Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

REACTION (FP7 248590)

ID2-9-2 Updated requirements report 2

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Table of Content

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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 2, and the current JIRA workflow management. The complete list of the requirements at the end of iteration cycle 2 is reported in a separate appendix.
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0.1	F. Chiarugi, D. Manousos, M. Spanakis	2012-03-02	ToC
0.2	F. Chiarugi	2012-05-23	Analysis of watch reports, JIRA statistics and change requests for the various WPs, list of requirements x WP and component
1.0	F. Chiarugi	2012-07-11	Incorporation of changes requested by the internal reviewers

Internal review history

Reviewed by	Date	Comments made
H. Udsen (IN-JET)	2012-06-28	Approved with comments
P. Rosengren (CNET)	2012-07-10	Approved with comments

1 Introduction

1.1 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.

1.1.1 Background and Context

The background and context of the work performed and described in this deliverable follow from deliverable ID2-8-3 “Change request and re-engineering report 2” describing the change requests and requirement re-engineering report at the end of the first iteration cycle. The work performed in cooperation with the WP leaders for the finalization of the second requirement revision, operated at the end of the second iteration cycle, is documented in this deliverable.

1.1.2 Target Audience

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

1.1.3 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. At the same time it provides also hints about the most relevant actions related to the requirement management that will be performed during the next iteration cycle.

1.1.4 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 a next prototype. Thus, the requirement management is a dynamic on-going process that will evolve and will be completed during 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, will be performed in the context of a user centred design approach.

The scope of this deliverable is restricted to the requirement revision at the end of the second iteration cycle. Nevertheless, it provides also some information about the main actions related to the requirement management that will be performed during the third iteration cycle.

1.2 Outline

The remaining document is structured as follows:

Section 2 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.

In Section 3, the suggested changes are presented and the implemented changes are finally described. In Section 4, the planned actions that will be performed on the requirement management during the next iteration cycle are presented.

In Section 5 the lists of the requirements per WP and component are shown and, finally, in Section 6 the main conclusions are reported.

The complete list of requirements is available in a separate appendix ID2-9-2 “Updated requirements report 2 (appendix)”.

2 Main Outcomes from the Second 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 watch reports including their literature search.

More details about the *Lessons Learned* can be found in ID2-8-3 “Change request and re-engineering report 2”.

A total of 64 *Lessons Learned* has been reported in the second 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.

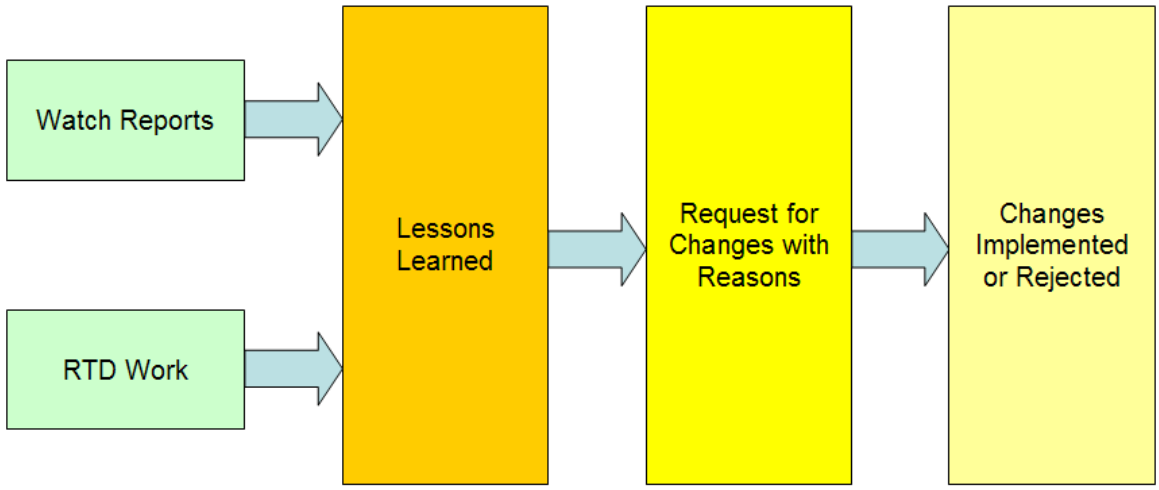

Figure 1: The requirement revision process at each iteration cycle

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. It is worth noting that also the main outcomes coming from the watch reports and with immediate impact in the next iteration cycle have been translated into specific *Lessons Learned* related to a specific WP.

2.1 Outcomes from the Watch Reports

During the second iteration cycle three watch reports have been produced and delivered 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*. Here below the main outcomes and their implications for the requirements will be discussed.

2.1.1 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 focused strategy (the one selected in REACTION primary care field trial) has greatest overall impact.

Further significant issues emerging from this watch report are:

- Little evidence 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
- There is no clearly defined treatment regimen 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
- Studies demonstrate that self-management of blood glucose produces significant improvements in clinical outcomes, including significant reduction of HbA1c
- 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 benefit from the use of CGM over self-monitoring of blood glucose in terms of HbA1c reduction, speed of reduction and lowering of 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 on the basic technology of the insulin pen, and no manufacturers have reported pens capable of sending information
- Resarch 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-permanetly 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 the performing of the 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)
- 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 (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

2.1.2 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 & symptoms, medication & side effects, diet & 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 cannot be established in the home 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 side 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 have to be used for the display of the monitoring results

2.1.3 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 entrance in force in all member states of the Amendment 2007/47/EC to the Medical Device Directive (MDD) 93/42/EC and its implication in 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 maintainance 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 of 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 (more than at a 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 in 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

2.1.4 Implications for the Requirements

The main implications for the requirements have to be evaluated also in the subsequent iteration cycles, once prototypes for the in-hospital as well as the primary care environments will be available.

At this second iteration only the main issues coming from the watch reports have been considered and used as *Lessons Learned*. The 5 *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). 3 *Lessons Learned* collected in WP4 and 1 in WP5 are specifically referred to Continua Alliance guidelines and the recommended standards which are main issue of the technology watch report but also of the market and regulatory standards watch reports. 2 *Lessons Learned* collected in WP10 and 1 in WP2 are specifically referred to the product life cycle management and to the requirement management as a part of the product life cycle management which are main issues of the market and regulatory standards watch reports.

Other issues, once consolidated during the third iteration cycle, will be accurately evaluated to ensure that they are properly covered by the existing requirements or if any change or addition to the existing requirements will be necessary.

2.2 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. WP2, WP8 and WP9) generated some *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 second 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 the implicit *Lessons Learned* collected in the activities performed in the second year iteration where several cross checks between the technical people and the clinical people were performed in order to test very frequently the prototypes in all phases of their design, implementation and tests. For example, for the primary care prototype the consolidation of the detailed specification phase allowed a clearer definition of the stakeholders' real needs and of the related requirements.

More details about the explicit *Lessons Learned* can be found in the detailed analysis contained in ID2-8-3 "Change request and re-engineering report 2". Here below a few significant examples have been reported.

A *Lesson Learned* in WP2 refers to the fact that detailed specifications for environments envisaged in the project were in some cases scheduled late in the project timeplan and impacted significantly in the review of the collected requirements changing some of them or putting some of them out of scope.

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 of signal drift due to thermal or differential heating.

Another *Lesson Learned* in WP4 and a similar one in WP5 refer to the high effort for the implementation of the standards recommended by Continua Alliance guidelines resulting in only a limited competitive advantage since the Continua certified devices are still very few.

A *Lesson Learned* in WP6 refers to the adoption of a uniform approach for the development of the risk models and this approach should be based on web service in order to facilitate the integration in the higher level shell (risk assessment and decision support system).

In WP8 the *Lessons Learned* are mainly referred to the first outcomes from the in-hospital field trials confirming that the developed prototype, even if not able yet to satisfy the main in-hospital glucose management requirements, has laid the foundation for attaining improvements in the glucose management in non-ICU hospital wards.

In WP9 several *Lessons Learned* focus on the stigmatization issue recommending a design able to avoid or minimize as much as possible stigmatization for the end user.

In WP10 an important *Lesson Learned* is focused on the highest flexibility in the selection of the development tools and technologies from all contributing partners. This approach exploits greatly the expertise of each partner but at the same time also increases the integration complexity.

2.2.1 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 3 the impact of the *Lessons Learned* on the requirements in each WP will be described.

2.3 Current Status of the Requirements and Statistics

Before analyzing the status of the requirements at the end of the second year and the related statistics, it is necessary to resume the main activities that were performed in the JIRA administration and were anticipated in ID2-9-1 “Updated requirements report 1” released at the end of the first iteration cycle. These activities consisted in the use of a single main project for the high-level requirement management, the optimization of the requirement workflow and the changes in the component list in order to better reflect the changes in the platform architecture.

2.3.1 High-Level Management of the Requirements

An effective high-level management of the REACTION requirements with the JIRA tool requires having all requirements contained in a single comprehensive project.

For this reason all the existing requirements of the two sub-projects “REACTION data management model requirements” and “REACTION Security Requirements” were individually analyzed and, when relevant, moved to the main “REACTION requirements” project. This action increased significantly the total number of requirements compared to the end of the first year.

2.3.2 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”.

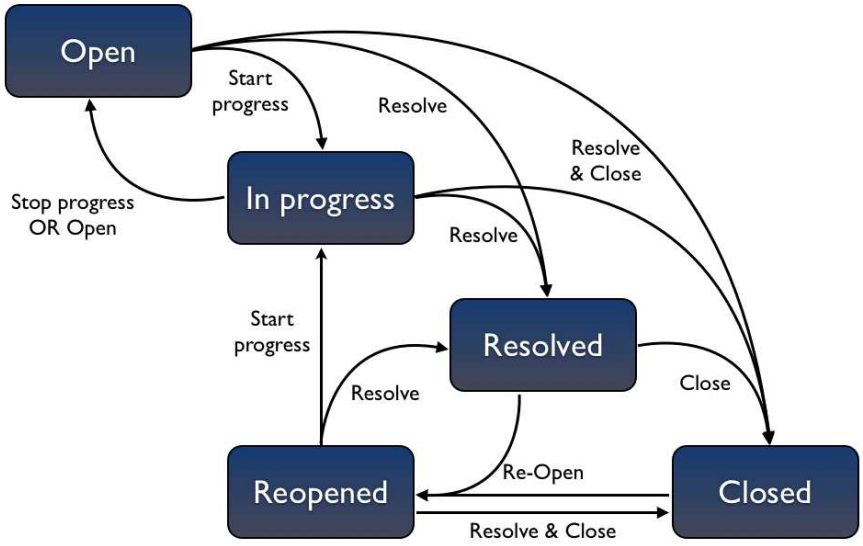

Figure 2: Default workflow scheme

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”.

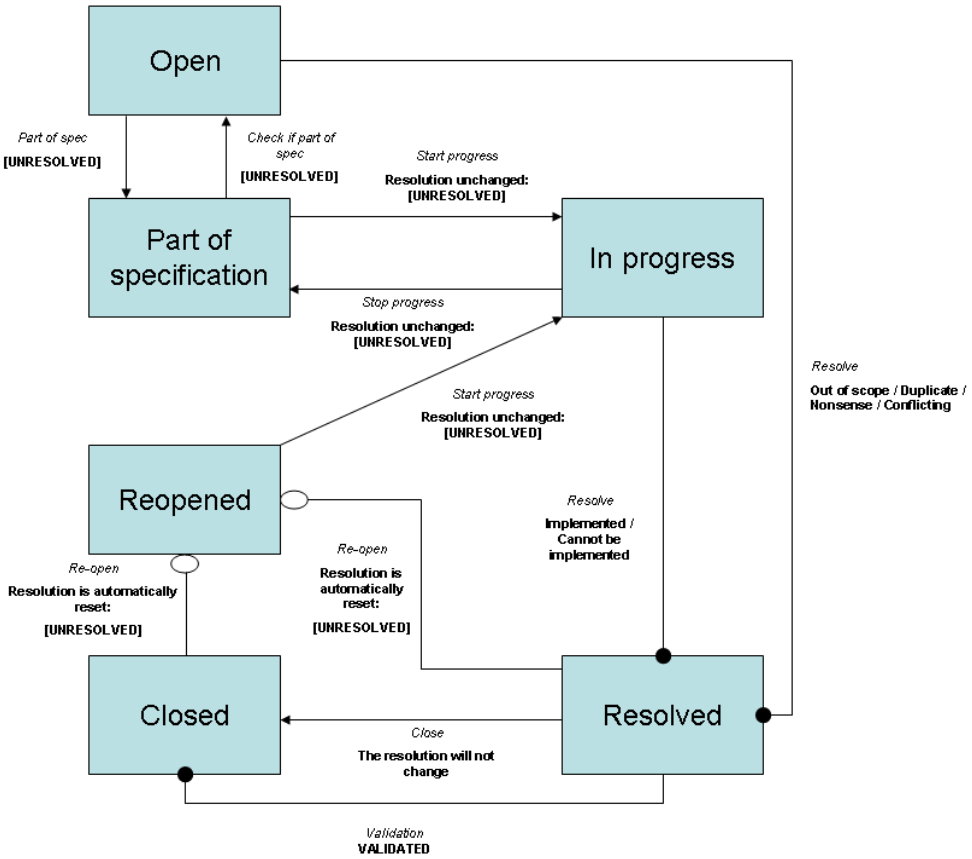

Figure 3: The new workflow

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 (these might be added to the list during the third year).

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”).

2.3.3 Changes in the Platform Architecture and Impact in 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 make 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)

The new list of components is:

- 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 EPR, LIS, 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.

2.3.4 Requirement Statistics and Progress

At the end of the second iteration cycle, the REACTION requirements registered in JIRA consists of 437 requirements in total (they were 281 at the end of year 1). From the statistics in Figure 4 it can be seen that 36% of the requirements are in the progress of being worked, while 6% of all requirements are still "Open", i.e. either they have not passed the initial quality check or have not been assigned for implementation. 21% of the requirements are in the "Part of specification" status, thus they have passed the initial quality check and are ready to be worked on. 21% of requirements are closed while 16% are resolved.

