interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-336	Functional - REACTION platform	Major	Patient enrolment (or recruitment)	*When an interoperable HIS or EPR is present in the managing organization, the patient data at the patient …*	*When an interoperable HIS/EPR is present, a new diabetic patient cannot be created in the REACTION …*
REACTION-352	Non-functional - Maintainability and portability	Major	Scalable / easy to use solution for REACTION software in GP surgery	*The REACTION software which is executed in the GP surgery has to be usable for practices in different setting …*	*REACTION software is easy to run beside an EHR application or …*
REACTION-362	Functional - In-hospital pilot application	Major	Interface to patient demographic register	*In order to import demographic data from the patient demographic register has to be imported from …*	Standardized interface (HL7) to patient demographic register is available for the In-hospital pilot application
REACTION-363	Functional - In-hospital pilot application	Major	Interface to Hospital Information System for clinical data import/export	*In order to exchange clinical data between In-hospital pilot application and Hospital information System (HIS) …*	Standardized Interface (HL7) to HIS / EPR to exchange clinical data.
REACTION-395	Constraint - End-User Workplace Environment	Major	A REACTION application needs to be executed in the patient surgery independent from the EPR	*As it is not possible to influence/ modify many EPR systems, REACTION features inside the GP surgery have …*	An easy to run possibility to run and access REACTION features inside the GP surgery is available.
REACTION-413	Functional - REACTION platform	Major	Connection with external services like MS HealthVault	External interfaces to services of MS HealthVault should be taken into account in the REACTION platform.	Interfaces to MS HealthVault will be available.

6.4 Requirements of WP5 – Network Management and Service Execution

6.4.1 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-220	Functional - In-hospital pilot application	Major	*Healthcare professionals perform the safe glycaemic control in In-hospital environment (not self- …*	*In In-hospital environment, the blood glucose level measurements are in most cases performed by nurses …*	*Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses...*

6.4.2 Internal communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-1	Functional - Primary care pilot application	Major	*Internet communication between patient home and primary/secondary healthcare structures based on public …*	A basic communication infrastructure has to be assumed	Tests will be based on this assumption
REACTION-83	Functional - REACTION platform	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 …*	Data will be available shortly after measurement in the REACTION database
REACTION-88	Functional - Primary care 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

6.4.3 Medical & environmental devices

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 …*	*The commercial devices not developed by the consortium have to be compliant with relevant communication …*
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 …*	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 …*	*BAN and PAN integration will be tested on the same portable device which will collect measurements …*

6.4.4 Network management

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 …*	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-54	Functional	Major	Network & system monitoring	*Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using…*	none
REACTION-87	Non-functional - Operational	Major	Define network architectural model	*Handle resources and services in heterogeneous networks (define heterogeneous networks)…*	None
REACTION-89	Functional - REACTION platform	Major	Network management subsets	*Define network management subsets for data traffic management between Patient's sphere and …*	None
REACTION-123	Functional - REACTION platform	Critical	Define components and services	*Define the necessary components, services and orchestration methods under a Service Oriented …*	none
REACTION-173	Functional - In-hospital pilot application	Major	*Platform should allow ubiquitous access to end-users and sharing of information among …*	*The system should allow caregivers to be independent from location and time; one or more caregivers should …*	Achieving location independence and multi-user support

6.4.5 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-34	Functional - Primary care pilot application	Major	Define "black box" to be used in primary care environment	*Define the hardware to be used in primary care environment for acquiring and transmitting sensor data to …*	None
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 …*	Specific tests have to be performed when public wireless network is not available at home.
REACTION-168	Functional - Primary care pilot application	Major	Remote Patient Monitoring (RPM)	*RPM has to be used in the Primary care Pilot Applications in order to improve the supervision of …*	RPM module has to be present in the Primary care field trials

6.4.6 Security and safety management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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

6.5 Requirements of WP6 – Integrative Risk Assessment and Feedback

6.5.1 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-73	Functional - Primary care pilot application	Major	Short-term risk management (primary care)	*Identification of short-term risks would help to optimize the patient's management and to prevent the development …*	A module is available for the identification of short-term risks (based on pattern management).
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-165	Functional - In-hospital pilot application	Major	Error Messages	*Error messages for every component within the application have to be foreseen so that they are …*	Services and feedback to user.
REACTION-255	Functional - In-hospital pilot application	Minor	Management of missing data	*Mandatory fields have to be filled otherwise the user cannot go on the workflow of the inpatient prototype…*	Mandatory fields have to be filled in a safe and traceable manner!
REACTION-337	Functional - Primary care pilot application	Major	Health status model	*The health status model serves as a generic prototype for Personal Health Status Profiles, i.e. defines its …*	A health status model is present.
REACTION-392	Functional - Primary care pilot application	Major	Personal Health Status Profiles	*Personal Health Status Profile for each patient must be generated, stored and regularly updated. It serves …*	Personal Health Status Profiles can be generated.

