Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

REACTION (FP7 248590)

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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 cycle 1 and the current JIRA workflow management. The complete list of the requirements at the end of cycle 1 is reported in a separate appendix.
Comments	
Status	☐ Draft ☒ Task leader accepted ☒ WP leader accepted ☒ Technical supervisor accepted ☐ Medical Engineering supervisor accepted ☐ Medical supervisor accepted ☒ Quality manager checked ☒ Project Coordinator accepted
Action requested	☐ to be revised by partners involved in the preparation of the deliverable ☐ for approval of the task leader ☐ for approval of the WP leader ☐ for approval of the Technical Manager ☐ for approval of the Medical Engineering Manager ☐ for approval of the Medical Manager ☐ for approval of the Quality Manager ☐ for approval of the Project Coordinator **Deadline for action**: N/A
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0.1	F. Chiarugi	2011-04-21	ToC
0.2	F. Chiarugi, H. Udsen	2011-04-28	Review of ToC and structure of the document
0.3	F. Chiarugi, H. Udsen, T. Klotzbuecher, S. Spat, K. Neubauer	2011-06-03	Insert the contributions sent by the WP leaders and by IN-JET
0.4	F. Chiarugi, M. Spanakis	2011-07-25	Updated based on the final version of ID2-8-2 and retrofits from WP3, WP6, WP8 and WP10 leaders.
0.5	F. Chiarugi, D. Manousos	2011-08-26	Finalized after fruitful discussion with the WP leader.
1.0	F. Chiarugi	2011-09-02	Answered reviewers' comments.
1.1	F. Chiarugi, J. Thestrup, H. Udsen	2011-09-09	Reduced the document length, create a separate document with the complete set of requirements and restructured the contents.
			Final version submitted to the European Commission

Internal review history	Reviewed by	Date	Comments made
	Matts Ahlsen	2011-08-31	
	Tamas Toth	2011-08-30	

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 ID2-8-2 “Change request and re-engineering report 1” 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 first requirement revision, operated at the end of the first 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 elicited 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 all the 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 first iteration cycle. Nevertheless, it provides also some information about the main actions related to the requirement management that will be performed during the second 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 of 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.

In Section 3, the suggested changes are presented and the implemented changes are finally described. In Section 4, the main actions that will be performed on the requirement management during the next iteration cycle are presented. They consist mainly in a revision of the logical and physical components (including hardware and software) after the architectural consolidation and in the optimization of the requirement workflow in order to achieve a more effective and clear management from each WP leader.

Section 5 discusses the status of the requirements after their first year revision and provides some significant statistical information. In Section 6, the main conclusions are reported. Finally, in Section 7 the list of the requirements per WP and component is shown.

The complete list of the requirements is reported as appendix in a separate document.

2. Main Outcomes from the First 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 analyses and reports their 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 during watch reports including their literature search.

More details about the Lessons Learned can be found in ID2-8-2 “Change request and re-engineering report 1”.

A total of 47 *Lessons Learned* has been reported in the first iteration cycle. All *Lessons Learned* have been stored in a repository of the REACTION TWiki.

The analysis of the Lessons Learned produces request for changes that have to be examined and finally the suggested changes can be implemented or rejected. The whole process is summarized in Figure 1.

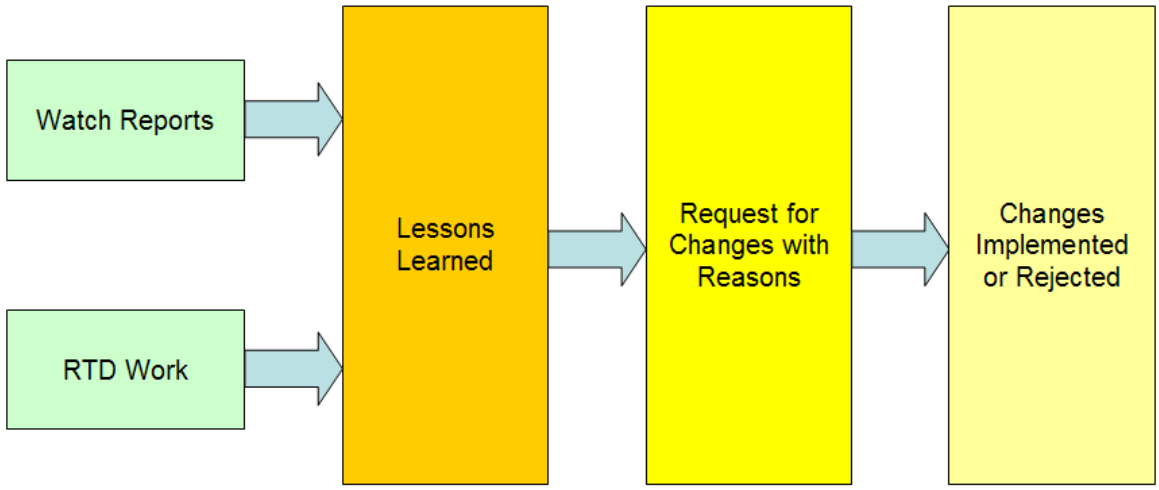

Figure 1: The requirement revision process at each iteration cycle.