The progress compared to the end of the first year is relevant. In fact, despite an increment in the total requirements of 56% compared to the first year and mainly due to the incorporation during the second year of the JIRA sub-projects in a unique main requirement project, the number of requirement resolved or closed is 37% (it was 14% in year 1). A similar progress can be also observed in the reduced amount of requirements on which any work has not started yet (27% in year 2 while it was 49% in year 1).

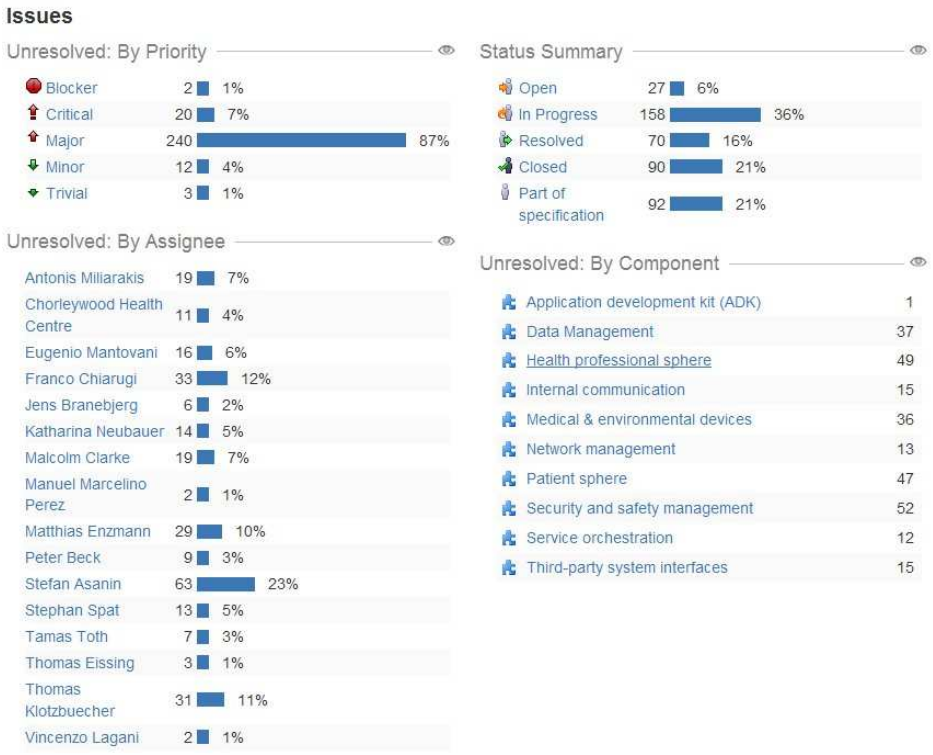

Figure 4: The REACTION requirements progression

Requirements are classified as functional, non-functional or constraints as reported in D2-5 “Initial requirements report”. In Figure 5 the classification according to the requirement type is shown. One can see most requirements are functional, while very few requirements are constraints.

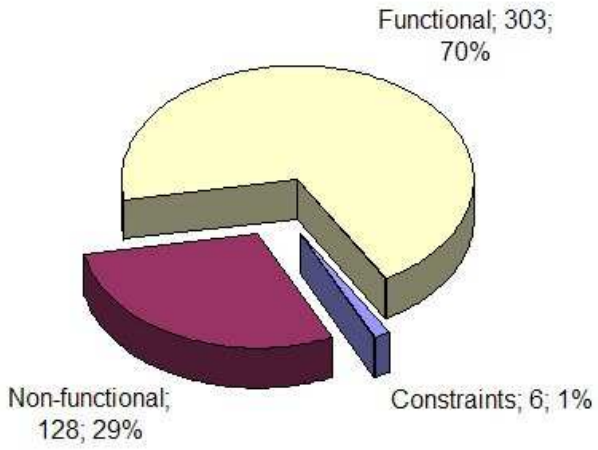

Figure 5: The REACTION requirements classified by requirement type

The classification of functional requirements based on their subtype is shown in Figure 6. One can see a better balance of the number of requirements for the 3 different categories, since the detailed specifications of the primary care environment have also been made available during the second year of the project. It is worth remembering that at the end of the first iteration cycle most functional requirements were related to the in-hospital environment since this environment was at a higher stage of development, while detailed specifications for the primary care environment were not available.

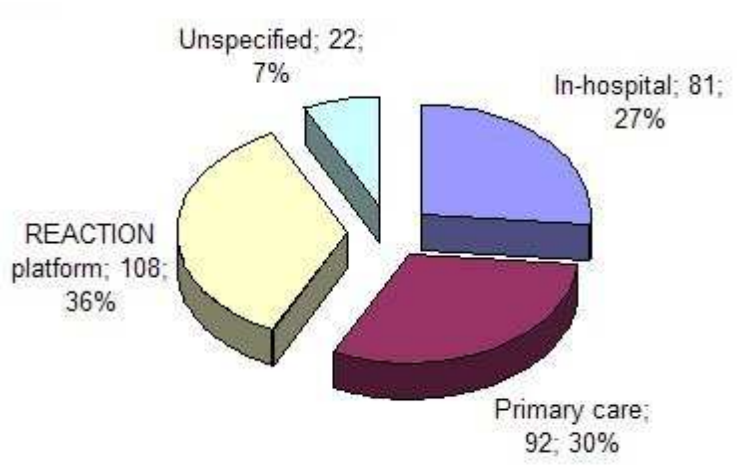

Figure 6: The REACTION functional requirements classified by requirement subtype

The classification of non-functional requirements based on their subtype is shown in Figure 7. One can see that also in this second 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.

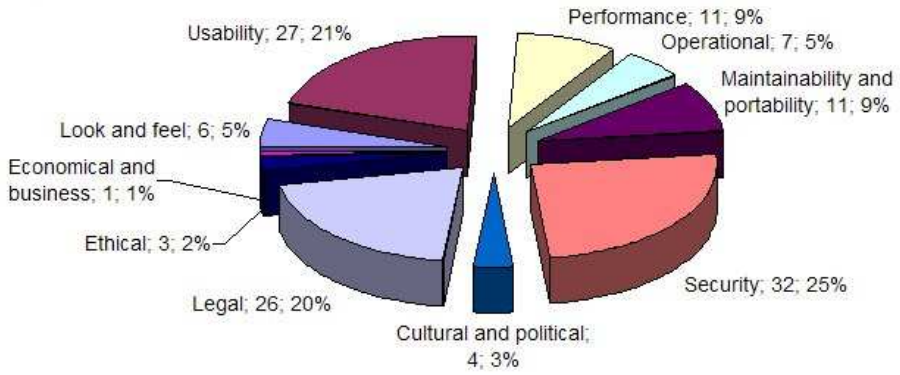

Figure 7: The REACTION non-functional requirements classified by requirement subtype

Finally, in Figure 8 the classification of constraints based on their subtype is shown.

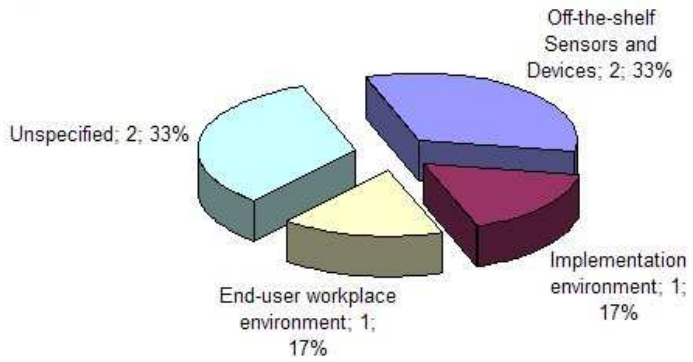

Figure 8: The REACTION constraints classified by their subtype

Requirements follow the workflow associated to the REACTION requirements JIRA projects as they evolve through the various statuses.

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

In Figure 9 the status of all REACTION requirements is presented:

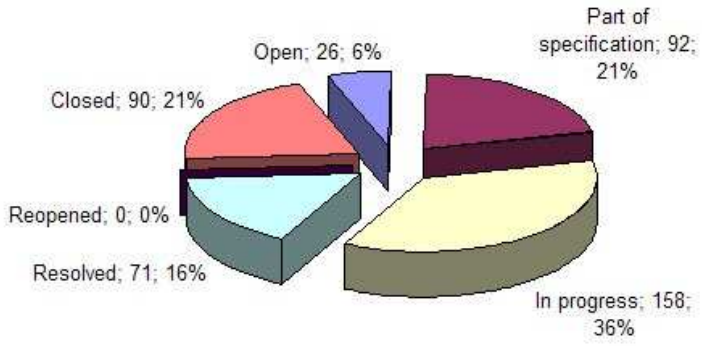

Figure 9: The status of all REACTION requirements at the end of the second iteration cycle

Most requirements are either “In progress”, “Resolved” or “Closed”, while only 26 requirements (~6%) are still in the “Open” (or “Reopened”) status and some of them are waiting either for a proper review of their formulation or for a quality check in order to decide if they are really part of the specifications or out of the scope.

The “Open” or “Reopened” requirements are grouped by components in Figure 10.

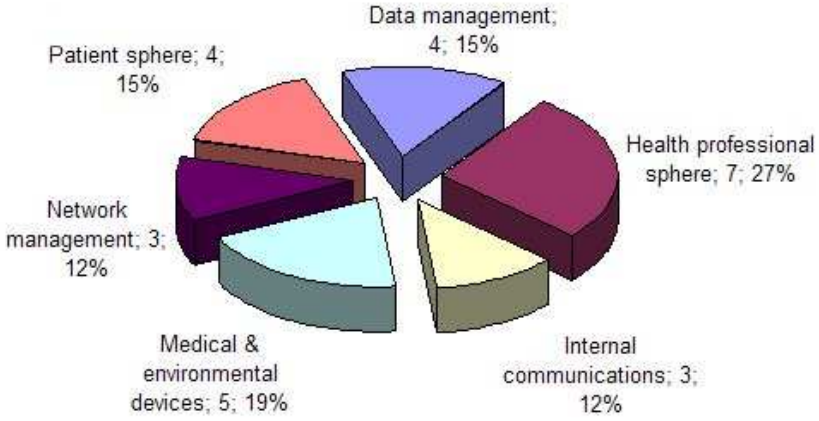

Figure 10: The “Open” or “Reopened” requirements grouped by components at the end of the second iteration cycle

158 requirements (~36%) are “In progress” and in Figure 11 and Figure 12 respectively the distribution of these requirements per component and per actor 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 11). Consortium partners more active in this phase of implementation are FORTH, IMM and FHG-SIT as can be seen in Figure 12.

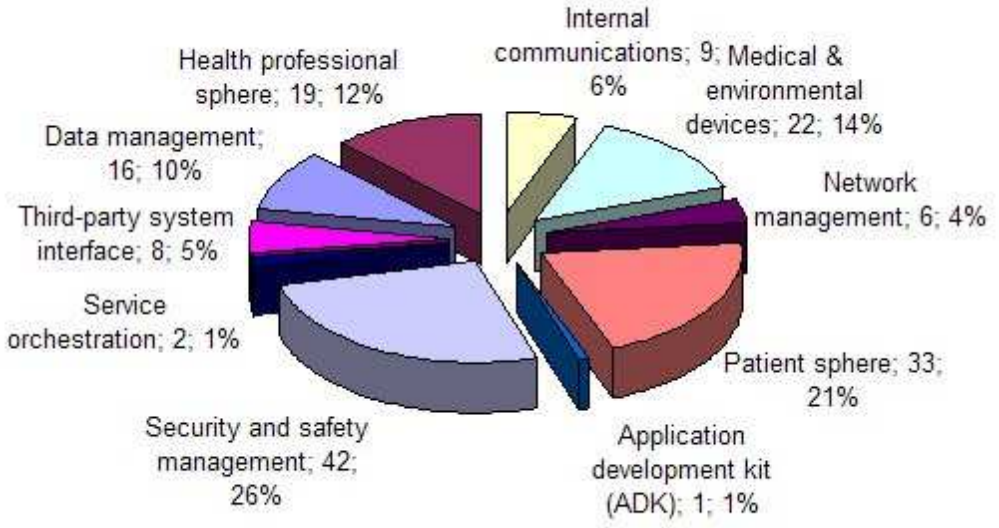

Figure 11: The components to which the “In progress” requirements are associated

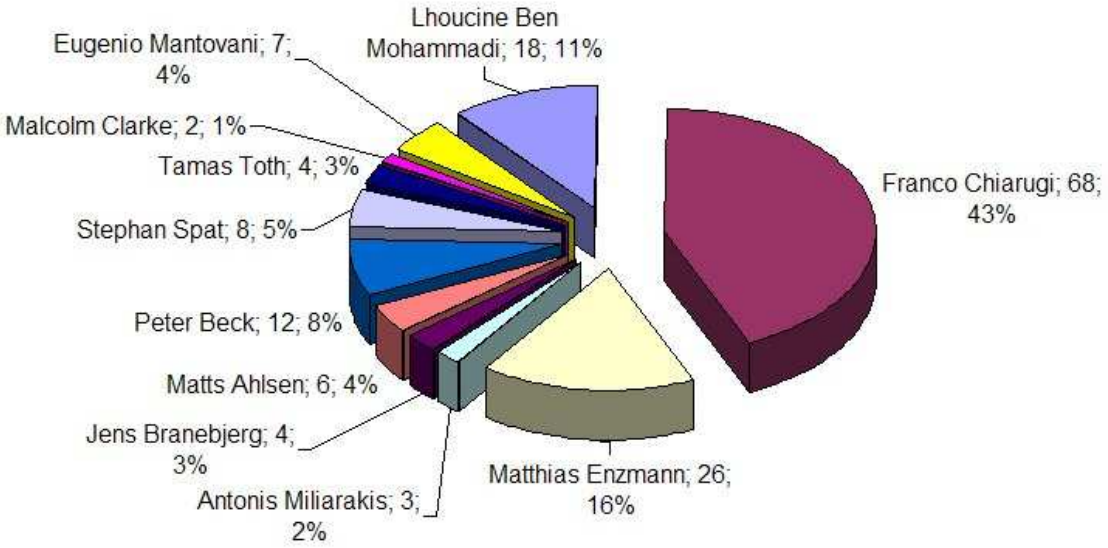

Figure 12: The actors to which the “In progress” requirements are assigned

There are 161 “Resolved” or “Closed” requirements (~37%) of which 62 have been resolved as duplicates and 38 as out of scope. In Figure 13 the resolutions associated to the “Resolved” or “Closed” requirements are shown.