6.5.2 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - In-hospital 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 …*	eDSS is available for the REACTION platform
REACTION-81	Functional - Primary care pilot application	Major	Long-term risk calculation and health professional-oriented presentation	*Calculate long-term risk based on patient health profile and visualize in a health professional-oriented form …*	The REACTION platform offers a service to calculate diabetes dependent long-term risks
REACTION-86	Functional - Primary care pilot application	Major	Estimate short- and medium-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: …*	*Health risk profiles (short- and medium-term) are available for risk profiling, and knowledge discovery within …*

REACTION-193	Functional - Primary care 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 …*	*Some serious or life-threatening situations can be simulated in the integration environment and the …*
REACTION-409	Functional - Primary care pilot application	Major	Risk assessment models and rules	Models and rules must be defined to determine personal risks.	Models and rules for risk assessment are present.
REACTION-421	Functional - REACTION platform	Major	Models and rules for insulin dose prediction (In-hospital)	*A physiologic model and calculation rules/algorithm must be stored for insulin dosing support based on …*	Necessary models and rules are defined and stored.

6.5.3 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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.**	**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 …*	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)

6.5.4 Third-party system interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-346	Functional - REACTION platform	Major	Knowledge Discovery from unstructured clinical text information	*EPRs often contain unstructured text information. In order to use this information for decision …*	*REACTION provides a knowledge discovery module to process unstructured information and store this …*

6.6 Requirements of WP7 – Security, Privacy and Safety

6.6.1 Security and safety management

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 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 …*	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 …*	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., …*	Availability of a mechanism that allows to verify the authenticity of some information
REACTION-92	Non-functional - Security	Major	*Integrity: Information, in particular health data, must be protected from any kind of unintended changes …*	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
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,…*	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 …*	Availability of a mechanism allowing to control access to sensitive data
REACTION-104	Non-functional - Security	Major	*Need-to-know Basis: Stakeholders processing information should only learn what is necessary to carry…*	*In an information processing chain, several stakeholders might be involved but it might not be necessary for every …*	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 …*	*If allegedly secure functions do not live up to their expected functionality, the whole platform could be …*	Successful review of expected security functionality.
REACTION-197	Functional - Primary care pilot application	Major	Care spaces in the primary care environment	*Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to …*	Each member of the care space will have specific roles and tasks in the patient's care.
REACTION-323	Functional - Primary care pilot application	Major	Providing a complete audit trail for each user's data and action taken on the system	*There must be a complete audit trail of all actions taken in the system by any user. No user shall have the …*	*The system shall foresee the possibility of traceability for each action which has been taken in the system by the …*
REACTION-339	Non-functional - Security	Major	*Communication between the Reaction Device Hosting Server and the patient's/GP's web browser MUST be …*	*It must be assumed that data transmission from the Reaction Device Hosting Server to the patient's/GP's …*	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
REACTION-341	Non-functional - Security	Major	*Roles MUST be defined for stakeholders of the Reaction platform, e.g., doctor, nurse, patient, informal carer, …*	*Each person in the Reaction platform has the right to perform a certain set of actions. In order to simplify …*	Roles are defined for every actor from the Reaction use cases.
REACTION-343	Non-functional - Security	Major	Every person represented in the Reaction platform MUST be assigned to one or more roles.	*In order to interact with the Reaction platform, persons need certain rights. As rights are associated with roles, …*	Each person is assigned to at least one role.
REACTION-354	Non-functional - Security	Major	*Data/messages exchanged between the Reaction Host Client and the Reaction Device Hosting Server ...*	*The security of messages transferred between the Reaction Host Client and the Reaction Device Hosting …*	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
REACTION-382	Non-functional - Security	Critical	Privacy enhancing technology	Protect the privacy of users personally identifiable information (PII) and further more personal data.	*It must not be possible for any third party to determine the relation between a measurement and the …*
REACTION-385	Non-functional - Security	Major	*Digital identities for the Reaction platform MUST only be issued or revoked by trusted (third) parties, e.g., …*	*Without a trusted party (TP), anyone could produce its own digital identity and someone relying on such an identity …*	Availability of a party which is trusted to orderly issue and revoke digital identities.

REACTION-400	Non-functional - Security	Major	*Data/messages exchanged between the Reaction Device Hosting Server and the EPR/EHR System …*	*The security of messages transferred between the Reaction Device Hosting Server and the EPR/EHR …*	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
REACTION-403	Non-functional - Security	Major	Each entity in the Reaction platform MUST be representable by a digital identity.	*In the Reaction platform, entities must be uniquely identifiable and recognisable in order to allow repeated …*	Availability of a digital identity mechanism.
REACTION-414	Non-functional - Security	Major	*Communication between the Reaction Hosting Client and the Reaction Device Hosting Server MUST be authentic …*	*It must be assumed that data transmission from the Reaction Hosting Client to the Reaction Device Hosting …*	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
REACTION-415	Non-functional - Security	Major	Each person MAY only perform actions permitted by her role.	*Before a requested action is performed, a control mechanism has to check whether the requested …*	*Availability of a control mechanism which decides whether a requested action may be granted or denied …*
REACTION-431	Non-functional - Security	Major	*Data/messages exchanged between the Reaction Device Hosting Server and the GP EPR SHOULD be authentic …*	*The security of messages transferred between the Reaction Device Hosting Server and the GP EPR …*	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
REACTION-437	Non-functional - Security	Major	Each role MUST be assigned to a set of permissible actions.	*Since some actions are reserved for specific roles it has to be decided which actions are permissible for …*	According to the roles' needs, each role is assigned to a set of appropriate permissions.
REACTION-438	Non-functional - Security	Major	*Communication between the Reaction Device Hosting Server and the GP EPR MUST be authentic (entity …*	*It must be assumed that data transmission from the Reaction Device Hosting Server to the GP EPR and …*	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
REACTION-452	Non-functional - Security	Major	*Communication between the Reaction Device Hosting Server and the EPR/EHR System MUST be authentic …*	*It must be assumed that data transmission from the Reaction Device Hosting Server to the EPR/EHR …*	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
REACTION-480	**Non-functional - Security**	**Major**	**Access control mechanisms should be able to process context information.**	**It may not be sufficient to make access control decisions based only on the role(s) owned by a user. In some use cases, access restrictions depend on context information like time, location, and access history, etc. For example, a physician should only be able to treat patients that are assigned to her own ward. Therefore, access control mechanisms applied in REACTION should be able to process**	**Availability of a control mechanism which decides whether a requested action may be granted or denied based on context information.**