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 has to be noticed 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 first iteration cycle two watch reports have been produced and delivered in the context of the work performed in WP2: D2-4 “Market and Regulatory Standards Watch Report” and ID2-3 “Technology Watch Report”. A clinical watch report is also foreseen in the course of the project but it will be delivered at M24.

The main outcomes of the watch reports with potential impact on the project requirements can be also expressed also in terms of *Lessons Learned*. Here below the main outcomes and their implications on the requirements will be discussed.

2.1.1 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.

Further significant issues emerging from this watch report are:

- Focus on user friendliness and user acceptance
- Creation of an improvement compared to the current diabetes management
- Broad management of diabetes including insulin-dependent patients (focus is on the glucose measurement and insulin administration) and non insulin-dependent patient (focus has to be also on lifestyle management)
- Flexibility versus the different national healthcare systems across Europe with different actors for running healthcare services and different reimbursement approaches
- Necessity of interoperability capabilities across different environments and existing technologies
- Selection of the applicable security standards
- Selection of the applicable standards on risk management
- Selection of the interoperability standards to be adopted
- Necessity of a lifecycle management with the adoption of relevant standards
- Selection of proper standards related to the informed consent and the authorization for the data transmission

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 in the medical device field, even if the level of maturity of the standards is still not very high. Being all other conditions equal, Continua compliant device should be considered and preferred for their use in the REACTION platform. That would also have a positive impact in the adoption of interoperability standards.

Further significant issues emerging from this watch report are:

- Necessity of supporting non-Continua protocols (especially for environmental and fitness/wellbeing devices)
- In chronic disease management also the following parameters should be monitored: signs & symptoms, medication & side effects, diet & lifestyle, compliance information
- In addition, psychological-mental aspects may also be considered since stress, depression, coping with the disease influence the patient's behaviour, e.g. their compliance, and ultimately the success of diabetes management
- 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
- PAN/BAN node should be used also for receiving and showing patient reminders
- Environmental data to be considered are: position (GPS), ambient temperature, physical activity
- Existing systems are based on glucose and a few other parameters: integration of other parameters is a key for going beyond the state of the art

- In the primary care environment the availability of a patient diary 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 inducing unacceptable overhead in the patient
- Colourful interfaces have to be used for the display of the monitoring results

2.1.3 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 first iteration only the main issues coming from the two watch reports have been considered and used as Lessons Learned. In fact, 7 Lessons Learned specifically referred to Continua have been collected in WP4 and 2 Lessons Learned specifically referred to the amended MDD have been collected in WP10.

Other issues, once consolidated during the second iteration cycle, will be accurately evaluated if they are properly covered by the existing requirements or if any change or addition to the existing requirements will be necessary for taking them properly into account.

2.2 Outcomes from the RTD Work

Lessons have been learned mainly in the technical work packages, but also the non-technical work packages generated some Lessons Learned.

Different Lessons Learned were collected in the various work packages and most of them did not have any impact in the requirements established at the start of the related 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 first year iteration where several cross checks between the technical people and the clinical people were performed in order to test very frequently the prototype under development and its usability and expected functionalities.

More details about the explicit Lessons Learned can be found in the detailed analysis contained in ID2-8-2 “Change request and re-engineering report 1”. Here below a few significant examples have been reported.

A Lesson Learned referred to the need to have earlier in the project an architecture (including its building blocks) able to perform all the major tasks of the envisaged platform. This Lesson Learned impacted in the project planning for the second iteration cycle but not in the requirements.

Another Lesson Learned assessed the impact of the Amendment 2007/47/EC to the Medical Device Directive (MDD) 93/42/EC. Now also software for medical purposes is considered a “medical device” and there is an impact and an overhead in all the system development cycles. Procedures and documentation have to be provided and quality standards have to be accurately applied in order to assure compliance with the amended MDD.

A Lesson Learned addressed the importance of timely delivery of work products such as requirement specifications, source code, components etc. in order to allow the release in time of the prototypes foreseen in the project. The overall work plan since the release of the detailed specification for the architectural design, the release of the components and the integration phase has to be accurately followed. The probable approach of sharing components for the primary care environment instead of sharing components and source code (the approach used for the in-hospital prototype) will imply a heavier integration phase. Thus the timely provision of all the necessary elements in order to start in time the integration phase will be extremely important.

Another Lesson Learned dealt with the subject of reusability. As also foreseen in the DoW reusability has to be applied in the REACTION project if we wish to contain the development costs (already enhanced due to the implications of the amended MDD). An accurate architectural analysis, particularly at the beginning of year 2 when the development cycle for the first prototype of the primary care environment will start, has to be performed in order to properly identify reusable (in practice) components that can be used across the various clinical environments.