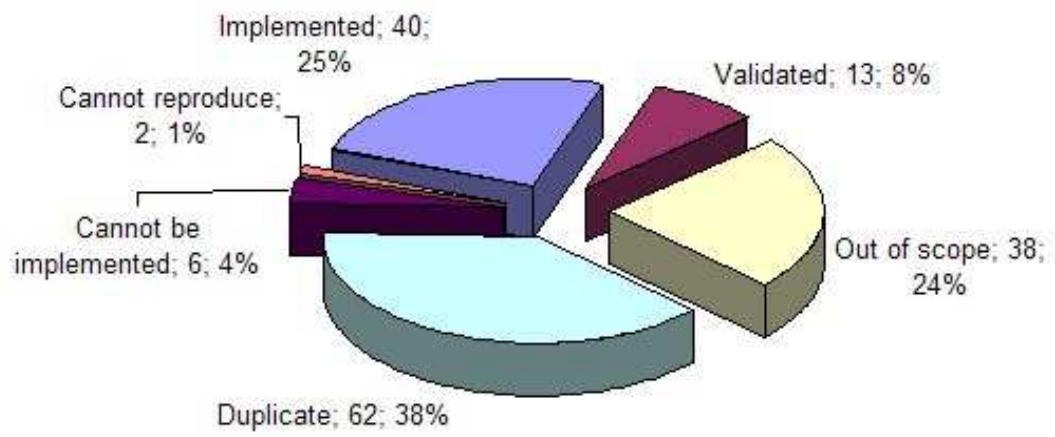

Figure 13: The resolutions of all the “Resolved” requirements at the end of the first iteration cycle

A total of 53 requirements (~16% of the effective requirements) have been implemented at the end of the second year, but 40 are still waiting for user validation, while 13 have been already validated and then closed. Despite of the increment in the total number of requirements there has been a significant increment in the resolved requirements compared to the first year (only 7%). This has been mainly due to the consolidation of the in-hospital prototype and the release of the first primary care prototype. That implied also a significant increment of the “In progress” requirements, again compared to the first year.

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

Each *Lesson Learned* reported in cycle 2 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 the requirements in WP2 and WP9 and in some technical work packages (i.e. WP3, WP4, WP5, WP6, WP7 and WP10). The 5 *Lessons Learned* in WP8 did not produce any changes in the requirements and for this reason their impact is not analyzed in this section. Furthermore, WP1, WP11, WP12 and WP13 have reported no *Lessons Learned* in the second iteration cycle.

The implications of the *Lessons Learned* for the requirements resulted in 155 proposed new requirements, 2 requirements proposed for update and 29 requirements proposed for deletion.

After an accurate evaluation of the proposed changes finally 116 new requirements were inserted, 2 requirements were updated (one of them also resolved as not implementable) and no requirement was deleted, but 29 resolved as duplicate, out of scope or not implementable.

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 availability of detailed specifications also for the primary care environment 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 explicitely 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 ID2-8-3 “Change request and re-engineering report 2”.

3.1 Change Request and Re-Engineering Originating from WP2

An analysis of all *Lessons Learned* (5 *Lessons Learned* in WP2) was performed. Based on LL WP2-2 all requirements initially contained in the two JIRA sub-projects RDMM and RSR had to be inserted in the main REACTION requirements project in order to assure an overall high-level requirement management in the REACTION project. No requirement was identified as subject to possible updating or deleting.

The impact of these *Lessons Learned* on the requirements related to WP2 has been summarized in the following table.

Key	Summary	Priority	Suggestions for Changes
	Requirements related to security or data management collected in JIRA sub-projects	Major	Those requirements contained in the RSR and RDMM JIRA sub-projects have to be inserted in the main REACTION requirements project.

3.1.1 New Requirements

Requirements from REACTION-322 to REACTION-468 have been inserted (146 in all). However, not all of them, after quality check, have been considered part of specification and part of them have been resolved as out of scope or duplicate. These requirements considered part of specification (107 in all), which can be categorized as “consolidation requirements”, are listed in Section 3.9.

3.1.2 Updated Requirements

No requirement has been updated.

3.1.3 Deleted Requirements

No requirement has been deleted.

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

No requirement has been resolved with one of the above resolutions.

3.2 Change Request and Re-Engineering Originating from WP3

All *Lessons Learned* (9 *Lessons Learned* in WP3) collected in WP3 were analyzed. LL WP3-7 identified the need of a new requirement focused on minimization of the recalibration procedures. All other *Lessons Learned* were dealing with sensor accuracy and the factors influencing sensor accuracy. Changes in only one requirement were considered necessary since stabilization and ensuring the same temperature in the two channels of the IR sensors seem to be sufficient in order to guarantee good accuracy. In such respect another requirement was considered obsolete since it does not take into account the difference of temperature between the two channels and was suggested to be deleted or better resolved as duplicate, since its real scope was now covered by the modified requirement.

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
	The recovery for microdialysis based glucose sensors should be monitored to avoid recalibration	Major	Since the application of a microdialysis based glucose sensor during the first clinical trials is most likely, the point of recovery change by sensor fouling has to be address in a new requirement, introducing an additional sensor to monitor the recovery, if frequent recalibration of the sensor should be avoided.
REACTION-270	Operating temperature of sensors should be specified	Major	The temperature should be specified and maintained on equal level on the two channels of the IR sensor.
REACTION-29	Accurate data acquirement	Critical	This seems to be covered by the modified REACTION-270 and might be considered as a duplicate.

As a consequence it has been suggested that:

- 1 new requirement should be defined.
- 1 requirement should be updated.
- No requirements have to be deleted.

3.2.1 New Requirements

One new requirement has been inserted.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-478	Functional	Major	The recovery for microdialysis based glucose sensors	Due to sensor fouling effects the recovery of a microdialysis catheter may change as a function of time, requiring sensor recalibration by a reference method. This could be avoided if	Recovery detection implemented

			should be monitored to avoid recalibration	an additional sensor is inmplemented measuring the change of recovery (e.g. ion density in the dialysate). This is relevant for microdialysis based glucose sensors.	

3.2.2 Updated Requirements

One requirement has been updated.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-270	Functional – REACTION platform	Major	Operating temperature of sensors should be specified and kept on equal level for the IR GM sensor reference and measuring channel	The temperature might influence the result of the measurement and its accuracy.	Either sensor manufacturers should specify the operating temperature of the sensors or the device should be able to adjust the measurement based on the temperature value (in this case a temperature sensor has to be integrated in the device)

3.2.3 Deleted Requirements

No requirement has been deleted.

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

REACTION-29 and REACTION-129 have been resolved as being Duplicate.

REACTION-405 and REACTION-427 have been resolved as Cannot be implemented.

3.3 Change Request and Re-Engineering Originating from WP4

All *Lessons Learned* (11 *Lessons Learned* in WP4) collected in WP4 were analyzed.

All in all, LL WP4-1, WP4-2, WP4-3 and WP4-6 deal with design, development and cooperation issues, LL WP4-4, WP4-5 and WP4-8 are all related to the decision to cooperate with the Continua Alliance and adopt the Continua Guidelines for compliance. What is trivial to point out is that the REACTION client environment should not just be composed of medical devices but also environmental and context-giving sensors and/or user input. The baseline technology in REACTION is based on the LinkSmart Middleware, which offers the possibility of rather fast integration of a variety of devices including medical devices. LinkSmart has through the DCK already the ability to incorporate IEEE 11073 agent specialisations but the market is not yet mature for full scale adoption.

LL WP4-7 concerns the relevance of context data. Given that, context is still relevant in the data collection stage of the primary care scenarios but as context is the most vital part of the data fusion functionality and is to be integrated in it for next iteration.

LL WP4-9 describes the advent of the 'Device-as-a-service' concept and the need to take into account service interoperability.

The rules referred to in LL WP4-10 and additional services described in LL WP4-11 imply that the Data Fusion Engine should automatically generate context data in close relationship to the available services in the REACTION platform.

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

- No new requirement should be defined.

- No requirement should be updated.
- No requirements have to be deleted.

3.3.1 New Requirements

No new requirement has been inserted.

3.3.2 Updated Requirements

No requirement has been updated.

3.3.3 Deleted Requirements

No requirements have been deleted.

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

Due to findings during the research and development process (strict requirements of the MDD) but also as the outcome of meetings with domain and medical experts, requirements REACTION-379, REACTION-417 and REACTION-418 have been resolved as being Out of Scope, while REACTION-359 was resolved as being not implementable. Moreover, several other requirements have been resolved as out of scope, duplicate, cannot be implemented or cannot reproduce.

More precisely, REACTION-10, REACTION-11, REACTION-16, REACTION-21, REACTION-27, REACTION-137, REACTION-164, REACTION-167, REACTION-257, REACTION-355, REACTION-368, REACTION-377 and REACTION-469 have been resolved as being Out of Scope.

REACTION-22, REACTION-154, REACTION-157, REACTION-158, REACTION-159, REACTION-163, REACTION-182, REACTION-187, REACTION-201, REACTION-218, REACTION-239, REACTION-248, REACTION-332, REACTION-350, REACTION-366, REACTION-384, REACTION-394, REACTION-406, REACTION-411, REACTION-420, REACTION-422, REACTION-436, REACTION-440, REACTION-446 and REACTION-450 have been resolved as being Duplicate.

REACTION-447 has been resolved as Cannot be implemented.

REACTION-39 and REACTION-43 have been resolved as Cannot Reproduce. This resolution might be reviewed in the third year and substituted with a more appropriate one, since “Cannot reproduce” is more suitable for bugs than for requirement management.

3.4 Change Request and Re-Engineering Originating from WP5

All *Lessons Learned* (6 *Lessons Learned* in WP5) collected in WP5 were analyzed.

The first two *Lessons Learned* in WP5 are related to the medical devices to be used in the REACTION framework and more specifically to time delays in their selection as well as their compliance with the Continua protocols (similar *Lessons Learned* were reported also in WP4).

The remaining four *Lessons Learned* are related to the Network Monitoring System (NMS) and refer to the extension of the NMS client to other Operating Systems, to the ease of use, to the automation of the network alert generation and to the architectural choices (single-server approach) used for REACTION.

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

- No new requirement should be defined.
- No requirement should be updated.
- No requirements have to be deleted.

3.4.1 New requirements

No requirements have been added.

3.4.2 Updated requirements

No requirements have been updated.

3.4.3 Deleted requirements

No requirements have been deleted.

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

REACTION-19, REACTION-328 and REACTION-329 have been resolved or closed as being Out of Scope.

REACTION-252 has been resolved as being Duplicate.

3.5 Change Request and Re-Engineering Originating from WP6

All *Lessons Learned* (7 *Lessons Learned* in WP6) collected in WP6 were analyzed.

The *Lessons Learned* focus on two different aspects of the work in work package 6. LL WP6-1 to LL WP6-3 address the difficulty of transforming the insulin dosing protocol – which is usually used in paper form in clinical practice – in a flexible computerized system meeting the requirements of users (including workflow support) and especially the very strict regulations of the Medical Device Directive.

LL WP6-4 through LL WP6-7 deal with the second aspect, which focuses on the long-term risk modelling based on publicly available diabetes data sets. These data sets are available under some pre-conditions but their usage for risk modelling is only possible with technical restrictions due to the specific patient cohort or the age of the dataset. Furthermore, proper approaches for the implementation are presented in order to facilitate the integration of the long-term risk models in the higher level shells.

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

- No new requirement should be defined.
- No requirement should be updated.
- No requirements have to be deleted.

3.5.1 New requirements

No requirements have been added.

3.5.2 Updated requirements

No requirements have been updated.

3.5.3 Deleted requirements

No requirements have been deleted.

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

REACTION-98, REACTION-353 and REACTION-364 have been resolved as being Out of Scope.

REACTION-222 and REACTION-233 have been resolved as being Duplicate.

3.6 Change Request and Re-Engineering Originating from WP7

One *Lesson Learned* was collected in WP7 and analyzed.

LL WP7-1 deals with the issue of consent. The EU Privacy Directive 95/46/EC in general forbids the processing of personal data under Article 8.1. However, there are a number of derogations from this general prohibition. One of these derogations is if the data subject, such as a patient, gives her/his consent to the processing of her/his data, as specified in Article 8.2 (a). Since the REACTION platform will process personal, medical data of patients, it was expected that managing patient consents would be necessary. However, after the scenarios, use cases and detailed specifications of REACTION became clearer, it turned out that the processing being done in REACTION is permitted by another derogation, namely Article 8.3. This article says that a patient's consent is not required, where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

Therefore, the requirements concerning patients' consents have been considered out of scope.

3.6.1 New requirements

No requirements have been added.

3.6.2 Updated requirements

No requirements have been updated.

3.6.3 Deleted requirements

No requirements have been deleted.

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

Requirements REACTION-102, REACTION-103, REACTION-370, REACTION-373, REACTION-398, REACTION-407, REACTION-412, REACTION-429 and REACTION-464 were closed with resolution Out of Scope, as patients' consents need not be dealt with for the purpose of REACTION. Also REACTION-259 has been resolved as being Out of Scope.

REACTION-198 has been resolved as being Duplicate.

REACTION-461 has been resolved as Cannot be implemented.

3.7 Change Request and Re-Engineering Originating from WP9

All *Lessons Learned* (12 *Lessons Learned* in WP9) collected in WP9 were analyzed.

Lessons Learned from LL WP9-1 to LL WP9-4 are about stigmatization when portable devices and components are visible. Each LL suggested the introduction of a new requirement.

LL WP9-5 deals with requirements for Data Breach Notification, which are not explicitly foreseen in the Data Protection Directive. The creation of a new requirement was suggested by this LL.

LL WP9-6 describes the need for Log and log-in system. According to Data Protection Directive, the data controller "must implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing" (European Parliament and the Council of the European Union (1995), Directive 95/46/EC). The creation of a new requirement was suggested by this LL.

In LL WP9-7 Data Protection Impact Assessment is considered. Article 33 of the Proposed Regulation on Data Protection and concerns the obligation of data controllers to carry out Data protection impact assessments. 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”. The creation of a new requirement was suggested by this LL.