				access rules that rely on context constraints.	
REACTION-497	**Functional - In-hospital pilot application**	**Major**	**Management Functionality for the Identities used in the In-Hospital-Scenario.**	**Administrators must be able to add or modify existing profiles of users. This should be possible in a user-friendly way, i.e., by a management application designed for user management tasks.**	**Availability of a management application**

6.7 Requirements of WP8 – Clinical Practise and Field Trials

6.7.1 Health professional sphere

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-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-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 …*	*Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work …*
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 …*	*In the filed trials evaluation additional workflow shall be assessed by questionnaire or quantitative measurements …*
REACTION-263	Functional - In-hospital pilot application	Major	Improve documentation quality and streamlined access to information	*The registration of all measurements, additional information, decision on treatments, drug …*	*The platform shall allow the registration of all relevant information and its contextualized retrieval. In …*
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-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.
REACTION-325	Functional - Primary care pilot application	Major	The possibility to manage user accounts by user name and password and secure log in and log out	*Administrator of the system shall have full ability to reset user name and password of users, Add , Delete and …*	*The system shall differ between active and suspended user accounts. Active users shall be …*

6.7.2 Medical & environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-281	Non-functional - Legal	Major	*Clinical trials CE- certification OR certification that the medical device fulfils the MDD 93/42/EEC and …*	*For clinical trials applied sensors, devices or software (as medical device) must fulfil the medical device …*	Sensors/devices/software (as medical device) applied in clinical trials fulfil the MDD.

6.7.3 Network management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 …*	*Qualitative or quantitative measurements of productivity, efficiency and cost shall be foreseen in the field trials in …*

6.7.4 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-330	Functional - Primary care pilot application	Major	*Patient access to a library of diseases with questionnaires which help the patient to better manage his lifestyle …*	*An educational library with helpful content about patient's lifestyle shall be created. This library shall contain …*	It should be evaluated by focus group and the test plan.
REACTION-331	Functional - Primary care pilot application	Major	The patient portal's screen shall be easy to read and use	*The interface screen used by patients shall be easily customised, e.g., different font sizes, with clear …*	The user friendliness and useability of the interface shall be evaluated with a focus group and the test plan.
REACTION-416	Functional - Primary care pilot application	Major	Patient education	Continuous education of the patient adjusted to his/her needs.	Educational material is available.

6.7.5 Security and safety management

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 …*	*There should be no corrupted data or loss of information whatever the action of the user is or whenever the …*
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 …*
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-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-321	Non-functional - Operational	Major	Risk analysis	*Risk Analysis has to be started in the very early stage of the development. The identified risks have to be …*	All risks must be in an acceptable range according to the assessment criteria.

6.8 Requirements of WP9 – Socio-Economic Framework

6.8.1 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-141	Non-functional - Legal	Major	The user should have choices regarding all data collection activities concerning his personal data	*User control implies the option to make choices, even if this means the end of an interaction or transaction…*	*Offering the user opt-in and opt-out choices for particular uses of collected data is an element of choice. When …*
REACTION-151	Non-functional - Legal	Major	The user must be able to correct, rectify, block or erase personal data that has been disclosed	*People make mistakes and novel information may render earlier decisions unfortunate. This goes for users and …*	*Levels of ex-post user control that can be distinguished are:* *- rectify: the power to …*
REACTION-475	Non-functional - Legal	Major	Log and log-in system	*One requirement is a 'log-in system' used to identify and authenticate a given person when s/he accesses the …*	EU case law (e.g. I v Finland) D9.2
REACTION-493	**Non-functional - Legal**	**Major**	**The user must be able to correct, rectify, block or erase personal data that has been disclosed - In-Hospital.**	**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.**	**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?**

				This is strengthened in the new proposal on a data protection framework of the EC.	