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 gathered requirements has been accurately evaluated. In the next chapter the impact of the Lessons Learned on the requirements gathered in each WP will be described.

2.3 Current Status of the Requirements and Statistics

At the end of the first iteration cycle, the REACTION requirements registered in JIRA consists of 281 requirements in total. From the statistics in Figure 2 it can be seen that 34% of the requirments are in the progress of being worked, while 49% of all requirements are still Open, i.e. either they have not passed the initial quality check or have not been assigned for implementation. This means that the project is slightly ahead of a linear progression of requirements implementation.

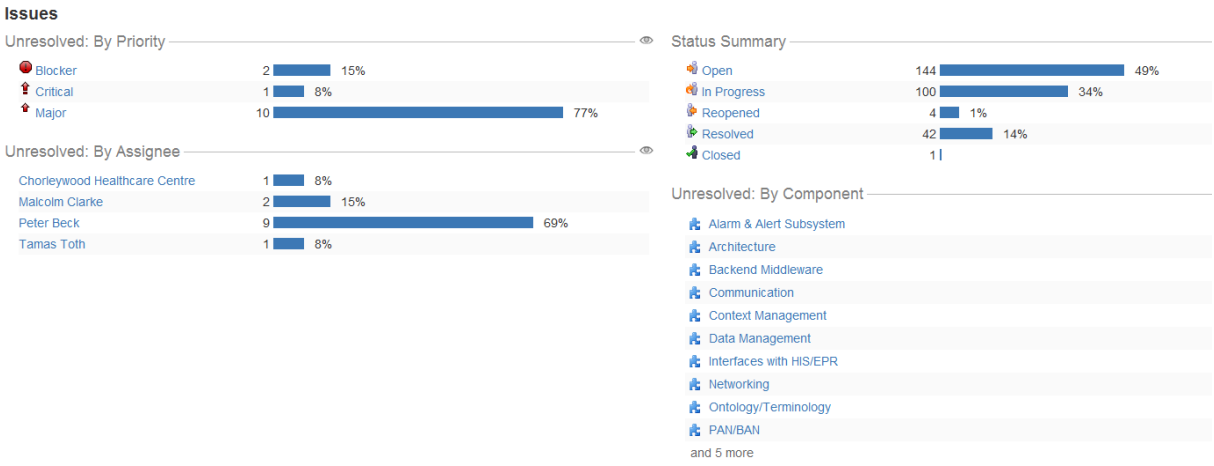

Figure 2: The REACTION requirements progression.

Requirements are classified as functional, non-functional or constraints in accordance to what reported in D2-5. In Figure 3 the classification according to the requirement type is shown. One can see the majority of requirements is functional, while very few requirements are constraints.

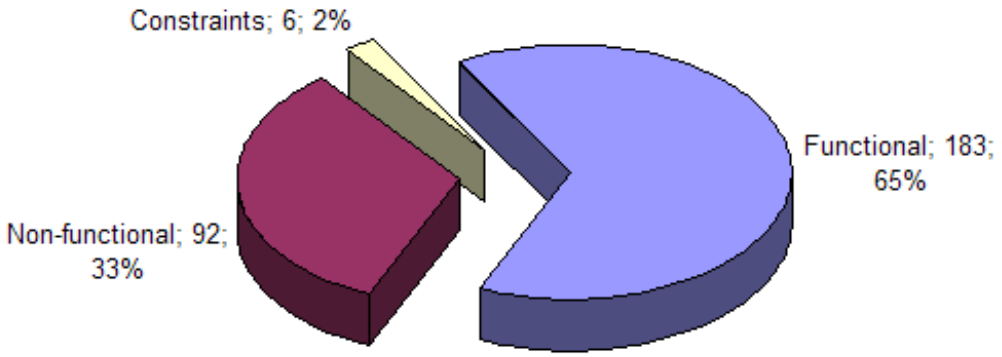

Figure 3: The REACTION requirements classified by requirement type.

The classification of functional requirements based on their subtype is shown in Figure 4. One can see the majority of requirements is related to the in-hospital environment since this environment is at a higher stage of development, while detailed specifications for the primary care environment should be available during the second year of the project.

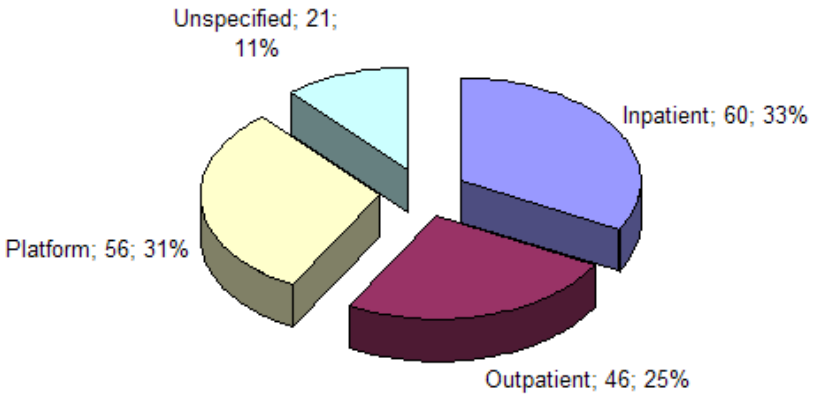

Figure 4: The REACTION functional requirements classified by requirement subtype.