LL WP9-8 involves Liability and compensation for unlawful data processing. The proposed Regulations introduce a new regime for penalties and administrative fines. As a consequence the creation of a new requirement was suggested.

The other *Lessons Learned* had no impact in the requirements.

Key	Summary	Priority	Suggestions for Changes
	The potential stigmatising effect of REACTION due to increased visibility should be decreased to a minimum.	Major	A new requirement specifying that, since diabetic patients experience stigmatization, visibility of components and also electronic visibility of networking components should therefore be kept to a minimum.
	Individuals that suffer stigmatisation (including through conditions such as diabetes) often value the ability to socialise with others having a similar condition or sympathetic healthcare professionals. REACTION should not eliminate this possibility.	Major	A new requirement specifying that, since diabetic patients experience stigmatization, the REACTION platform should not eliminate the possibility of socializing with others having similar conditions.
	A portable sensor patch should have as reduced visibility as is technically feasible.	Major	A new requirement specifying that, since diabetic patients experience stigmatization, the lower the visibility of such portable sensors the less the chance that an individual's condition might become apparent to others in situations where the patient does not wish this to happen
	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.	Critical	A new requirement specifying that, since diabetic patients experience stigmatization, 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 others.
	Data breach notification duty	Major	A new requirement specifying that, even if data breach notification requirements are not explicitly foreseen in the Data Protection Directive, it is very likely that there will be a general European-wide data breach notification in future and the duty of notification of a data breach will have to be foreseen.
	Log and log-in system	Major	A new requirement specifying that a 'log-in system' for the identification and authentication of a given person when s/he accesses the medical data and a 'log system' that records the actions performed by users in an audit log have to be used. This would contribute to realise those "technical and organizational measures" capable of ensuring the traceability of those who access the data of patients.
	Data protection impact assessment	Major	A new requirement specifying that an institution operating a system such as REACTION, for instance a hospital or a national health service, should carry out an impact

			assessment.
	Liability of controller for damages due to unlawful processing	Major	A new requirement specifying that REACTION could consider the allocation of compensation or insurance schemes in case errors occur in the processing of medical data.

As a consequence it has bees been suggested that:

- 8 new requirements should be defined.
- No requirements had to be updated.
- No requirements had to be deleted.

3.7.1 New requirements

The *Lessons Learned* in the second cycle have resulted in the addition of eight new requirements.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-470	Non-functional - Look and feel	Major	The potential stigmatising effect of REACTION due to visibility should be decreased to a minimum.	Most diabetic patients experience diabetes as 'discreditable' individuals in terms of stigmatisation (See ethical analysis - task 9.1). For such individuals control over personal information is extremely important. Individual patients will not want to unnecessarily increase visibility of their condition as this will mean that they have reduced level of control over their personal information and will therefore have less ability to control who they reveal their condition to. Visibility of components and also electronic visibility of networking components should therefore be kept to a minimum.	Patients should feel that a REACTION like platform will not result in a overall increase in the visibility of their condition and consequently a reduction in their ability to conceal it, it they should wish to do so.
REACTION-471	Non-functional - Cultural and political	Major	Individuals that suffer stigmatisation (including through conditions such as diabetes) often value the ability to socialise with others having a similar condition or sympathetic healthcare professionals. REACTION should not eliminate this possibility.	Individual patients often use the opportunity to meet such groups as a coping mechanism for the stigmatising effects there condition can entail. A REACTION platform should not reduce such possibilities too much. Where such possibilities are drastically reduced alternatives should be offered, for example online social networking possibilities.	Individuals should not feel that a REACTION platform has eliminated their access to other patients and sympathetic health care professionals which represent an important coping mechanism for individuals that feel stigmatised.
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 apparent to others in situations where the patient does not wish this to happen. This is important in connection	Equipment should have as low a level of visibility as is technically possible.

				with issues of stigmatization - see task 9.2	
REACTION-473	Functional - REACTION platform	Critical	All public networks (e.g. WIFI) created as a result of REACTION should have as low visibility and as high security as is technically 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.
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. 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.	Requirements of the proposed regulation
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 medical data. Another requirement is a 'log system' that records who did what and when in an audit log. This would contribute to realise those "technical and organizational measures" capable of ensuring the traceability of those who access the data of patients. Besides robust log-in and log systems showing who has accessed information and when.	EU case law (e.g. I v Finland) D9.2
REACTION-476	Non-functional - Legal	Major	Data protection impact assess-ment	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	Proposed regulation on data protection

				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	
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.	EU case law Armonias v Lithuania

3.7.2 Updated requirements

No requirements have been updated.

3.7.3 Deleted requirements

No requirements have been deleted.

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

No requirement has been resolved with one of the above resolutions.

3.8 Change Request and Re-Engineering Originating from WP10

All *Lessons Learned* (8 *Lessons Learned* in WP10) collected in WP10 were analyzed.

LL WP10-8 describes the huge differences in the specifications for the primary care and for the in-hospital environments. This produced an impact in the software development making impossible the implementation of applications which can be simply configured for the different environments. Now different applications have to be built increasing significantly the required effort.

Key	Summary	Priority	Suggestions for Changes
REACTION-69	System Configuration	Critical	Additional resources have to be allocated since a single reconfigurable application cannot be built after the release of the detailed specifications. The priority has to be changed to Major and the requirement has to be resolved as not implementable.

As a consequence it has bees been suggested that:

- No new requirements should be defined.
- One requirement had to be updated.
- No requirements had to be deleted.

3.8.1 New Requirements

No new requirements have been added.

3.8.2 Updated Requirements

Requirement REACTION-69 has been reviewed because it refers to easy configurability of applications in different environments. Since this cannot be obtained as explained in LL WP10-8, an

increased implementation effort has been required in order to solve this Major issue (which was initially considered Critical). However, given the detailed specifications for the in-hospital and primary care environments this requirement cannot be implemented and has been resolved with this resolution.

Details of the modified requirement are shown below.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-69	Functional - REACTION platform	Major	System Configuration	The components and applications should be made in a way that makes easy the configuration	Theoretically without any recompilation, the application should be easily configurable for the different environments

3.8.3 Deleted requirements

No requirements have been deleted.

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

REACTION-13, REACTION-36, REACTION-322, REACTION-327 and REACTION-335 have been resolved as being Out of Scope.

REACTION-47, REACTION-61, REACTION-135, REACTION-152, REACTION-177, REACTION-178, REACTION-199, REACTION-203, REACTION-242 and REACTION-397 have been resolved as being Duplicate.

REACTION-69 has been resolved as Cannot be Implemented.

3.9 List of Consolidated Requirements

This section contains the 146 requirements added to the JIRA REACTION requirements project after the incorporation of the sub-projects in the main project. The lists below focused on the 107 new requirements from REACTION-322 to REACTION-468 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 (26 in all), functional requirements of the REACTION platform (37 in all), functional requirements of the in-hospital pilot application (18 in all) and functional requirements of the primary care pilot application (26 in all).

The first list below contains all constraints and non-functional requirements (26 in all).

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 platform. In case of doubt, the user must be warned and asked how to proceed. The user must be able to correct mistakes easily.	The functional test should include specific tests in order to verify such circumstances.
REACTION-339	Non-functional - Security	Major	Communication between the Reaction Device Hosting Server and the patient's/GP's web browser MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the Reaction Device Hosting Server to the patient's/GP's web browser and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	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, administrative personnel etc.	Each person in the Reaction platform has the right to perform a certain set of actions. In order to simplify the administration of these rights, each person is assigned to a role and roles are assigned to permissible actions. The advantage of this approach is that it is easier to manage the rights of a role than managing individual rights for each person.	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, persons MUST have at least one role to interact with the Reaction platform.	Each person is assigned to at least one role.
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 alarms or alerts (hypo or hyper), based on configurable thresholds.	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, adherence to clinical pathways, education, self management)	Questionnaire for patients in order to collect qualitative (or quantitative but not directly measurable) information related to the parameters to be monitored has to be available. They are part of the monitoring (using a frequency set) administered by the responsible clinician.	The mobile device shall have user interfaces allowing completion of these questionnaires.
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 with different EPR systems. It should provide a user interface for disease management as well as Web Services which can be implemented by EPR manufacturers to easily integrate REACTION features into their products.	REACTION software is easy to run beside an EHR application or EHR manufacturer is satisfied with ease of integration of REACTION
REACTION-354	Non-functional - Security	Major	Data/messages exchanged between the Reaction Host Client and the Reaction Device Hosting Server MUST be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the Reaction Host Client and the Reaction Device Hosting Server must be ensured even _after_ the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
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 device should offer the possibility of manual insertion of measurement data .	Check that measurements can be inserted manually using the mobile device .

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-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 measured patient's real world identity.
REACTION-385	Non-functional - Security	Major	Digital identities for the Reaction platform MUST only be issued or revoked by trusted (third) parties, e.g., a certification authority (CA).	Without a trusted party (TP), anyone could produce its own digital identity and someone relying on such an identity would have to trust that the claimed identity is genuine. By incorporating a TP, relying parties trust that the TP ensures that its issued digital identities are genuine. This makes life easier for relying parties as they only have to establish a single trust relationship (with the TP) as opposed to having a multitude of trust relationships with others. The same goes for parties that had been excluded from the Reaction platform, as each relying party would have to determine by itself if another party is still part of the Reaction platform or not. In case of a trusted party, the relying part could simply query the TP if some identity is still valid or had been revoked, e.g., because its owner left the platform.	Availability of a party which is trusted to orderly issue and revoke digital identities.
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, hospital bed, physician(s) in charge, nurse(s) in charge) - demographic data (age, sex, date of birth) - medical history (type of diabetes, medication, comorbitities, former complications, pre-existing conditions) - anamnesis data (fever, infections, diarrhea, vomiting, hypo- hyperglycemia) - lab data (glucose level, HBA1c, ...) - external input (food intake, insulin sensitivity, ...) - context data (time of glucose measurement, what device, ...)	Required data fields will be provided by data structure.

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 to be provided by a dedicated and independent application. This application communicates with - the REACTION platform over the Internet. - other systems in the surgery (EPR, lab, etc.) This application can be server-based and always on, for a prototype also an application client could be used.	An easy to run possibility to run and access REACTION features inside the GP surgery is available.
REACTION-400	Non-functional - Security	Major	Data/messages exchanged between the Reaction Device Hosting Server and the EPR/EHR System SHOULD be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the Reaction Device Hosting Server and the EPR/EHR System must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
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 specialization has to be completed. Measurements which cannot be collected using IEEE 11073 device specialization are also to be mentioned in this list. The complexity of the IEEE 20601 manager also depends on the number of device specializations to be managed.	For each device the supported standard has to be specified (or the company documentation).
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 communication, referrals, accountability of actions, exclusion of ill-behaving entities, etc.	Availability of a digital identity mechanism.
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.
REACTION-414	Non-functional - Security	Major	Communication between the Reaction Hosting Client and the Reaction Device Hosting Server MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the Reaction Hosting Client to the Reaction Device Hosting Server and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	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 action is part of the requester's set of permissible actions according to its role.	Availability of a control mechanism which decides whether a requested action may be granted or denied according to the requester's role.
REACTION-423	Non-functional - Operational	Major	Sensor quality parameters	The REACTION data management model should consider data storage for sensor quality parameters from devices reports like for example mis-calibration, or low battery. The parameters should be used for QoS.	Data fields for sensor quality parameters are available in the data management model.
REACTION-431	Non-functional - Security	Major	Data/messages exchanged between the Reaction Device Hosting Server and the GP EPR SHOULD be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the Reaction Device Hosting Server and the GP EPR must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	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 which role.	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 authentication), with integrity, and confidential.	It must be assumed that data transmission from the Reaction Device Hosting Server to the GP EPR and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	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 (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the Reaction Device Hosting Server to the EPR/EHR System and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.

In the list below all new functional requirements of the REACTION platform are listed (37 in all).

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 enrolment should be obtained from the HIS or EPR through interoperable user interfaces.	When an interoperable HIS/EPR is present, a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a

					diabetic patient is created, his/her data have to be taken from the HIS/EPR.
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 administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable).
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 PAN. The Data Fusion needs to take place close to the patient/user.	Low-level data fusion will be available for the REACTION platform (middleware).
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 end-user application running in the AHD. The data fusion engine also needs to be configured based on which values the clinician wants to observe. There is also a need for 2-way communication from the point of view of error handling. If the observed values suddenly appear out-of-range it might be necessary to check with the client if this is an error state. Other devices/sensors, e.g.the Continua-devices, might also require different types of communication. It might be necessary to reverse a patient's consent that had to be given 'remotely', e.g. at the doctor's surgery, because the hosting client at the patient's home is simply a 'box' with no display or input capabilities. In this restricted 'boxed case', it would be hard to change the patient's privacy settings, once they are initially configured, if we were unable to push data back to the box.	Two way communication between Client and Server will be available for the REACTION platform in order to perform: e.g. data fusion configuration, error-handling, data security (consent management).
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 support or diabetes management the information has be pre-processed. NLP-technologies to find relevant information for REACTION applications from these data bases (annotation of text information: anamnesis information, co-morbidities, medical history, ...) can be a useful tool.	REACTION provides a knowledge discovery module to process unstructured information and store this information in the data storage for further processing.
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 REACTION platform. The high-level data-fusion should provide the integration of external gathered information to the REACTION platform data structure and the fusion of	High-level data fusion functionality will be available for the REACTION hosting server.

				REACTION-internal processed data.	
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 data") "The LinkSmart Network Manager has two roles, it takes care of the P2P between different nodes. It also keeps a list of LinkSmart Identifiers for different devices/services and there local endpoints. In this way it "virtualizes" devices, services, and applications behind identifiers."	TODO (Peter Rosengren)
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.
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).
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 (to be specified for the two environments).	Collect measurements about physical activity, environmental data, additional information and evaluate the activity patterns verifying their correctness.
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-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 when and how they must be sent with which parameters.	Alerts and reminders can be defined and stored.
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 people and stakeholders.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
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.