6.8.2 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 …	The application should cater for configuring at least: - language settings - different sets of symbols …
REACTION-495	**Non-functional - Cultural and political**	**Major**	**It should be possible to configure the application to different socio-cultural settings - Clinician portal.**	**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?**

6.8.3 Medical & environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-470	Non-functional - Look and feel	Major	The potential stigmatising effect of REACTION due to increased visibility should be decreased to a minimum.	*Most diabetic patients experience diabetes as 'discreditable' individuals in terms of stigmatisaiton …*	*Patients should feel that a REACTION like platform will not result in a overall increase in the visibility of their …*

6.8.4 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-145	Non-functional - Legal	Major	The user must consent to the collection of personal data whenever possible	*The user is taken to be an autonomous individual who, in principle, decides what personal data to disclose …*	*The fact that consent is instrumental to a number of fundamental values, means that it has to be revocable …*
REACTION-471	Non-functional - Cultural and political	Major	*Individuals that suffer stigmatisation (including through conditions such as diabetes) often value the …*	*Individual patients often use the opportunity to meet such groups as a coping mechanism for the …*	*Individuals should not feel that a REACTION platform has eliminated their access to other patients and …*
REACTION-494	**Non-functional - Cultural and political**	**Major**	**It should be possible to configure the application to different socio-cultural settings - Patient Portal.**	**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?**

6.8.5 Security and safety management

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 …*

6.9 Requirements of WP10 – Platform Integration and Implementation

6.9.1 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 …*
REACTION-169	Functional - In-hospital pilot application	Major	*Display and input of data should be possible at different locations simultaneously (centrally managed data …*	*A centrally managed data repository enables easy updating of information and access to the latest version …*	Clinicians can input relevant information via tablet PC from every place within the hospital ward.
REACTION-226	Functional - In-hospital 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, …*	*In the design of the data management and of the user interface the electronic fever/sugar chart has to be …*
REACTION-250	**Functional - In-hospital pilot application**	**Major**	**Different contextualization of the patient clinical information**	**Different modes of visualisation with different relevant parameters for decision support shall be foreseen. 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 sugar chart) has to be present.**

6.9.2 Health professional sphere

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 …*	At least to provide a two way communication, e.g. shared white board.
REACTION-85	Functional - Primary care 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 …*	Front-end for therapy-scheme quality presentation
REACTION-96	Functional - In-hospital 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 …*	Inpatient REACTION pilot offers dynamic visualization module for decision support

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 …*	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-153	Functional - Primary care pilot application	Major	Symptoms of diabetes or hyperglycaemia	*At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening …*	Specific design in the user interfaces, ontologies and data management
REACTION-162	Non-functional - Usability	Major	Documentation of user interfaces - in-hospital prototype	Documentation for User Interface of all frontend applications.	User manual for all frontend applications
REACTION-170	Functional - In-hospital pilot application	Major	Selection of a mobile device for In-hospital glucose control based on given requirements	*The devices should be:* *- Lightweight/portable* *- Easy to hold / handle and ergonomic design …*	Devices with desired functionality are available within the project
REACTION-171	Functional - In-hospital pilot application	Major	Data input application for In-hospital glucose control	*The system should ask for data entry of relevant parameters.* *…*	Data entry system will be available for In-hospital decision support system with devices (tablet PC)
REACTION-179	Functional - Primary care 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 …*	*The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-…*
REACTION-181	Functional - Primary care pilot application	Major	Decision on therapy in Primary care environment	*At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and …*	*Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user …*
REACTION-189	Functional - Primary care pilot application	Major	Other implications for type I diabetic patients	*Type I diabetic patients may have signifcant risk of developing complications (neuropathy, nephropathy, …*	*In the care program, management of diabetes (through insulin) should be accompanied by the …*
REACTION-230	Functional - In-hospital pilot application	Major	Therapy adjustment in In-hospital environment	*Supervision of glycaemia and according treatment is performed once a day. Adaptation of therapy or …*	Every day an evaluation report has to be stored and available in the In-hospital application
REACTION-234	Functional - In-hospital pilot application	Major	Determination of health status in In-hospital environment	*At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual …*	*After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy …*
REACTION-235	Functional - In-hospital pilot application	Major	Therapy scheme in In-hospital environment registered immediately after the patient enrolment	*The therapy scheme is continued for patients with known diabetes and defined and started for patients …*	*The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the …*
REACTION-241	Functional - In-hospital pilot application	Major	Management of hypoglycaemic episodes in In-hospital environment	*The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, …*	*A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow …*

REACTION-285	Functional - In-hospital pilot application	Major	User interface for the clinical data stored in the In-hospital environment	*The user interface shall allow the insertion, modification and visualization of the clinical data registered at the …*	There shall be a user interface which allows the insertion and the update of all the listed parameters.
REACTION-326	Functional - Primary care pilot application	Major	*The registration of the enrolled patient on to the system shall be accured manually by the Care giver …*	*The clinician shall be able to monitor the patient's input data .The patient's account will be managed by the …*	NON
REACTION-492	**Functional - REACTION platform**	**Major**	**Components should reflect national requirements, policies, guidelines or provisions.**	**National organisations can provide specific requirements, policies and guidelines for health care systems. They may also make national provision for health care services ans IT that are required to be used. Components should be flexible to be substituted to match these national requirements. An example is the SMS messaging service provided by NHS on its secure network.**	**Components**
REACTION-496	**Non-functional - Usability**	**Major**	**Documentation of user interfaces - primary care prototype**	**Documentation for User Interface of all frontend applications.**	**User manual for all frontend applications**

6.9.3 Internal communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 …*	For each interface/interconnection specify the data content and physical material content.
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 …*	*Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician …*	*Writing complete and understandable manuals for each tool of the platform. The manuals should be shared …*
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 …*	*For each application, developers must ensure that error messages should be brief, easy to read, …*
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 …*	*Criteria are different depending on the user action. For time-critical actions the response should be …*