The classification of non-functional requirements based on their subtype is shown in Figure 5. One can see 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 for the usability, FHG-SIT for the security and VUB for the legal aspects.

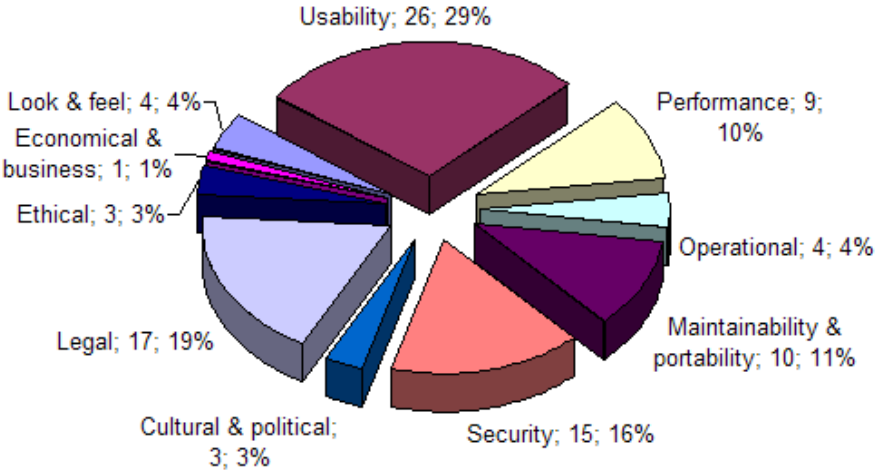

Figure 5: The REACTION non-functional requirements classified by requirement subtype.

Finally, in Figure 6 the classification of constraints based on their subtype is shown.

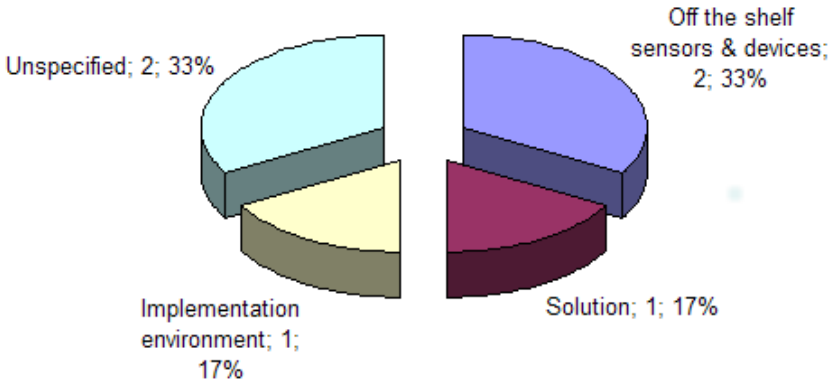

Figure 6: The REACTION constraints classified by their subtype.

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

The status and the resolution of each requirement provided an indication about its advancement towards the completion.

In Figure 7 the status of all REACTION requirements is presented:

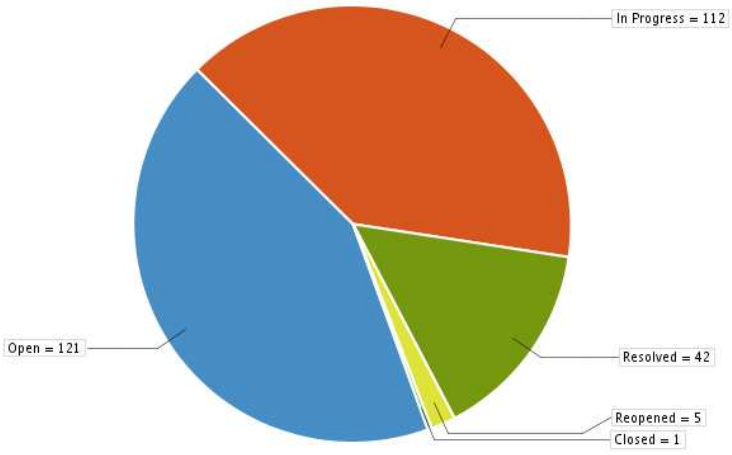

Figure 7: The status of all REACTION requirements at the end of the first iteration cycle.