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 form) by patients before they can be enrolled in the REACTION platform.	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the signed paper This procedure shall be completed before any other operation can be performed.
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 two parameters cannot be directly measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.). Glucose control algorithm and physiology models should use these two parameters.	The data management has to allow for the insertion and subsequent modifications of these values by clinicians.
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-408	Functional - REACTION platform	Major	Non-pharmacological and/or pharmacological treatment	Non-pharmacological (diet, lifestyle, education) and pharmacological (OAD, insulin and interfering drugs) treatments have to be assigned to each patient and can be modifed at each check.	In the ontologies and data management there should be the possibility of registering the different types of treatment for each patient and of modifying them at each check.
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.
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. Personalization is possible through the use of individual thresholds and other parameters.	Event rules can be defined and stored.
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 clinical protocols.	Necessary models and rules are defined and stored.
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.
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-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 management of the diabetic patient.	In the design of data management and ontologies the possibility of registering the co-morbidities with a basic set of attributes has to be guaranteed. Co--morbidities with their

					attributes have to be registered at the patient enrolment and at each subsequent visit or evaluation when new co-morbidities take place.
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, remidners to patients	Client schedules can be defined and stored
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?
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 continue the process later and b) prevent corrupted / incomplete data to be uploaded to the main server.	The functional test should include specific tests in order to ensure that there is no data loss in case of network failure.
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 hospital or primary care with blood glucose and glycated haemoglobine).	Should be able to import and export data in an interoperable way (e.g. HL7) to third-party systems.
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 Message Service (fast delivery, provides an alternative data path when an Internet connection is not available etc) the time critical messages for the patients should be able to be forwarded as SMS messages.	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 between these two prototypes (e.g. SOA). Thus, the data model should consider how the prototypes can be merged in future within the REACTION platform. A data/communication interface has to be defined.	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 (e.g. IHE-PCD01) in order to transport data from client to server side (and vice versa).	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.

REACTION-455	Functional - REACTION platform	Major	REACTION data storage	The REACTION platform should provide a storage module (database). Data gathered within REACTION should be stored here, as well as relevant data from external sources. The REACTION data storage should also use security mechanisms to include/exclude patient data access.	The REACTION platform provides a persistence layer for data storage with emphasis on data security and data access.
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.
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 measured every 2-6 months until the blood glucose level is stable on unchanging therapy in outpatient environment and at the patient enrolment in the inpatient environment (updates are decided by clinicians).	Specific fields have to be foreseen in data management.
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.
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 should be provided.	The Data Model for REACTION should provide a regular update mechanism for personal health care profiles.

The list below contains all new functional requirements which refer to the in-hospital pilot application (16 in all).

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion

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 the HIS. A standardized interface e.g. HL7 has to be used for data interchange. Required data fields are: - unique PID - name - age (data of birth) - sex - address	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) an interface based on HL7 has to be provided.	Standardized Interface (HL7) to HIS / EPR to exchange clinical data.
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.
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 on patient history and associated parameters. It might imply changes in the therapy scheme.	The pharmaceutical and non-pharmaceutical treatment (or therapy scheme) has to be stored in the data management and can be modified during any clinical evaluation of the patient. It has to be initialized immediately after the patient enrolment.
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 nurses with treatment performed by clinicians and/or nurses.	Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.
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) has to be immediately registered in the data management by the administering nurse.	Data on drugs administered have to be stored in the data management where they can be also retrieved as part of the fever/sugar chart.
REACTION-432	Functional - In-hospital pilot	Major	Special examinations/treatments to be registered	For some examinations/treatments in the hospital the patients have to be	These events (special examination/treatme

	application		in fever chart	in a fasting and/or euglycaemic condition. Iin such cases treatment must therefore be adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). However a problem may arise if the patient has to wait longer than expected due to unforseen delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). The dose of insulin and/or OADs will therefore need to be adapted, the patient receives some food in the event of hypoglycaemia and receives insulin by injection in the event of hyperglycaemia.	nts) have to be registered in the data management where they can be retrieved for the composition of the fever/sugar chart.
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.
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 basal), based also on additional parameters and insulin administration.	There should be the possibility of acquiring, storing and retrieving all the information generated during any basic workflow performed during any time of the day/night.
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).
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 use of glycaemic index and load tables for various types of food might be taken into account). 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 shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
REACTION-459	Functional - In-hospital pilot application	Major	Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.

REACTION-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-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 REACTION applications like decision support. For example pre- or post-meal glucose values have very different meanings for treatment. Therefore the data management model has to provide context management.	The data management model support context management functionality for the inpatient prototype application.
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 has to be produced daily. Adaptation of therapy or changes of medications has to be evaluated including by consultation with the duty-physician.	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 system to the physician. The physician can use the result for decision support. The service uses data stored in the data storage and user additional user input as input for processing.	A service will be available to support physician with glucose control of patients.

Finally the last list below contains all new functional requirements which refer to the primary care pilot application (28 in all).

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 permission to permanently delete data from the system. This refers to the system logging and all actions taken by different users. The system shall also provide traceability of each action to the user taken those actions.	The system shall foresee the possibility of traceability for each action which has been taken in the system by the user.
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.
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 Edit user accounts. The users shall be added to the system by their name and their role (user type) and also the ability to suspend and reactivate the user's account.	The system shall differ between active and suspended user accounts. Active users shall be displayed both with colour indicator and as a list function.

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 at the Primary Care	The clinician shall be able to monitor the patient's input data .The patient's account will be managed by the patient's care giver. In addition the clinician shall have the ability to add, delete, edit, search a patient by a list of patients. This list shall be sorted by ; Active , Non active, Last name or Disease Category	NON
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 and disease	An educational library with helpful content about patient's lifestyle shall be created. This library shall contain information about diet, activity, medication and advice to the patient in response to patient's lifestyle, etc.	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 instructions to the patient. It is recommended the use of large fonts, use of colours with strong contrast, possible use of audio messages and implementation of other commonly used accessibility options (utilization of full screen size on small as well as large screens), for the interface used by patients.	The user friendliness and useability of the interface shall be evaluated with a focus group and the test plan.
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
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-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 data content. This helps to define personal models (profiles), which permit the personalised disease management.	A health status model is present.
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 patient status. So telemonitoring data needs to be visualized in a flexible way (aggregation level, combination of parameters ...) Data has to be handled in a way that this visualization can be generated on-demand with good performance.	Data can be visualized flexibly and with good performance to professionals
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.

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 broadband network is not available.	In the event that the hosting client is not connected through a broadband connection, the patient will be able to upload data using GPRS / 3G data networks. In this case we need to examine possible limitations.	Functional test uploading data over slow mobile networks.
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 inserted in the platform.	The data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrollment).
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, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies and data management.
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.
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 status assessment.	Self-management is supported.
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.
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 as an input for risk assessment and disease management.	Personal Health Status Profiles can be generated.
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 infrastructure (e.g. IHE-XDS) from where documents can be received.	Referrals can be documented and are considered in decision support, summary letters can be received via an appropriate data interface.

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.
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 their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients.	Specific fields have to be present in ontologies and data management
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-416	Functional - Primary care pilot application	Major	Patient education	Continuous education of the patient adjusted to his/her needs.	Educational material is available.
REACTION-435	Functional - Primary care pilot application	Major	Outcomes of regular visits at primary healthcare centres	Outcomes of regular visits at the primary healthcare centre shall be registered through the data management.	The outcomes of each visit have to be stored as much as possible in a structured way.
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 complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems).	Data management should include the necessary structures for assuring the storage of all necessary information for the management of complications.
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 the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in ontologies and data management.
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 management, risk management and lifestyle plan. Personalization methods must be defined.	Care plan can be personalized.
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.

4 The Next Iteration Cycle

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 (the user licence was upgraded from 25 to 50 users during the second year). A review of the list of resolutions might be performed.

5 The Requirements of the REACTION Platform after the Second Year Revision

In this chapter the requirements of the REACTION platform after the second 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 second iteration cycle are still "Unresolved" or "Implemented" or "Validated". A complete list of the requirements (with resolution "Unresolved", "Implemented" or "Validated") after the second 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 has been assigned only to one component, and for each requirement a WP of major impact has been 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 at the end of the second iteration cycle are listed entirely 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 second 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 progresses of the requirements of her/his WP.

5.1 Requirements of WP3 – Sensors Monitoring and Contextualisation

5.1.1 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

5.1.2 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…*

5.1.3 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**

			and measuring channel		**or the device should be able to adjust the measurement based on the temperature value (in this case a temperature sensor has to be integrated in the device)**
REACTION-271	Functional - REACTION platform	Major	The calibration of the sensors should be specified (strategy, intervals, reference, algorithms)	*The sensor must be calibrated before usage and might be re-calibrated after a certain time, also might the calibration…*	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 apparent to others in situations where the patient does not wish this to happen. This is important in connection with issues of stigmatization - see task 9.2**	**Equipment should have as low a level of visibility as is technically possible.**
REACTION-478	**Functional**	**Major**	**The recovery for microdialysis based glucose sensors should be monitored to avoid recalibration**	**Due to sensor fouling effects the recovery of a microdialysis catheter may change as a function of time, requiring sensor recalibration by a reference method. This could be avoided if an additional sensor is inmplemented measuring the change of recovery (e.g. ion density in the dialysate). This is relevant for microdialysis**	**Recovery detection implemented**

				based glucose sensors.	

5.1.4 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, …*

5.1.5 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 …*

5.2 Requirements of WP4 – Data Management and Service Orchestration

5.2.1 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.

5.2.2 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 have a good development practice	The test facility will take into account also the version of 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-195	Functional - Primary care pilot	Major	*Data management should*	*The complications considered*	In the ontology, user

	application		*handle different types of complications for the diabetic patients in the Primary care …*	*for the diabetic patient in the Primary care environment are: cardiovascular, renal…*	interfaces and applications these complications have to be present
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 administration (always subcutaneous for outpatient environment).**	**Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable).**
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 REACTION platform. The high-level data-fusion should provide the integration of external gathered information to the REACTION platform data structure and the fusion of REACTION-internal processed data.**	**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 patient status. So telemonitoring data needs to be visualized in a flexible way (aggregation level, combination of parameters ...) Data has to be handled in a way that this visualization can be generated on-**	**Data can be visualized flexibly and with good performance to professionals**

				demand with good performance.	
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.**
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 (to be specified for the two environments).**	**Collect measurements about physical activity, environmental data, additional information and evaluate the activity patterns verifying their correctness.**
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, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet**	**Specific fields have to be present in ontologies and data management.**

				and lifestyle measures).	
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 people and stakeholders.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
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.
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.
REACTION-423	Non-functional - Operational	Major	Sensor quality parameters	The REACTION data management model should consider data storage for sensor quality parameters from devices reports like for example mis-calibration, or low battery. The parameters should be used for QoS.	Data fields for sensor quality parameters are available in the data management model.
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.
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 complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems).	Data management should include the necessary structures for assuring the storage of all necessary information for the management of complications.

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 the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in 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 REACTION should be stored here, as well as relevant data from external sources. The REACTION data storage should also use security mechanisms to include/exclude patient data access.	The REACTION platform provides a persistence layer for data storage with emphasis on data security and data access.
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 use of glycaemic index and load tables for various types of food might be taken into account). 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 shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
REACTION-459	Functional - In-hospital pilot application	Major	Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions,	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.

			treatments, events	**information for the diabetic patient management in the Inpatient environment.**	
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 measured every 2-6 months until the blood glucose level is stable on unchanging therapy in outpatient environment and at the patient enrolment in the inpatient environment (updates are decided by clinicians).**	**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 REACTION applications like decision support. For example pre- or post-meal glucose values have very different meanings for treatment. Therefore the data management model has to provide context management.**	**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.**

5.2.3 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 Glucose Management	*Currently all actions are recorded on a paper chart/record. Because of data privacy protection and …*	The inpatient pilot application stores data records/charts
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…*	*The nurse through an appropriate user interface can check the last drug administration and insert …*
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 inserted in the platform.**	**The data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrollment).**
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 on patient history and associated parameters. It might imply changes in the therapy scheme.**	**The pharmaceutical and non-pharmaceutical treatment (or therapy scheme) has to be stored in the data management and can be modified during any clinical evaluation of the patient. It has to be initialized immediately after the patient enrolment.**
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.**
REACTION-388	**Functional - REACTION platform**	**Major**	**Insulin sensitivity and insulin resistance**	**Insulin sensitivity and insulin resistance have to**	**The data management has to allow for the insertion**

				be used in the evaluation of the insulin dosage. However, these two parameters cannot be directly measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.). Glucose control algorithm and physiology models should use these two parameters.	**and 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, hospital bed, physician(s) in charge, nurse(s) in charge) - demographic data (age, sex, date of birth) - medical history (type of diabetes, medication, comorbitities, former complications, pre-existing conditions) - anamnesis data (fever, infections, diarrhea, vomiting, hypo-hyperglycemia) - lab data (glucose level, HBA1c, ...) - external input (food intake, insulin sensitivity, ...) - context data (time of glucose measurement, what device, ...)**	**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 their diabetes, check effectiveness of lifestyle**	**Specific fields have to be present in ontologies and data management**

				and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients.	
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 nurses with treatment performed by clinicians and/or nurses.	Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.
REACTION-408	Functional - REACTION platform	Major	Non-pharmacological and/or pharmacological treatment	Non-pharmacological (diet, lifestyle, education) and pharmacological (OAD, insulin and interfering drugs) treatments have to be assigned to each patient and can be modifed at each check.	In the ontologies and data management there should be the possibility of registering the different types of treatment for each patient and of modifying them at each check.
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 management of the diabetic patient.	In the design of data management and ontologies the possibility of registering the co-morbidities with a basic set of attributes has to be guaranteed. Co--morbidities with their attributes have to be registered at the patient enrolment and at each subsequent visit or evaluation when new co-morbidities take place.
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) has to be immediately registered in the data management by the administering nurse.	Data on drugs administered have to be stored in the data management where they can be also retrieved as part of the fever/sugar chart.

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 euglycaemic condition. Iin such cases treatment must therefore be adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). However a problem may arise if the patient has to wait longer than expected due to unforseen delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). The dose of insulin and/or OADs will therefore need to be adapted, the patient receives some food in the event of hypoglycaemia and receives insulin by injection in the event of hyperglycaemia.	These events (special examination/treatments) have to be registered in the data management where they can be retrieved for the composition of the fever/sugar chart.
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?