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 …*	A server for the containment of the components will be set-up

6.9.4 Medical & environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-225	**Functional - In-hospital pilot application**	**Major**	**PoC device for blood glucose measurement will be used by the in-hospital glucose management system.**	**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.**	**a) The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. b) The acquired measurements will be manually inserted using the front-end in the tablet PC and stored in the REACTION data management.**

6.9.5 Network management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 interactions have to be …*	*Simulated components performing the same operations with exactly the same interface have to be …*
REACTION-138	Non-functional - Performance	Major	*The platform shall be expected to operate within reasonable maintenance effort for all the duration of …*	Problems at the field trials should be minimized	Problems signalled at the field trials should be under a fixed threshold

6.9.6 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-8	Functional - Primary care pilot application	Major	User interface for manual entry of lifestyle data	*To supply and support feedback on effectiveness of lifestyle behaviour and therapies to clinicians and …*	User interface exists.
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 …*

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 …*	No complex user interfaces, the user should be familiar with the applications in short time (training is foreseen)
REACTION-77	Functional - Primary care pilot application	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-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 …*
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 …*	User learning curve (especially with elderly people) should be very quick
REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	*Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia …*	*There should be a user-friendly interface for the registration of significant event and also a …*
REACTION-190	Constraint - Implementation Environment	Major	*In the Primary care environment the medications are usually self-administered by the patient himself or by …*	Usual practice for diabetic patient outside of 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 …*
REACTION-245	Functional - In-hospital pilot application	Trivial	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 …*	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.
REACTION-247	Functional - In-hospital pilot application	Major	Mobile access point in wards of In-hospital environment	*Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile …*	*User interfaces have to be targeted on mobile devices like tablet PCs. One specific type of mobile device for …*

6.9.7 Security and safety management

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 …*	*For any "intelligent" action of software component, a properly published manual shall exist justifying its …*
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 …*	The functional test should include specific tests in order to verify such circumstances
REACTION-65	Functional - REACTION platform	Major	System availability	*The system should be continually monitoring and gathering data about the*	The end user applications and the devices in the vicinity of the patient should always

				patients status with no …	operable
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.

6.9.8 Service orchestration

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-223	Functional - In-hospital pilot application	Major	Basic workflow for insulin treatment in In-hospital environment	*The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or …*	The basic workflow should be easily accessible in the REACTION In-hospital application
REACTION-224	Functional - In-hospital pilot application	Major	Basic workflow is repeated 4 times a day in In-hospital environment	*The first workflow is in the morning a little before breakfast time (administration of bolus insulin), the …*	These 4 loops should be easily identified in the In-hospital application

6.9.9 Third-party system interfaces

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 …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-172	Functional - In-hospital pilot application	Minor	*The system should automatically transfer measurements from the POCT devices into the …*	*The system should automatically transfer measurements from the POCT devices into the …*	POCT data is transmitted within short time to the platform
REACTION-174	Functional - In-hospital pilot application	Blocker	*The system must provide interfaces to HIS and implement data management and data structures for …*	*The platform must offer interface to HIS; moreover the system needs data structures and data management …*	Data structures and data management functionality
REACTION-258	Functional - In-hospital 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 …*	*The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their …*
REACTION-443	Functional - REACTION platform	Major	Data exchange with third party systems	*Ideally integrates information from outside the REACTION platform (e.g. Laboratory Information Systems in …*	Should be able to import and export data in an interoperable way (e.g. HL7) to third-party systems.

6.10 Requirements of WP13 – Training

6.10.1 Patient sphere

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

Lessons Learned (58 in the third year) and the 3 watch reports have induced changes in the requirements which have resulted in 13 new requirements and 5 updated requirements (no requirement was deleted). Furthermore, 51 requirements were resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce (other 24 during the first year and other 86 during the second year were resolved with these resolutions). A full list with these 51 requirements is shown in the table below.

The third-year changes in the component list and the assignment of each requirement to only one component together with the identification of a WP of major impact allowed for the allocation of each requirement to one WP and one component, thus simplifying the list provided in the previous chapter compared to the one published in the first internal deliverable ID2-9-1 "*Updated requirements report 1*". This provides an improved overview of requirements for the WP leaders.

The work performed during the first year was mainly dedicated to the development of a prototype for the in-hospital environment and to architectural studies and general component development. During the second year major focus was put on the primary care environment from the detailed specifications to the development of the first primary care prototype, achieving a deeper understanding of the requirements for the primary care domain. During the third year, the prototypes for the clinical trials in the in-hospital and in the primary care environments were developed and deployed and the more frequent interaction with the end users allowed a further refinement of the requirements.

The result is that at the end of the third iteration cycle, the total number of REACTION requirements registered in JIRA is 461 (they were 437 at the end of year 2 and 281 at the end of year 1). It can be seen that 16% of the requirements are "In progress", while only one requirement is still "Open". 5% of the requirements are in the "Part of specification" status, thus they have passed the initial quality check and are waiting to be worked on. 25% of requirements are closed while 53% are resolved (they were 21% and 16% at the end of year 2, respectively).

The progress compared to the previous years is significant. In fact, the number of requirements resolved or closed is now 78% (it was 37% in year 2 and 14% in year 1). A similar progress can be also observed in the reduced amount of requirements on which work has not started yet which is only 5% while it was 27% at the end of year 2 and 49% at the end of year 1.