Most requirements are either “In progress” or “Resolved”, while 126 requirements (~45%) are still in the “Open” (or “Reopened”) status and some of them are waiting either for a proper review of their formulation or for the finalization of the detailed specifications of the primary care prototype in order to understand if they are really part of the specifications or out of the scope.

The resolutions associated to the “Open” or “Reopened” requirements are shown in Figure 8.

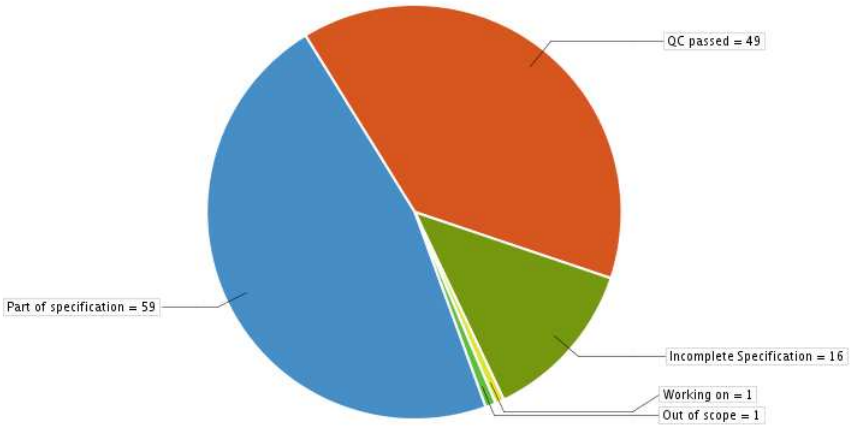

Figure 8: The resolutions associated to the "Open" or "Reopened" requirements at the end of the first iteration cycle.

112 requirements (~40%) are "In progress" and in the next Figure 9 and Figure 10 the distribution of these requirements per component and per actor are respectively shown. This shows a fairly high level of activity across all types of components as seen in Figure 9.

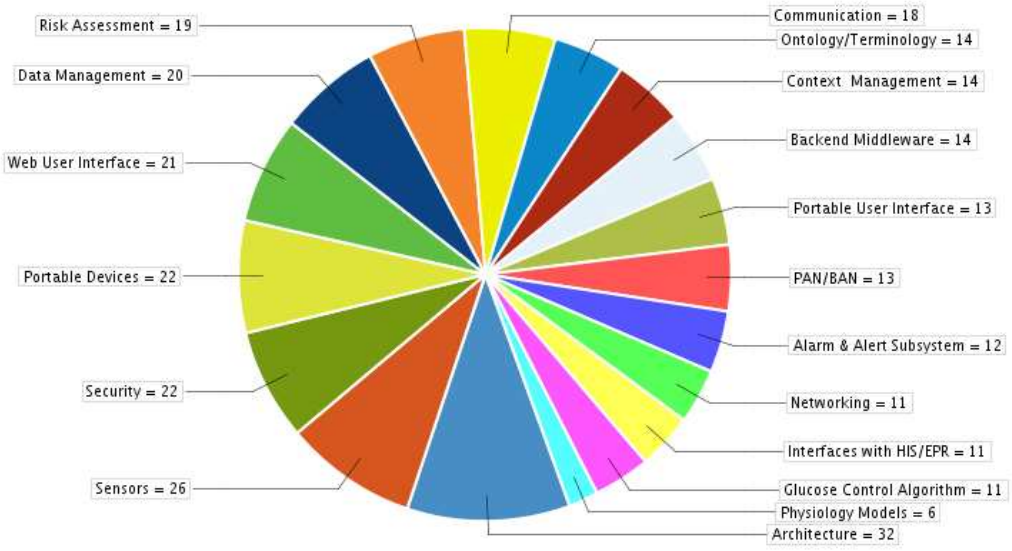

Figure 9: The components to which the "In progress" requirements are associated. Note that any requirements can be associated to more than one component.

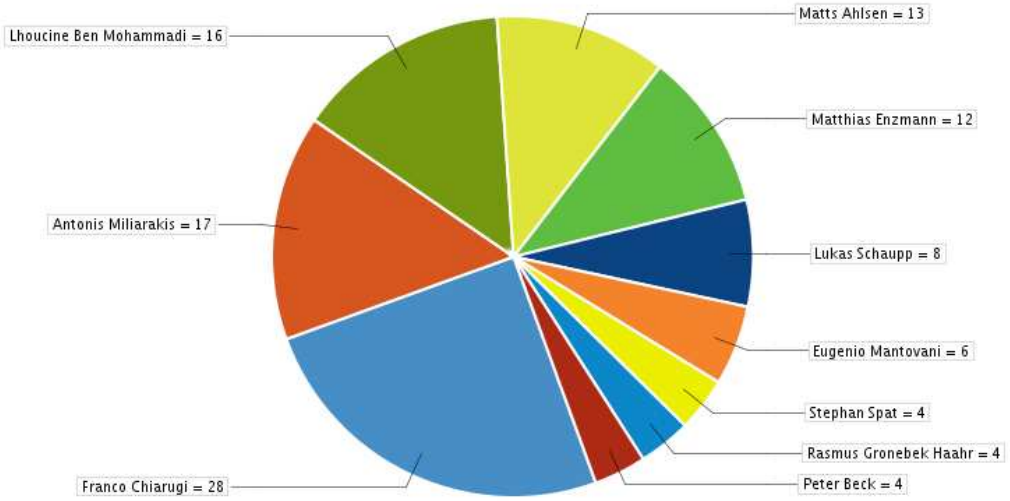

Figure 10: The actors to which the "In progress" requirements are assigned.