REACTION-435	Functional - Primary care pilot application	Major	Outcomes of regular visits at primary healthcare centres	Outcomes of regular visits at the primary healthcare centre shall be registered through the data management.	The outcomes of each visit have to be stored as much as possible in a structured way.
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).
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 management, risk management and lifestyle plan. Personalization methods must be defined.	Care plan can be personalized.
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.
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.

				has to be produced daily. Adaptation of therapy or changes of medications has to be evaluated including by consultation with the duty-physician.	
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 system to the physician. The physician can use the result for decision support. The service uses data stored in the data storage and user additional user input as input for processing.**	**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 should be provided.**	**The Data Model for REACTION should provide a regular update mechanism for personal health care profiles.**

5.2.4 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 end-user application running in the AHD. The data fusion engine also needs to be configured based on which values the**	**Two way communication between Client and Server will be available for the REACTION platform in order to perform: e.g. data fusion configuration, error-handling, data security (consent management).**

				clinician wants to observe. There is also a need for 2-way communication from the point of view of error handling. If the observed values suddenly appear out-of-range it might be necessary to check with the client if this is an error state. Other devices/sensors, e.g.the Continua-devices, might also require different types of communication. It might be necessary to reverse a patient's consent that had to be given 'remotely', e.g. at the doctor's surgery, because the hosting client at the patient's home is simply a 'box' with no display or input capabilities. In this restricted 'boxed case', it would be hard to change the patient's privacy settings, once they are initially configured, if we were unable to push data back to the box.	
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 broadband network is not available.	In the event that the hosting client is not connected through a broadband connection, the patient will be able to upload data using GPRS / 3G data networks. In this case we need to examine possible limitations.	Functional test uploading data over slow mobile networks.
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.

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 Message Service (fast delivery, provides an alternative data path when an Internet connection is not available etc) the time critical messages for the patients should be able to be forwarded as SMS messages.**	**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 between these two prototypes (e.g. SOA). Thus, the data model should consider how the prototypes can be merged in future within the REACTION platform. A data/communication interface has to be defined.**	**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 (e.g. IHE-PCD01) in order to transport data from client to server side (and vice versa).**	**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.**

5.2.5 Medical & environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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
REACTION-237	Functional - In-hospital pilot application	Major	Annotation of blood glucose values, especially in In-	*In the hospital with associated laboratories there exists the*	*The blood glucose values have to be annotated*

			hospital environment	*possibility that specially trained nurses …*	*specifying if collected with PoC devices or by …*
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**
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-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.**
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 specialization has to be completed. Measurements which cannot be collected using IEEE 11073 device specialization are also to be mentioned in this list. The complexity of the IEEE 20601 manager also depends on the number of device specializations to be managed.**	**For each device the supported standard has to be specified (or the company documentation).**

5.2.6 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 data")** **"The LinkSmart Network Manager has two roles, it takes care of the P2P between different nodes. It also keeps a list of LinkSmart Identifiers for different devices/services and there local endpoints. In this way it "virtualizes" devices, services, and applications behind identifiers."**	**TODO (Peter Rosengren)**
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.**
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 continue the process later and b) prevent corrupted / incomplete data to be uploaded to the main server.**	**The functional test should include specific tests in order to ensure that there is no data loss in case of network failure.**

5.2.7 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-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**	**The functional test should include specific tests in order to verify such**

				functioning of the platform. In case of doubt, the user must be warned and asked how to proceed. The user must be able to correct mistakes easily.	circumstances.
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 PAN. The Data Fusion needs to take place close to the patient/user.	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 alarms or alerts (hypo or hyper), based on configurable thresholds.	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, adherence to clinical pathways, education, self management)	Questionnaire for patients in order to collect qualitative (or quantitative but not directly measurable) information related to the parameters to be monitored has to be available. They are part of the monitoring (using a frequency set) administered by the responsible clinician.	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 device should offer the possibility of manual insertion of measurement data .	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 status assessment.	Self-management is supported.

5.2.8 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 form) by patients before they can be enrolled in the REACTION platform.**	**The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the signed paper This procedure shall be completed before any other operation can be performed.**
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**	**Privacy Enforcement Point is available for the REACTION client side.**

				client side. The Privacy Enforcement Point should perform as a counterpart of the Consent Manager at the Reaction Device Hosting Server.	

5.2.9 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-211	Functional - Primary care pilot application	Major	*Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan…*	*A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk …*	These 3 components should be part of the care management for any diabetic patient
REACTION-213	Functional - Primary care pilot application	Major	*Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment …*	*The completion of the accurate check shall be accompanied by changes in the patient treatment (if …*	*The system shall allow at the end of any clinical case conference the insertion of changes in the non …*
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 when and how they must be**	**Alerts and reminders can be defined and stored.**

				sent with which parameters.	
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. Personalization is possible through the use of individual thresholds and other parameters.**	**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-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**
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 basal), based also on additional parameters and insulin administration.**	**There should be the possibility of acquiring, storing and retrieving all the information generated during any basic workflow performed during any time of the day/night.**

5.2.10 Third-party system interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 …*	*Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits …*	*In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference …*
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 enrolment should be obtained from the HIS or EPR through interoperable user interfaces.**	**When an interoperable HIS/EPR is present, a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created, his/her data have to be taken from the HIS/EPR.**

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 with different EPR systems. It should provide a user interface for disease management as well as Web Services which can be implemented by EPR manufacturers to easily integrate REACTION features into their products.	REACTION software is easy to run beside an EHR application or EHR manufacturer is satisfied with ease of integration of REACTION
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).
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 the HIS. A standardized interface e.g. HL7 has to be used for data interchange. Required data fields are: - unique PID - name - age (data of birth) - sex - address	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) an interface based on HL7 has to be provided.	Standardized Interface (HL7) to HIS / EPR to exchange clinical data.

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 infrastructure (e.g. IHE-XDS) from where documents can be received.	Referrals can be documented and are considered in decision support, summary letters can be received via an appropriate data interface.
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 to be provided by a dedicated and independent application. This application communicates with - the REACTION platform over the Internet. - other systems in the surgery (EPR, lab, etc.) This application can be server-based and always on, for a prototype also an application client could be used.	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.
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	Standardized Interface (e.g. based on HL7) to Lab Information System (LIS) for glucose data import.

				the LIS has to be defined. HL7 would be a suitable standard.	

5.3 Requirements of WP5 – Network Management and Service Execution

5.3.1 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...*

5.3.2 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

5.3.3 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 …*

5.3.4 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
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.**

5.3.5 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-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-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

5.3.6 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

5.4 Requirements of WP6 – Integrative Risk Assessment and Feedback

5.4.1 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-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 data content. This helps to define personal models (profiles), which permit the personalised disease management.**	**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 as an input for risk assessment and disease management.**	**Personal Health Status Profiles can be generated.**
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.**

5.4.2 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-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
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 …*	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-162	Non-functional - Usability	Major	Documentation of user interfaces	Documentation for User Interface of all frontend applications.	User manual for all frontend applications
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 …*	*Thresholds have to be foreseen in the risk assessment module and advices have to be sent to …*
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 …*	*Once made sure the blood glucose level was correctly measured, values under specific thresholds …*
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-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…*	These scores have to be implemented in the risk assessment component
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. …*	*The data management and the user interface shall allow the insertion of time and composition of nutrition …*
REACTION-244	Functional - In-hospital pilot application	Minor	*The data management and the user interface shall allow the insertion of specific interfering drugs (including …*	*Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing …*	*The data management and the user interface shall allow the insertion of specific interfering drugs (including …*
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 clinical protocols.**	**Necessary models and rules are defined and stored.**

5.4.3 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…*	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)
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
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.**

5.4.4 Security and safety management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-165	Functional - REACTION platform	Major	Error Messages	*Error messages for every component within the application have to be foreseen so that they a …*	Services and feedback to user.

5.4.5 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 support or diabetes management the information has be pre-processed. NLP-technologies to find relevant information for REACTION applications from these data bases (annotation of text information: anamnesis information, co-morbidities, medical history, ...) can be a**	**REACTION provides a knowledge discovery module to process unstructured information and store this information in the data storage for further processing.**

				useful tool.	

5.5 Requirements of WP7 – Security, Privacy and Safety

5.5.1 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 permission to permanently delete data from the system. This refers to the system logging and all actions taken by different users. The system shall also provide traceability of each action to the user taken those actions.**	**The system shall foresee the possibility of traceability for each action which has been taken in the system by the user.**
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.**
REACTION-339	**Non-functional - Security**	**Major**	**Communication between the Reaction Device Hosting Server and the patient's/GP's web browser**	**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**

			MUST be authentic (entity authentication), with integrity, and confidential.	**web browser and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.**	**confidentiality.**
REACTION-341	**Non-functional - Security**	**Major**	**Roles MUST be defined for stakeholders of the Reaction platform, e.g., doctor, nurse, patient, informal carer, administrative personnel etc.**	**Each person in the Reaction platform has the right to perform a certain set of actions. In order to simplify the administration of these rights, each person is assigned to a role and roles are assigned to permissible actions. The advantage of this approach is that it is easier to manage the rights of a role than managing individual rights for each person.**	**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, persons MUST have at least one role to interact with the Reaction platform.**	**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 MUST be authentic (message authentication), with integrity, and confidential.**	**The security of messages transferred between the Reaction Host Client and the Reaction Device Hosting Server must be ensured even _after_ the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.**	**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 measured patient's real world identity.
REACTION-385	Non-functional - Security	Major	Digital identities for the Reaction platform MUST only be issued or revoked by trusted (third) parties, e.g., a certification authority (CA).	Without a trusted party (TP), anyone could produce its own digital identity and someone relying on such an identity would have to trust that the claimed identity is genuine. By incorporating a TP, relying parties trust that the TP ensures that its issued digital identities are genuine. This makes life easier for relying parties as they only have to establish a single trust relationship (with the TP) as opposed to having a multitude of trust relationships with others. The same goes for parties that had been excluded from the Reaction platform, as each relying party would have to determine by itself if another party is still part of the Reaction platform or not. In case of a trusted party, the relying part could simply query the TP if some identity is still valid or had been revoked, e.g., because its owner left the platform.	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 SHOULD be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the Reaction Device Hosting Server and the EPR/EHR System must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves	Availability of mechanisms to provide data authenticity, integrity, and confidentiality

				MUST be self-contained with respect to 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 communication, referrals, accountability of actions, exclusion of ill-behaving entities, etc.	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 (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the Reaction Hosting Client to the Reaction Device Hosting Server and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	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 action is part of the requester's set of permissible actions according to its role.	Availability of a control mechanism which decides whether a requested action may be granted or denied according to the requester's role.
REACTION-431	Non-functional - Security	Major	Data/messages exchanged between the Reaction Device Hosting Server and the GP EPR SHOULD be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the Reaction Device Hosting Server and the GP EPR must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained	Availability of mechanisms to provide data authenticity, integrity, and confidentiality

				with respect to 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 which role.**	**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 authentication), with integrity, and confidential.**	**It must be assumed that data transmission from the Reaction Device Hosting Server to the GP EPR and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.**	**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 (entity authentication), with integrity, and confidential.**	**It must be assumed that data transmission from the Reaction Device Hosting Server to the EPR/EHR System and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.**	**Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.**

5.6 Requirements of WP8 –Clinical Practise and Field Trials

5.6.1 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 Edit user accounts. The users shall be added to the system by their name and their role (user type) and also the ability to suspend and reactivate the user's account.**	**The system shall differ between active and suspended user accounts. Active users shall be displayed both with colour indicator and as a list function.**

5.6.2 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.

5.6.3 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 …*

5.6.4 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 and disease**	**An educational library with helpful content about patient's lifestyle shall be created. This library shall contain information about diet, activity, medication and advice to the patient in response to patient's lifestyle, etc.**	**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 instructions to the patient. It is recommended the use of large fonts, use of colours with strong contrast, possible use of audio messages and implementation of other commonly used accessibility options (utilization of full screen size on small as well as large screens), for the interface used by patients.**	**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.**

5.6.5 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.

5.7 Requirements of WP9 – Socio-Economic Framework

5.7.1 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-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. 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**	**Requirements of the proposed regulation**

				future.	
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 medical data. Another requirement is a 'log system' that records who did what and when in an audit log. This would contribute to realise those "technical and organizational measures" capable of ensuring the traceability of those who access the data of patients. Besides robust log-in and log systems showing who has accessed information and when.	EU case law (e.g. I v Finland) D9.2
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	Proposed regulation on data protection

				assessment	
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.**	**EU case law Armonias v Lithuania**

5.7.2 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 (See ethical analysis - task 9.1). For such individuals control over personal information is extremely important. Individual patients will not want to unnecessarily increase visibility of their condition as this will mean that they have reduced level of control over their personal information and will therefore have less ability to control who they reveal their condition to. Visibility of components and also electronic visibility of networking components should therefore be kept to a minimum.**	**Patients should feel that a REACTION like platform will not result in a overall increase in the visibility of their condition and consequently a reduction in their ability to conceal it, it they should wish to do so.**

5.7.3 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-142	Non-functional - Ethical	Major	The user should have a certain level of control over information relating to him/her	*Users are taken to be individuals who can make autonomous choices about their life. Although they can …*	*User control means that the user should be able to: - control of how personal data is handled …*
REACTION-143	Non-functional - Ethical	Major	*The user should be aware of the essential events, processes, stakeholders and attributes of the collection …*	*In order for data collection and use to be fair (see for instance, preamble 38 Directive 95/46/EC), users …*	*The user should be aware of: - when data collection occurs - who collects the (personal) data …*

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 …*	*Users should be able to understand:* *• how their personal data is collected and used …*
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-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-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 …*	*Does the application provide a set of default settings that cover the needs of the majority of users? …*
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 …*	Does the application have a reasonable cost? Is the application easy to install and maintain?
REACTION-471	**Non-functional - Cultural and political**	**Major**	**Individuals that suffer stigmatisation (including through conditions such as diabetes) often value the ability to socialise with others having a similar condition or sympathetic healthcare professionals. REACTION should not eliminate this possibility.**	**Individual patients often use the opportunity to meet such groups as a coping mechanism for the stigmatising effects there condition can entail. A REACTION platform should not reduce such possibilities too much. Where such possibilities are drastically reduced alternatives should be offered, for example online social networking possibilities.**	**Individuals should not feel that a REACTION platform has eliminated their access to other patients and sympathetic health care professionals which represent an important coping mechanism for individuals that feel stigmatised.**

5.7.4 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 …*
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 …*	*Does the application provide information about its trustworthiness?* *Does the application …*

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 …*	*Does the application provide ways to establish the trustworthiness of the operators? …*

5.8 Requirements of WP10 – Platform Integration and Implementation

5.8.1 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 …*	The possibility of configure the display of the patient clinical data (mainly the fever chart) has to be present.