A total of 201 requirements (~69% of the effective requirements) have been implemented at the end of the second year, but 183 are still waiting for user validation, while 18 have been already validated and then closed. That clearly describes the huge implementation work finalized in the course of the third iteration period since only 53 requirements (~16% of the effective requirements) had been implemented at the end of the second year, with 40 waiting for user validation and 13 validated and then closed. The reported progress is also an indication of the successful finalization of the in-hospital and primary care prototypes and their consequent deployment in the clinical sites for the start of the field trials.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion	Resolution
REACTION-15	Functional - Primary care pilot application	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.	Out of scope
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.	Cannot be implemented
REACTION-97	Functional - In-hospital 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	Out of scope
REACTION-101	Functional - Primary care 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	Out of scope
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	Duplicate
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 requirement must be updated and better specified in the light of the Proposed Data Protection Regulation COM(2012) 11 final: While it is difficult to ensure that users are and remain aware of the essential events, processes, stakeholders and attributes of the collection and use of personal data, the controller should adopt transparent and easily accessible policies with regard to the processing of personal data and for the	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?	Duplicate

				exercise of data subjects' rights. Any information and any communication relating to the processing of personal data to the data subject should be made available in an intelligible form, using clear and plain language, adapted to the data subject.		
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	Duplicate
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?	Duplicate

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?	Out of scope
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)?	Out of scope
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?	Out of scope
REACTION-175	Functional - In-hospital pilot application	Minor	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	Out of scope
REACTION-184	Functional - Primary care 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.	Out of scope
REACTION-185	Functional - Primary care pilot application	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	Out of scope

REACTION-191	Functional - Primary care 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.	Duplicate
REACTION-192	Functional - REACTION platform	Major	The system should provide configurable 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.	Out of scope
REACTION-194	Functional - Primary care 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	Out of scope
REACTION-195	Functional - Primary care pilot application	Major	Data management should handle different types of complications for the diabetic patients in the Primary care environment.	The complications considered for the diabetic patient in the Primary care environment are: cardiovascular, renal, ophthalmology, management of foot and neuropathy problems.	In the ontology, user interfaces and applications these complications have to be present	Duplicate
REACTION-196	Functional - Primary care pilot application	Major	End of process for the diabetic patient in the primary care 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.	Out of scope
REACTION-200	Functional - Primary care pilot application	Minor	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	Out of scope
REACTION-211	Functional - Primary care 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	Duplicate
REACTION-212	Functional - Primary care 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	Out of scope
REACTION-213	Functional - Primary care pilot application	Major	Outcomes of the clinical case conference shall be social intervention (changes	The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in	The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and	Nonsense

			in non-pharmacological treatment and education) and therapeutic intervention (changes in therapy).	the RPM schema have to be allowed	pharmacological treatment	
REACTION-216	Functional - Primary care 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).	Out of scope
REACTION-240	Functional - In-hospital pilot application	Trivial	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	Out of scope
REACTION-243	Functional - In-hospital pilot application	Trivial	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.	Out of scope
REACTION-244	Functional - In-hospital pilot application	Minor	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.	Out of scope
REACTION-324	Functional - Primary care pilot application	Major	Providing a secure log in and log out for the user	The system shall be protected with a secure login for each user on the web portal, users shall be required to log out upon the end of the task. The system shall have a clear hierarchy for different type of users (Patient, Clinic, etc) and each user logging into the system shall be logged into the correct user type.	The system shall automatically log out the user when being dormant longer then a predefined time. The system shall be validated according to the predefined test plan.	Duplicate
REACTION-333	Functional - Primary care pilot application	Major	Devices should be single communication technology	Single communication technology will reduce cost of end system and simplify use for end user	Device specification	Conflicting

REACTION-357	Functional - Primary care pilot application	Major	Power management techniques to decrease power consumption	Power management techniques can be used to decrease the power consumed by sensors.Some non-critical sensors can power down when activity is not required, waking up in time to receive and transmit messages as necessary.	The functional test should include specific tests in order to ensure that power consumption is at an acceptable level.	Out of scope
REACTION-360	Functional - REACTION platform	Major	Mechanistic model and rules for insulin dose prediction (primary care).	A physiologic model and calculation rules/algorithm must be stored for insulin dosing support.	Necessary models and rules are defined and stored.	Out of scope
REACTION-361	Functional - REACTION platform	Major	Baseline and clinical history handled in the data management	Immediately after patient recruitment, his/her baseline and clinical history has to be entered in the platform. This can be done by extracting this information from the HIS/EPR (if available and interoperable) and completing manually (through a proper UI) the missing information.	The data management should allow the storage of baseline and clinical history and these data can be extracted from the HIS/EPR (if available and interoperable).	Cannot be implemented
REACTION-369	Functional - In-hospital pilot application	Major	Storage of hyperglycaemic or hypoglycaemic episodes	Reasons for any cases of 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. Should the blood glucose level rise above a certain threshold, a hyperglycaemic episode has occurred. The reasons for such an episode have to be registered along with ensuing changes in treatment.	Specific procedures have to be present for the management of hyperglycaemic or hypoglycaemic episodes. These procedures shall also allow for the recording of the significant parameters and actions.	Out of scope
REACTION-378	Functional - Primary care pilot application	Major	Energy friendly data aggregation for mobile devices	Aggregation techniques should be used for reducing the overall data traffic to save energy. Depending on the need for a real-time response, the redundancy of the data, etc., specific data-propagation strategies should be defined.	The functional test should include specific tests on battery consumption using different communication methods with the sensors.	Out of scope
REACTION-386	Functional - REACTION platform	Minor	Medical knowledge base	Contains the relevant medical knowledge or is able to connect to external sources, e.g. evidences, drug information etc.	A medical knowledge base is built.	Out of scope
REACTION-389	Functional - Primary care pilot application	Major	Different stages for the patient management in primary care environment.	Different actions have to be performed at different stages (newly diagnosed / medication titration / investigative stage, ongoing management) of patient management in primary care environment.	The data management has to allow the storage of the stage of management for each patient.	Duplicate
REACTION-393	Functional - Primary care pilot application	Major	Management of referrals to and responses from other physicians (via EHR interface).	Referrals are part of clinical pathways and treatment plan. Referrals should be documented and the recommendation of referrals should be considered in decision support rules... Summary letters and other "responses" from other healthcare professionals should be managed. - Optimal solution would be an interface to a regional or national EHR	Referrals can be documented and are considered in decision support, summary letters can be received via an appropriate data interface. The system should transfer the following patient demographic data and selected clincial information to the care plan. • Name • Address	Out of scope