There are 42 "Resolved" requirements (~15%) of which 23 have been resolved as duplicates and 1 as out of the scope. In Figure 11 the resolution associated to the "Resolved" requirements is shown.

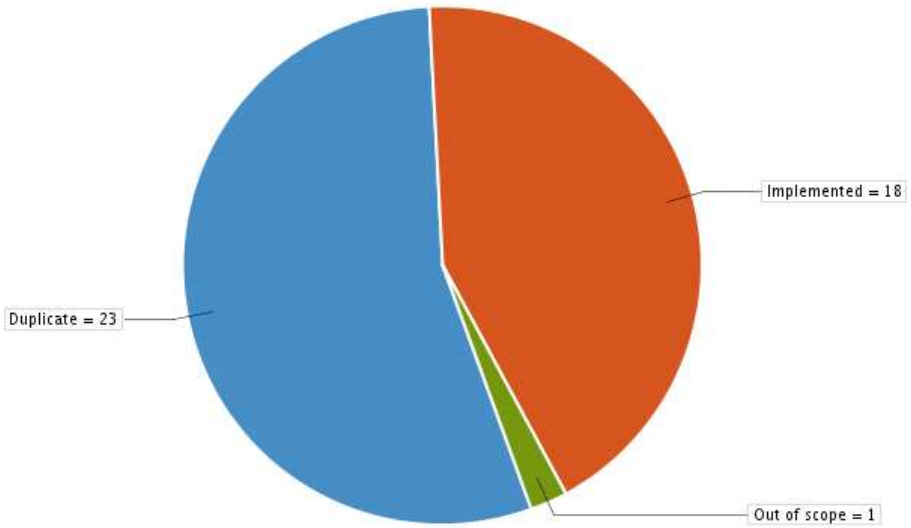

Figure 11: The resolutions of all the "Resolved" requirements at the end of the first iteration cycle.

A total of 19 requirements (~7%) have been implemented at the end of the first year, but 18 are still waiting for user validation (see Figure 12), while 1 has been already validated and then closed. This is an expected result since the first year prototype is to be regarded as a proof-of-concept prototype where some founctionalities are only partly implemented so that the corresponding requirement cannot be classified as resolved.

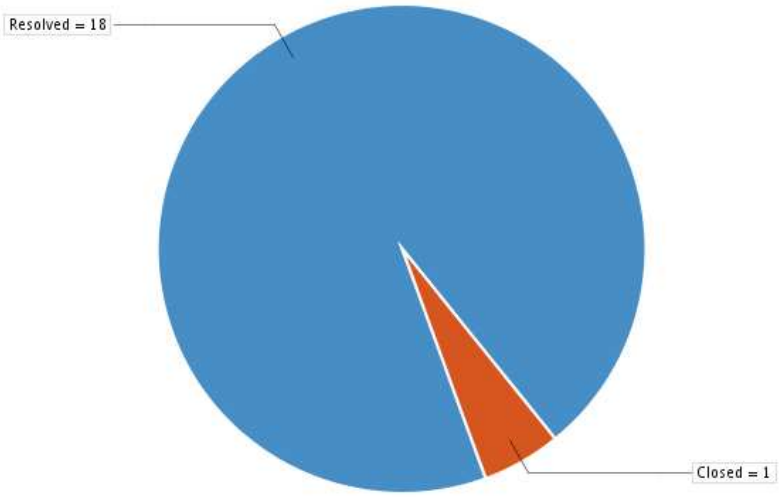

Figure 12: The REACTION requirements implemented or validated at the end of the first iteration cycle.

Finally, since the validation of the first year prototype is not fully completed, only a small number of the requirements can be classified as validated.

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

Each Lesson Learned reported in cycle 1 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 only in technical work packages and specifically in WP3, WP6, WP8 and WP10.

A few words have to be spent about WP4 and WP7. WP4 and WP7 during the first iteration cycle produced additional JIRA projects with special focus on the specific requirements of their WP.

More specifically, in the course of the first iteration a specific 'REACTION data management model requirements' JIRA project was created in order to have a better focus on the specific requirements related to the data management issues. This project consists of 133 requirements RDMM-2 through RDMM-134, but all requirements are either derived or clones/duplicates of the requirements listed in the main 'REACTION Requirements' JIRA project.