5.8.2 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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, …*	Individual patient can always be mapped into a work flow stage.
REACTION-23	Functional	Major	Clinician generated feedback to patient	*It should be possible for clinician/staff to submit additional information to patients, e.g. for …*	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-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-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-…*	The applications shall allow the implementation of the structured programme.
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 …*	Specific forms and user interfaces for the doctors/nurses have to be present
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 …*	*Patient discharge from the outpatient environment has to be foreseen only in case of a) death; b) patient removal …*
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 …*
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 at the Primary Care**	**The clinician shall be able to monitor the patient's input data .The patient's account will be managed by the patient's care giver. In addition the clinician shall have the ability to add, delete, edit, search a patient by a list of patients. This list shall be sorted by ; Active , Non active, Last name or Disease Category**	**NON**

5.8.3 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

5.8.4 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 in the first-year prototype	*The first-year prototype has to be ready quite early and at that time no sufficient development will be made …*	*The blood glucose measurement in the first-year prototype will be performed in the same way in which it is …*

5.8.5 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

5.8.6 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-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 …*	The insulin administration shall allow also the IV way in the user interface
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 …*

5.8.7 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 patients status with no …*	The end user applications and the devices in the vicinity of the patient should always 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.

5.8.8 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

5.8.9 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 hospital or primary care with blood glucose and glycated haemoglobine).**	**Should be able to import and export data in an interoperable way (e.g. HL7) to third-party systems.**

5.9 Requirements of WP13 – Training

5.9.1 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

6 Conclusions

Lessons Learned (64 in the second year) and watch reports (3 in the second year) have induced changes in the requirements which have resulted in 155 new requirements and 2 updated requirements (no requirement was deleted). Furthermore, 86 requirements have been resolved as Out of Scope, Duplicate, Nonsense, Conflicting, Cannot Be Implemented or Cannot Reproduce (other 24 were resolved with these resolutions during the first year). A full list with these 86 requirements is reported in the next table.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion	Resolution
REACTION-10	Functional	Major	Data fusion model	A description of how different data values are combined into medical data	The system can provide automatic aggregation of data values from at least two different sensors.	Out of scope
REACTION-11	Functional - Primary care pilot application	Major	Life style baseline data	The system needs to store a set of baseline data regarding life style for each patient.	Life style data can be retrieved and updated per patient	Out of scope
REACTION-13	Functional	Major	To update EPRs with collected data	Provide an interface for updating EPRs.	Support at least IHE-PCD01.	Out of scope
REACTION-16	Functional	Major	Individualized targets for patients needs to be stored and retrieved	Needed to determine the effectiveness of different therapies.	Possible to store targets.	Out of scope
REACTION-19	Non-functional - Maintainability and portability	Major	Necessity of a mobile solution for the Primary care sphere	People tend to be moving and travelling.	Same service everywhere.	Out of scope
REACTION-21	Functional	Major	Change log for feedback model	It must be possible to track changes in the feedback model, i.e. which data has been collected at certain times.	All changes to the feedback model are stored in a change log.	Out of scope
REACTION-22	Functional	Major	Local feedback on measured values	It should be possible to provide feedback on measured values, e.g. graphical representations, to those patients that request it.	Patient able to select requested feedback values.	Duplicate
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. When a software component introduces new terms or models, these should be justified after examining if they can be drawn from the existing ontologies.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).	Out of scope
REACTION-29	Functional - Primary care pilot application	Critical	Accurate data acquirement	IR-absorption glucose spectra are strongly temperature dependent	Integration of temperature sensor in the sensor platform	Duplicate
REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances	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 Reproduce

REACTION-43	Non-functional - Security	Critical	Protection against data loss System must protect against: *Loss or replication of data transferred between two systems; *Concurrency problems; *Disk crash; *Protection against physical means.	Data integrity has to be guaranteed. *Loss or replication of data transferred between two systems (e.g. system shutdown); *Concurrency problems (e.g. 2 doctors interact with the system simutaneously and prescribe different medicines, which one will the system pick?); *Disk crash (e.g. solution could be periodic backup or RAID); *Protection against physical means (e.g. solution could be remote backup)	The functional test should include specific tests in order to verify such circumstances	Cannot Reproduce
REACTION-47	Non-functional - Look and feel	Minor	Web pages must be suited for screen readers, scaling to visually-impaired users, and utilizing the full screen size on small as well as large screens.	Will allow the easy interaction with the platform. Will also provide, as much as possible, to people with disabilities the ability to use the platform.	Use of large fonts, use of colours with strong contrast, possible use of audio messages and implementation of other commonly used accessibility options, at the applications developed to be used by patients.	Duplicate
REACTION-61	Functional - REACTION platform	Major	Data exchange with third-party systems	Ideally accepts and integrates information from outside of the managing organization (e.g. pharmacies).	Should be able to import and export data in an interoperable way to third-party systems.	Duplicate
REACTION-69	Functional - REACTION platform	Major	System Configuration	The components and applications should be made in a way that makes easy the configuration	Theoretically without any recompilation, the application should be easily configurable for the different environments	Cannot be implemented
REACTION-98	Functional - Primary care pilot application	Minor	Support identification of "patients at risk" for developing diabetes in primary care	Support identification of "patients at risk" for developing diabetes. The risk management component shall be able to evaluate this kind of risk.	The platform provides a component to calculate the risk of diabetes.	Out of scope
REACTION-102	Non-functional - Legal	Major	Notice: Natural persons should be notified when, how, and to what extent their personal data are communicated to others	Handling of personal data has to conform to privacy laws	Process design takes into account the fair-processing principle	Out of scope
REACTION-103	Non-functional - Legal	Major	Data reduction and data economy: Personal data shall be collected, processed and used as little as possible.	Handling personal data has to conform to privacy laws. In particular, personal data shall be rendered anonymous or pseudonymous as allowed by the purpose for which they are collected and/or further processed or used. This (might be/) is in conflict with unnecessary collection of personal data, which are not required to fulfil a specific task.	Processes are designed such that personal data are only collected when necessary and anonymisation/pseudonymisation techniques are employed whenever possible	Out of scope
REACTION-129	Functional - REACTION platform	Major	Portable device should allow the notification of alarms & alerts	The use of the same device also for the reception of alarms and alerts simplifies and makes less expensive the overall solution	The reception of alarm and alerts will be checked on the portable device	Duplicate
REACTION-135	Non-functional - Performance	Major	The platform shall be available for use 24 hours per day, 365 days per year	The platform shall guarantee a continuous support for patients and clinicians	No periods of service interruption have to be present	Duplicate

REACTION-137	Non-functional - Performance	Major	The platform should be able to process the existing end users of the Primary care and In-hospital field trials. 300 end-users should be enough. In the market this number is expected to grow to 1000	In the workshops the maximum number of users in the Primary care and In-hospital field trials has been estimated.	The possibility of creating such number of end users will be tested.	Out of scope
REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from the HIS or EPR through interoperable user interfaces	In case an interoperable HIS/EPR is present a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created his data have to be taken from the HIS/EPR.	Duplicate
REACTION-154	Functional - Primary care pilot application	Major	Comorbidities have to be registered	Comorbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient	In the design of data management, ontologies and user interfaces the possibility of registering the comorbidities with a basic set of attributes has to be guaranteed	Duplicate
REACTION-157	Functional - Primary care pilot application	Major	Annual clinical checks	The annual clinical checks for the Primary care environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt thesefields (e.g. to add new parameters or to delete obsolete ones).	Duplicate
REACTION-158	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 the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt these fields (e.g. to add new parameters or to delete obsolete ones).	Duplicate
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform	Duplicate
REACTION-163	Functional - In-hospital pilot application	Minor	Archive system: data from former admissions of the same patient can be easily retrieved and used for decision making	The system should store and archive patient related information from former admissions	Data is stored in the system and available after re-admission	Duplicate
REACTION-164	Functional - REACTION platform	Major	Common schema for data exchange between user interface (Health Status Profile) and integrated modules within WP6	It is essential to define and set schemas for the communication and interaction between modules within the Health Status Profile system.	Standardises Interfaces	Out of scope

REACTION-167	Functional - REACTION platform	Major	Use of contextualized data at medical decision and predictive models	Medical decision and predictive models have to use contextualized data in such a way that measurements will be annotated with context before they can be used by any algorithm	Data for medical decision and predictive models.	Out of scope
REACTION-177	Functional - Primary care pilot application	Major	Investigative stage	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels. RPM and clinical decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.	Duplicate
REACTION-178	Functional - Primary care pilot application	Major	Ongoing management	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients. RPM and decision support algorithms can be used in this stage for an optimal clinical support.	Specific fields have to be present in data management, ontologies and web user interfaces.	Duplicate
REACTION-182	Functional - Primary care pilot application	Major	Measurement of HbA1c	The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy. Frequency depends on: level of blood glucose control, stability of blood glucose control and change in insulin dose or regimen. Clinicians take decision on the optimal frequency.	Specific fields have to be foreseen in data management, ontologies and user interfaces.	Duplicate
REACTION-187	Functional - Primary care pilot application	Major	Storage of administered insulin	Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)	Duplicate
REACTION-198	Functional - REACTION platform	Major	Information related to informed consent have to be stored in the REACTION platform	An ethical approved informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION platform.	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the paper form signed informed consent and this procedure shall be completed before any other operation can be performed.	Duplicate

REACTION-199	Functional - Primary care pilot application	Major	Baseline and clinical history should be handled by the data management system	Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.	Duplicate
REACTION-201	Functional - Primary care pilot application	Major	Record baseline physiological measurements at the first visit	At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the platform	The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrolment)	Duplicate
REACTION-203	Functional - Primary care pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization	Duplicate
REACTION-218	Functional - Primary care pilot application	Major	Patient monitoring either manually or through RPM	In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using RPM. Otherwise, the patient can be monitored in the traditional way (manually).	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.	Duplicate
REACTION-222	Functional - In-hospital pilot application	Major	Insulin evaluation in Inpatient environment	The data used for the insulin evaluation have to be contextualized before their usage and then passed to mathematical algorithms for the calculation of the required insulin doses. Results have to be fed to dedicated diabetes experts specialized in glycaemic control for verification and evaluation. Their appraisal have to be fed back to physicians and nurses at the point of care in the patient ward.	The glucose control algorithms have to evaluate the insulin based on the parameters described above.	Duplicate
REACTION-233	Functional - In-hospital pilot application	Major	Insulin sensitivity and insulin resistance	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).	Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion shall be available	Duplicate

REACTION-239	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 euglycaemic condition. Therefore, in such cases the treatment is adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). A problem for the patient may arise if the patient has to wait longer than expected due to unexpected delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). Therefore, the dose of insulin and/or OADs will be adapted, the patient will get some food which he can eat in case of hypoglycaemia and the patient will get insulin which will be injected in case of hyperglycaemia.	These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the therapy scheme.	Duplicate
REACTION-242	Functional - In-hospital pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered and the changes in treatment have to be documented as well.	A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.	Duplicate
REACTION-248	Functional - In-hospital pilot application	Major	Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.	Duplicate
REACTION-252	Functional - In-hospital pilot application	Major	When some measurements are missing the system shall remind it through an active alarm reminder	Sometimes nurses forget to perform measurements. An active alarm system shall remind to perform the missing measurements. Regular measurements are necessary in order to have an optimal clinical decision and to minimize adverse events.	When a configurable time after the expected measurement acquisition time is elapsed, the system should send (at regular intervals) an alert to the nurse(s) in duty in order to perform the missing measurements.	Duplicate
REACTION-257	Functional - In-hospital pilot application	Major	Automated transfer of measured and relevant data to the patient's record	Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is a manually-labour intensive procedure with risk of transcription errors (handwriting prone to errors). The acquired measurements shall be automatically available in the patient's record/chart.	The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored in the patient's record/chart. If different devices from PoC will be used the acquisition procedure shall automatically store the acquired measurements in the patient's record/chart.	Out of scope

REACTION-259	Functional - In-hospital pilot application	Major	Automated patient identification	Automated patient identification to avoid identification mistakes. Risks of wrong patient identification have to be negligible. The REACTION identification system must be flexible enough to integrate existing identification methods employed on site, e.g., wards in a hospital.	An effective, proper and easy-to-use way for automated patient identification, when mobile device is close to the patient (RFID, NFC?) has to be present. For example, each patient might wear wristband with a barcode which identifies the patient. This is standard in many hospitals and in some wards of the inpatient clinical site these wristbands are in use. This way shall reduce errors in patient identification and speed-up the patient management.	Out of scope
REACTION-322	Functional - Primary care pilot application	Major	Primary care application interface should be icon based	Interaction must be easy for the patient end user. The interface should provide feedback to the patient end user.	Focus group and test plan for validating interface	Out of scope
REACTION-327	Functional - Primary care pilot application	Major	Each patient's self-monitoring records shall be displayed to the clinican too	There should be individual records for each patient on the monitoring software that provides an overview of : Demographic detail, Devices assigned to, Disease category, Alert limits and questions sets , educational content , monitoring data, question response data.	How much detailed data is permitted to be displayed shall be verified by clinicians.	Out of scope
REACTION-328	Functional - Primary care pilot application	Major	Ability to manage alerts to the user as clinician	The clinician should be able to set/edit and remove alert parameters around the patients physiological data, for instance if the physiological value is above limits or data is missing or if there are any technical /communication problems. The system shall have an acceptance bandwidth; the data which is not within this defined bandwidth shall be recognized and the clinician shall be notified of them.	The functionality shall be evaluated with test plan.	Out of scope
REACTION-329	Functional - Primary care pilot application	Major	Ability to set up to monitor sessions per day	The patient shall be alerted to take their physiological measurements e.g., blood pressure. Time frame of the physiological data shall be determined and confirmed by the clinicians.	the determined time frame of the physiological data shall be verified by the clinicians.	Out of scope
REACTION-332	Functional - Primary care pilot application	Major	Devices should be Continua compliant	Single architecture will reduce cost of end systems and enable flexibility in adding new sensors (plug and play interoperable)	Specification of device	Duplicate
REACTION-335	Functional - Primary care pilot application	Minor	Pulling patient data from EPR in to the system	The transformation of the patient's demographic data from EPR in to the system.	Since the integration between electronic patient record system and REACTION has not been identified/implemented , The transformation of the patient's data as patient's demographic data needs to be done manually.	Out of scope