				infrastructure (e.g. IHE-XDS) from where documents can be received.	• Telephone Number • Gender • DOB • NI Number • Next of Kin	
REACTION-396	Functional - Primary care pilot application	Major	Consider patient's preferences, wishes and decisions	The data set should allow documentation of patient's preferences, wishes and decisions. This information should also be considered in the evaluation of rules etc., so that no recommendations against the will of the patient are made.	Patient's preferences, wishes and decisions can be documented and rules consider this data.	Out of scope
REACTION-410	Non-functional - Performance	Critical	Collecting measured data ("many to one" traffic pattern)	Different sensors can have different acquisition rates and relay data at different frequencies. Specific policy for data aggregation/fusion has to be defined.	Check the measurements collected by different sensors (times & values) and evaluate if there are critical delays.	Cannot be implemented
REACTION-424	Functional - REACTION platform	Major	Contextualization of measurements	The availability of all measurements (and mainly blood glucose levels) shall be accompanied also by the context of the measurements.	Measurements before any usage have to be contextualized.	Duplicate
REACTION-430	Functional - REACTION platform	Major	REACTION Hosting client scheduler	It should be possible to schedule activitites on the Reaction side, for instance when to send measurements, and/or, reminders to patients	Client schedules can be defined and stored	Duplicate
REACTION-433	Functional - REACTION platform	Major	Results of screening, symptoms and types of diabetes or hyperglycaemia.	At the diabetic patient enrolment his/her symptoms or results of screening confirming presence of 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).	Possible classifcations should be present in the knowledge base & ontology and in the database fields for multiple selections from the classifications. Does the data need to be stored at each subsequent visit or evaluation?	Out of scope
REACTION-434	Functional - In-hospital pilot application	Major	Interface to Lab Information System (LIS) for glucose data import	In order to perform decision support, the blood glucose value has to be imported from the Lab Information System (LIS). A standardized interface from inpatient pilot application to the LIS has to be defined. HL7 would be a suitable standard.	Standardized Interface (e.g. based on HL7) to Lab Information System (LIS) for glucose data import.	Out of scope
REACTION-445	Functional - In-hospital pilot application	Major	Registration of specific interfering drugs (including their dosage)	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). Their administration should be registered.	The data management shall allow for the insertion of specific interfering drugs (including their dosage).	Duplicate

REACTION-457	Functional - REACTION platform	Major	Privacy Enforcement Point	A component that could be added to the client side would be some kind of 'Privacy Enforcement Point'. Such a component could be examining outgoing data for information that the client did not authorize to be sent, yet. That is, the component would match the client's consents (with respect to the processing of her data) with the the kind of information from the outgoing message and, possibly, delay the transmission of certain information which the client has not decided on. The component could stay hidden in other components for the time being, such as the Network Manager on the client side. The Privacy Enforcement Point should perform as a counterpart of the Consent Manager at the Reaction Device Hosting Server.	Privacy Enforcement Point is available for the REACTION client side.	Out of scope
REACTION-458	Functional - Primary care pilot application	Major	Investigative stage	An investigative stage is required for all newly diagnosed diabetic patients. This stage (the duration of wich is determined by clinicians) is used to: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, carry out patient education , and reassure patients concerned about their blood sugar levels.	Specific fields have to be present in ontologies and data management.	Out of scope
REACTION-473	Functional - REACTION platform	Critical	All public networks (e.g. WIFI) created as a result of REACTION should have as low a visibility and as high a level of security as is technical possible.	The lower the visibility of such equipment (in terms of network visibility) the less the chance that an individual's condition might become apparent to those who do others in situations where the parent does not wish this to happen. This is important in connection to issues of stigmatization - see task 9.2	Networks should not be unnecessarily visible and should be secure.	Cannot be implemented
REACTION-474	Non-functional - Legal	Major	Data breach notification duty	Data Breach Notification requirements are not explicitly foreseen in the Data Protection Directive. However, a number of countries, such as Germany and Norway, have introduced a notification requirement for data breaches. In addition, the Article 29 Working Party has argued that an extension of personal data breach notifications, beyond telecoms firms, to Information Society Services is necessary given the ever increasing role these services play in the daily lives of European citizens, and the increasing amounts of personal data processed by these services, including access to medical records.	The requirements in the proposed regulation have to be fulfilled as soon as the new regiulation will be implemented. This is a requirement for the future. The exact criteria cannot been foreseen yet.	Cannot be implemented