In a similar way, the work in WP7 performed in the first iteration cycle resulted in the collection of 59 requirements in a separate project in JIRA specifically for security requirements ('REACTION Security Requirements' (RSR)). They have been numbered RSR-1 through RSR-59, but all the requirements are exact clones of the requirements listed in the main 'REACTION Requirements' JIRA project or in the 'REACTION data management model requirements'.

In this document we do not analyze the changes in these secondary JIRA projects but only in the primary 'REACTION requirements' JIRA project, which has the main purpose of giving a unified and global picture of the overall project.

In order to maintain a uniform and global view of the requirement of the REACTION project, during the second iteration cycle each requirement of the secondary projects will be individually analyzed and, if not an exact clone, its impact in the main requirement project will be evaluated with some consequent change, addition or deletion in the requirement of the primary 'REACTION requirements' JIRA project.

That has been already planned in order to guarantee a proper and effective requirement management using JIRA. Furthermore, a new and more effective and suitable workflow for managing transitions between various states is under investigation taking into account that the JIRA workflow tool manages transitions between various states and operates per issue in one project and cannot work synchronously on issues in several projects. The new workflow will eventually be applied during the second iteration cycle in place of the default.

Having this in mind and, thus, referring to the primary JIRA project 'REACTION requirements', no new requirements have been added, no requirements have been modified and no requirements have been deleted in WP4 and WP7.

After the above clarifications, it is possible to state that the work performed during the first iteration cycle and the lessons reported in cycle 1 have not resulted in any changes in the requirements for work packages WP1, WP2, WP4, WP5, WP7, WP9 and WP12. Furthermore, WP11 and WP13 have reported neither any Lessons Learned in the first cycle nor any change or impact in the gathered requirements.

Thus, only the technical work packages WP3, WP6, WP8 and WP10 had changes in their requirements due to the impact of the specific Lessons Learned.

The implications of the Lessons Learned for the requirements resulted in 1 proposed new requirement, 23 requirements proposed for update and 4 requirements proposed for deletion.

After an accurate evaluation of the proposed changes finally 1 new requirement was inserted, 22 requirements were updated and no requirement was deleted.

3.1 Change Request and Re-Engineering Originating from WP3

Based on the Lessons Learned (6 Lessons Learned in WP3) a set of 3 requirements have been identified as subjects to possible updating and 4 requirements as subjects to be deleted. More details about the explicit Lessons Learned can be found in the detailed analysis contained in ID2-8-2 “Change request and re-engineering report 1”.

The table containing the requirements subjects to possible updating with their summaries and the suggestions for the changes is shown here below.

Key	Summary	Priority	Suggestions for Changes
REACTION-8	User interface for manual entry of lifestyle data	Major	This requirement should apply only to the primary care pilot application and not to the in-hospital pilot application where the lifestyle (as long-term diabetes management) is not managed.
REACTION-183	The sensitivity of the glucose sensor should be high, the SNR must be large and changes of glucose concentration in the range 1-15 mM must be detectable	Major	The sensitivity of the glucose sensor should be high, the SNR must be large and changes of glucose concentration in the range 1-15 mM must be detectable. For AGC the accuracy should be +/-5% of the measured value in the specified range.
REACTION-274	The cost of the sensor should be specified	Major	The cost of the sensor should be specified and the cost should not exceed tbd EUR for in-hospital application, tbd EUR for primary care, tbd EUR for AGC. Cost has to be specified during Y2.

Some other requirements were analyzed as well in order to identify more accurately the WPs on which they have impact, but their meaning and main contents (expressed in their primary fields) did not need to be changed.

Furthermore, the following 4 requirements that could be deleted have been identified:

- REACTION-29, since it is the same as REACTION-183.
- REACTION-105, since it is the same as REACTION-49.
- REACTION-106, since it is the same as REACTION-50.
- REACTION-225, since it is not a requirement.

3.1.1 New Requirements

No new requirements have been inserted.

3.1.2 Updated Requirements

Some requirements (REACTION-72, REACTION-75, REACTION-87, REACTION-89, REACTION-124, REACTION-214, REACTION-257 and REACTION-267) were changed only in the WPs on which they impacted excluding WP3 or in other cases including WP8 since some clinical expertise was specifically required. These requirements are not reported in the list below since no changes were made in their primary fields (requirement type, priority, summary, rationale and fit criterion).

The list of the updated requirements in their primary fields is reported below.