REACTION-350	Functional - REACTION platform	Major	Connection with other external services	External interfaces to services of MS HealthVault and Google Health should be taken into account in the REACTION platform (RDMM 121). Other external services should be taken into account in the future.	Interfaces to other external services could be available (scalability).	Duplicate
REACTION-353	Functional - REACTION platform	Minor	Case generation	From the data of individual patients, a depersonalized case description is built which will be put in the case base.	Cases can be generated.	Out of scope
REACTION-355	Functional - REACTION platform	Major	Computer interpretable guidelines	Evidence based guidelines as important constituents of the knowledge base must be encoded in a computer-interpretable way for decision support.	Guidelines are encoded.	Out of scope
REACTION-359	Non-functional - Performance	Major	Maximum delay to transfer blood glucose value from POCT to In-hospital prototype	Up-to-date Blood glucose values are absolutely necessary for electronic decision support. In order to improve usability for physicians, the transfer delay from POCT device to In-hospital server application should be max. 3 seconds. Therefore the interface has to be appropriate to fulfil this constraint.	Delay of blood glucose transfer is max. 3 seconds	Cannot be implemented
REACTION-364	Functional - REACTION platform	Minor	Case base	The case base contains a set of cases generated in the platform and/or imported from existing case bases. It can be used together with other knowledge elements (e.g. evidences) to discover new knowledge.	A case base is present.	Out of scope
REACTION-366	Functional - REACTION platform	Major	Storage of events for context of measurements	Workshops	The data management should allow the storage of all events with impact on context.	Duplicate
REACTION-368	Functional - Primary care pilot application	Major	Clinical case conference	Any possible critical situation has to be accurately verified by the clinical care team with the support of virtual visits through e.g. the use of video-conference. The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed for. A clinical case conference report has to be stored.	Storage and retrieval of clinical case conference reports has to be possible.	Out of scope
REACTION-370	Non-functional - Legal	Major	A consent MUST NOT be considered valid if the patient was not involved in the decision.	If it cannot be verified that a consent was produced by or with the help of the affected data subject the 'expressed will' of the data subject is doubtful. Hence, no processing should be done as it is unclear that the data subject allowed it.	A mechanism is available that allows to verify (or infer) that a given consent was the data subject's own decision.	Out of scope
REACTION-373	Non-functional - Legal	Major	Data MUST NOT be processed at the Reaction Device Hosting Server if no consent is available and verifiable.	If patient data is to be processed at the REACTION Device Hosting Server, the server's provider must take the necessary steps to ensure that such a processing is permitted by the patient.	A 'watchdog' component must be in place that supervises the processing of patient data and takes action if data to be processed is not covered by the patient's consent.	Out of scope

REACTION-377	Functional - In-hospital pilot application	Major	Electronic fever/sugar chart	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.	In the design of the data management the electronic fever/sugar chart (or the possibility to compose it from the stored data) has to be present. Its access must be multi-user. The fever/sugar chart has to be initialized at the patient enrolment and updated at any data acquisition.	Out of scope
REACTION-379	Functional - In-hospital pilot application	Major	Interface for transmission of glucose values from POCT system to In-hospital prototype	As decision support is a time critical process, data from the POCT device should be transferred directly (without detour to LIS) to the In-hospital prototype in order to speed up the transmission process. Therefore an interface has to be provided.	Interface to POCT device is available for the In-hospital prototype.	Out of scope
REACTION-384	Functional - REACTION platform	Major	Communication failure recovery	In case of communication failure, the connection has to be restored ASAP and the information should not be duplicated or corrupted.	Ensure that there is no data loss in the event of communication failure.	Duplicate
REACTION-394	Functional - REACTION platform	Major	Support of continua compliant devices	Reaction platform should provide Continua compliant devices.	The REACTION platform supports Continua compliant devices.	Duplicate
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.	Duplicate
REACTION-398	Non-functional - Security	Major	If a consent was given, the patient's involvement in the decision MUST be verifiable by the Reaction Hosting Client, especially if the consent was given remotely, e.g., at the doctor's surgery.	Consents must be expressed by the data subject such that a third party, e.g., an AHD, can verify that the consent was actually given by the data subject herself -- this is especially relevant when the consent was given at the doctor's surgery and afterwards pushed back to the patient's AHD. Otherwise, anyone could produce a 'suitable' consent in the data subject's name.	Genuineness of a consent can be verified.	Out of scope
REACTION-405	Functional - Primary care pilot application	Major	Authentication and integrity of transmitted measurements MUST be ensured.	Without any data authentication, any measurement might be sent to the AHD without the AHD being able to distinguish between measurements from associated sensors and others. Also, if the measurements could be undetectably changed during transport, intentionally or unintentionally, this may have ill-effects on the patient's health because she may receive the wrong treatment due to 'false' measurements.	Mechanisms to ensure data integrity and entity authentication MUST be used for communication between sensors and AHDs.	Cannot be implemented

REACTION-406	Functional - REACTION platform	Major	IEEE 11073 support	The support for a specific subset of IEEE 11073 medical devices has to be provided.	Once specified which medical devices have to be supported, show that data can be collected from at least two of them.	Duplicate
REACTION-407	Non-functional - Legal	Major	If data was not transmitted for a lack of consent, the patient or her doctor (in case of a client without display and input capabilities) MUST be notified, e.g., through some pop-up or a notice in some message field.	Privacy laws require that data subjects have to consent to the transmission and processing of their data. If a new data item is to be transferred which was not foreseen in the initial consent, the subject has to give a 'new' consent before the new data item can be transferred and subsequently processed. If the subject's AHD has a display and input capabilities, the AHD may directly ask the subject for a new consent -- of course, the subject may also decline the request. If the AHD is an appliance without display, the transmission must include some kind of notice to inform the requesting party, usually the patient's doctor, that some data item was not transmitted and that the subject should be asked for an extended consent.	A notification mechanism for insufficient consents must be established for AHDs with and without display.	Out of scope
REACTION-411	Functional - REACTION platform	Major	Monitoring scheme	Individual monitoring scheme for each patient must be defined and stored. This describes what parameters and how often should be measured.	An individual monitoring scheme can be defined for each patient.	Duplicate
REACTION-412	Non-functional - Legal	Major	It MUST be possible to revoke a consent - data already stored MUST NOT be processed any further.	A patient must have the option to decide whether personal data is processed or not at any time. If the patient once gave her consent it must still be possible for the patient to revoke her consent, which means that any further processing of the affected data is forbidden. Also, if a patient revoked her consent the existing data may not necessarily be deleted, however, it MUST be excluded from any further processing.	Availability of mechanisms and procedures to enable consent revocation.	Out of scope
REACTION-417	Functional - In-hospital pilot application	Major	Dynamic data structure for In-hospital data storage	For the In-hospital pilot application (eDSS) a dynamic data structure for data storage has to be implemented. Data fields should be flexibly defined. A suitable model can be the Entity-attribute-value (EAV) model.	Dynamic data structure for data storage will be available for In-hospital pilot application.	Out of scope
REACTION-418	Functional - REACTION platform	Major	Context sensitive interface	"Best guesses" for input values and context-sensitive interface for data entry to keep efforts required for data entry as low as possible.	Users are satisfied with user input.	Out of scope
REACTION-420	Functional - Primary care pilot application	Major	Data should be automatically saved in temporary file when PDA's battery is running out.	In case of low battery the client application should be able to store temporary data. This will a) allow user to continue the process later and b) prevent corrupted / incomplete data to be uploaded to the main server.	The functional test should include specific tests in order to ensure that data are always stored correctly in case of a battery-forced shut down.	Duplicate

REACTION-422	Functional - REACTION platform	Major	User transparency in case of communication failure	In case of network error the client application should be able to store temporary data (RDMM 76). The system should detect problems on the network and start the local storage. From the client's viewpoint, failures should be perfectly masked, and service should be completely fault-tolerant.	User transparency refers to a combination of user friendliness' and 'high efficiency'.	Duplicate
REACTION-427	Functional - Primary care pilot application	Major	Confidentiality of transmitted measurements SHOULD be ensured.	Without any mechanism providing confidentiality, measurements sent from sensors might be overheard by third parties. This circumstance is alleviated a bit by the fact that sensors usually have a limited transmission range but active eavesdroppers may still use, say, antennas powerful enough to catch the signal.	A mechanism to ensure data confidentiality SHOULD be used whenever measurements are sent from the sensor to the AHD.	Cannot be implemented
REACTION-429	Non-functional - Legal	Major	Before transmitting any personal data, the patient's consent MUST be given. If no consent was given yet, the data MUST NOT be sent.	Privacy laws require that data subjects have to consent to the transmission and processing of their data. Without a consent, processing of personal data is not permitted by law.	A 'watchdog' component must be in place that supervises the transmission of personal data and takes action if data to be transmitted is not covered by the subject's consent.	Out of scope
REACTION-436	Functional - Primary care pilot application	Major	Care space in outpatient environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members.	The data management shall allow the storage of the care space for each patient with specific roles for each member of the care space.	Duplicate
REACTION-440	Functional - Primary care pilot application	Major	Reasons for end of process in Primary care environment	The primary care processes only ends in the event that the patient leaves the practice catchment area, voluntary withdraws from the REACTION monitoring system or dies.	Patient discharge from the Primary care environment shall have the following options: a) death; b) patient leaves the practice catchment area; c) patient voluntarilily stops being monitored by the REACTION platform.	Duplicate
REACTION-446	Functional - In-hospital pilot application	Major	Clinical data to be stored in the Inpatient environment	The data management shall be designed in order to allow the storage of the clinical data to be registered at the patient enrolment as well as other clinical parameters which have to be acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, comorbidities, therapy scheme. Other parameters have to be measuredmore frequently: glucose level, injected insulin, food	The data management shall allow the insertion and the update of all the listed clinical parameters.	Duplicate

				intake/nutrition, estimation of insulin sensitivity and resistance.		
REACTION-447	Functional - REACTION platform	Major	IEEE 11073-20601 compatibility of Solianis device	Solianis would like to provide IEEE 11073-20601 compatibility (IEEE PHD protocols) for their blood glucose device.	REACTION middleware supports support IEEE PHD protocols.	Cannot be implemented
REACTION-450	Functional - In-hospital pilot application	Major	Fever and infections shall be registered	Fever is very often associated with insulin resistance which means that the patient needs more insulin.	Fever and infections shall be registered in the data management where they can be retrieved for composing the fever/sugar chart. When estimating the insulin resistance, clinicians shall have access to this information.	Duplicate
REACTION-461	Functional - Primary care pilot application	Major	Sensor devices (PAN/LAN devices) and receiving devices (AHDs) MUST be paired to ensure entity authentication.	Without any authentication, sensors may send data to unintended receivers, which might become a privacy problem, or AHDs may receive measurements from devices which are not the patient's, which might become a security problem and eventually a health problem if the patient receives the wrong treatment due to 'false' measurements.	Some kind of 'pairing mechanism' or entity authentication MUST be used before any sensor data is transmitted or received.	Cannot be implemented
REACTION-464	Functional - REACTION platform	Major	Telemonitoring profile/consent manager	This module should provide security mechanism for data stored in the REACTION platform. Patients have to acknowledge that personal data gathered from them can be stored and transmitted within the technical infrastructure of REACTION. Therefore the patient has to sign a consent form and the information about this should be stored within the system. It should be possible to exclude several personal information from storage/transmission. This manager could be queried, e.g. by the data fusion component (or any other component that processes personal patient data) before anything is processed in order to determine if the processing was permitted by the patient. Such a permission would be expressed by way of a consent.	Telemonitoring profile/consent manager will be technically implemented into the REACTION platform.	Out of scope
REACTION-469	Functional - In-hospital pilot application	Major	Visualization of current "insulin on board" and "carbohydrates on board"	As part of electronic decision support the current "insulin on board" and "carbohydrates on board" should be presented to the physicians and nurses. Methods/Functions: - trend information - active profile of insulin on board (using physiological models)	Inpatient prototype provides visualization of current "insulin on board" and "carbohydrates on board" for decision support.	Out of scope

The 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 simplifying the list provided in the previous chapter.

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 has been on the primary care environment from the detailed specifications to the development of the first primary care prototype, and through this process the consortium as a whole has achieved a deeper understanding of the requirements for the primary care domain.

The result is that at the end of the second iteration cycle, the REACTION requirements registered in JIRA consist of 437 requirements in total (they were 281 at the end of year 1). It can be seen that 36% of the requirements are in the progress of being worked, while 6% of all requirements are still “Open”, i.e. either they have not passed the initial quality check or have not been assigned for implementation. 21% of the requirements are in the “Part of specification” status, thus they have passed the initial quality check and are waiting for being worked. 21% of requirements are closed while 16% are resolved.

The progress compared to the end of the first year is significant. In fact, despite an increment in the total requirements of 56% compared to the first year and mainly due to the incorporation during the second year of the JIRA sub-projects in a unique main requirement project, the number of requirement resolved or closed is 37% (it was 14% in year 1). A similar progress can be also observed in the reduced amount of requirements on which work has not started yet (27% at the end of year 2 while it was 49% at the end of year 1).

A total of 53 requirements (~16% of the effective requirements) have been implemented at the end of the second year, but 40 are still waiting for user validation, while 13 have been already validated and then closed. Despite of the increment in the total number of requirements there has been a significant increment in the resolved requirements compared to the first year (only 7%). This has been mainly due to the consolidation of the in-hospital prototype and the release of the first primary care prototype. That implied also a significant increment of the “In progress” requirements, again compared to the first year.