				Accordingly, the Proposed Data Protection Regulation foresees the duty of notification of a data breach. It is therefore very likely that there will be a general European-wide data breach notification in future. Organisational rather than technical requirement. This applies to future structures in REACTION which do not exist at the moment. Therefore, it is an issue which will be very relevant in the future but cannot be solved at the moment. - A a due date cannot be specified!		
REACTION-476	Non-functional - Legal	Major	Data protection impact assessment	Data protection impact assessments are to be carried only in certain circumstances, e.g., when data processing operations 'are likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes.' Recital 71 indicates that the requirement to conduct them should apply in particular 'to newly established large scale filing systems, which aim at processing a considerable amount of personal data at regional, national or supranational level and which could affect a large number of data subjects.' The foregoing suggests that an institution operating a system such as REACTION, for instance a hospital or a national health service, should carry out an impact assessment. This applies to future structures in REACTION which do not exist at the moment. Therefore, it is an issue which will be very relevant in the future but cannot be solved at the moment. - A a due date cannot be specified!	Procedures according to the proposed regulation on data protection have to be implemented and documented as soon as the regulation comes into force.	Cannot be implemented
REACTION-477	Non-functional - Legal	Major	Liability of controller for damages due to unlawful processing	REACTION could consider the allocation of compensation or insurance schemes in case errors occur in the processing of medical data. Organisational rather than technical requirement. This applies to future structures in REACTION which do not exist at the moment. Therefore, it is an issue which will be very relevant in the future but cannot be solved at the moment. - Therefore a due date cannot be specified!	Established compensation or insurance schemes for errors in data processing.	Cannot be implemented
REACTION-479	Functional - Primary care	Minor	Support identification of "patients at risk" for need for	Support identification of "patients at risk" for need for insulin treatment in primary care	If a diabetic patient is not on insulin therapy, the platform shall be able to	Out of scope

	pilot application		insulin treatment in primary care.	(when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of risk.	estimate the risk for the particular patient to become insulin-dependent.	

8 Definitions and Abbreviations

ADK	Application Development Kit
AGC	Automatic Glucose Control
ANT+	Wireless interoperable technology for monitoring devices from ANT+ Alliance
BAN	Body Area Network
CE	Conformité Européenne
CGM	Continuous Glucose Monitor
DCCT	Diabetes Control and Complications Trial, a landmark medical study conducted by the United States National Institute of Diabetes and Digestive and Kidney Diseases
DOB	Date of Birth
DSS	Decision Support System
EC	European Community
eDSS	Electronic Decision Support System
EEC	European Economic Community
EHR	Electronic Health Record
EN	European Norm
ePatch	Electronic Plaster
EPR	Electronic Patient Record
EU	European Union
GCA	Glucose Control Algorithm
GCS	Glucose Control Suite
GIM	Glucose-Insulin metabolism
GM	Glucose measuring
GP	General Practitioner
GPS	Global Positioning System
GSM	Global System for Mobile Communications
GUI	Graphical User Interface
HbA1c	Glycated Hemoglobin
HIS	Hospital Information System
HL7	Health Level 7
ICT	Information and Communications Technology
ICU	Intensive Care Unit
IEEE	Institute of Electrical and Electronics Engineers
IHE-PCD01	Integrating the healthcare enterprise - patient care devices technical framework version1
IHE-XDS	Integrating the healthcare enterprise - cross-enterprise document sharing
IR	Infrared
ISF	Interstitial fluid
ISO	International Organization for Standardization
IT	Information Technology
IV	Intra-venous
JIRA	Issue and Project Tracking Tool by Atlassian
LIS	Laboratory Information System
LL	Lesson Learned
M2M	Machine-to-machine
MDD	Medical Device Directive
MPC	Model predictive control
MS	Microsoft
NHS	National Health Service
NI	National Insurance
NLP	Natural Language Processing
OAD	Oral Antidiabetic Drug
PAN	Personal Area Network
PBPK/PD	Physiology-based pharmacokinetics/pharmacodynamics
PC	Personal Computer
PID	Proportional integrative derivative
PII	Personally Identifiable Information
PoC	Point-of-Care
POCT	Point of Care Technology

RBAC	Role-Based Access Control
RFID	Radio Frequency Identification
RPM	Remote Patient Monitoring
RTD	Research and Technological Development
SC	Subcutaneous
SDK	Software Development Kit
SGC	Safe Glycaemic Control
SMS	Short Message Service
SNR	Signal to Noise Ratio
SOAP	Simple Object Access Protocol (xml protocol)
TBD	To be defined
TGC	Tight Glucose Control
TP	Trusted Party
UI	User Interface
USB	Universal Serial Bus
WAN	Wireless Area Network
WAN-IF	Wireless area network interface
WiFi	A technology that allows an electronic device to exchange data wirelessly
WP	Work Package