Note that the costs left undefined in REACTION-274 will be finally specified during the second iteration cycle.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-8	Functional - Outpatient 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 patients.	User interface exists.
REACTION-183	Functional - REACTION platform	Major	The sensitivity of the glucose sensor should be high, the SNR must be large and changes of glucose concentration in the range 1-15 mM must be detectable	For AGC the accuracy should be +/-5% of the measured value in the specified range. For a closed loop sensor system (glucose measurement + insulin dosage) especially in the lower concentration range of about 3-4 mM or less a high accuracy is required to avoid mistreatments in the hyperglycaemic range.	Performance of reference measurements on defined samples.
REACTION-274	Functional - REACTION platform	Major	The cost of the sensor should be specified	The cost of the sensor determines its later potential for a certain application (outpatient or inpatient use) and is influenced by its production effort.	The cost of the sensor should be specified by the sensor manufacturers and be as low as possible. The cost of the sensor should be specified and the cost should not exceed tbd EUR for inpatient application, tbd EUR for primary care, tbd EUR for AGC.

3.1.3 Deleted Requirements

No requirement has been deleted. In fact, REACTION-29 is not exactly the same as REACTION-183. REACTION-105 and REACTION-106 are clearly duplicates of REACTION-49 and REACTION-50, but duplicates have been set as resolved (with “Duplicate” resolution) according to the established workflow. Finally, REACTION-225 has not been deleted since identifies some major features of the first-year prototype.

3.2 Change Request and Re-Engineering Originating from WP6

More details about the explicit Lessons Learned can be found in the detailed analysis contained in ID2-8-2 “Change request and re-engineering report 1”. Based on the 6 Lessons Learned and the work performed in the first iteration cycle in WP6 the following main issues resulted:

- A user-centred approach for workflow and risk assessment application definition proved to be successful.
- Data acquisition (DCCT dataset) for long-term risk models is time-consuming and needs the acknowledgement of ethical committee (*working with large datasets for risk modelling*).
- Due to the relatively small available EPR dataset data mining methods may be restricted and not all ideas can be satisfied in the first run. EPR and sensor data are very rare within the project setting. Maybe not all planned techniques can be applied on this data.
- Four specific scenarios for risk assessment applications have been chosen for the development work in year 2:

- Decision Support for Insulin Dosing (Diabetes Type 2)
- Decision Support for Insulin Dosing (Diabetes Type 1)
- Adaptive long-term risk predication for risk communication
- Risk classification of diabetic patients at risk for bad glucose control

- Requirements for visualisation of medical (laboratory) values changed party according to change comment on REACTION-96.
- HbA1c data field is currently not foreseen for the in-hospital prototype.
- Thresholds for blood glucose borders will be set for all patients at ward equally in the first iteration steps, while the possibility of personalizing them will be analyzed in the next prototypes.
- Detailed nutrition information is not needed for the in-hospital insulin dosing protocol (only whether or not the patient will eat before insulin administration).
- Smart “guessing” for default values is not safe enough for a medical device; therefore this requirement will not be implemented.

The impact of the above issues in the requirements resulted in the identification of 7 requirements for possible update.

Key	Summary	Priority	Suggestions for Changes
REACTION-70	Processing of multi-parametric clinical and non-clinical data from different sources	Blocker	Four specific risk assessment applications refines these requirement
REACTION-73	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Major	Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication 2) Risk classification of diabetic patients at risk for bad glucose control
REACTION-96	Visualization individual patient data to support glucose control (decision support)	Major	Partly changed: 1) personal configuration not required any more 2) assembling of data is also not necessary 3) overview screen for all patients is currently no requirement 4) parameters ordered hierarchically is not required
REACTION-98	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital	Minor	This requirement has been assigned for the primary care prototype (not for hospital anymore)
REACTION-185	Diabetic management for type I diabetic patients	Major	OAD as addition for insulin treatment will be documented for in-hospital patients
REACTION-219	Safe Glycaemic Control (SGC)	Major	Thresholds for blood sugar are defined for all patients at ward according to internal standards
REACTION-255	Management of missing data	Major	Mandatory fields have to be filled otherwise the user cannot go on the workflow of the in-hospital prototype. Guessing for default values is not safe enough for a medical device.

No need for new requirements or for the deletion of any existing requirements came out.

3.2.1 New Requirements

No new requirements have been added.

3.2.2 Updated Requirements

6 requirements have been updated and they are listed in the table below. It is important to notice that no changes have been made to REACTION-185 since patients with type I diabetes are insulin-dependent and administration of OAD has to be allowed only on patients with type II.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-70	Functional – REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data. Four different applications have been identified in ID6-5 of WP6: 1) Decision Support for Insulin Dosing in Hospital a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes b. Decision Support for Insulin Dosing in Hospital for patients with type I diabetes 2) Primary Care Risk Assessment Applications a. Long-term risk assessment application b. Short-term risk assessment application Details of the applications can be found in ID6-5.	Platform flexibly supports processing of data from multiple sources
REACTION-73	Functional – Outpatient pilot application	Major	Provide decision support for insulin dosing for physicians and/or patients (outpatient)	Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)	Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5
REACTION-96	Functional – Inpatient pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")	Inpatient REACTION pilot offers dynamic visualization module for decision support
REACTION-98	Functional - Outpatient pilot application	Minor	Support identification of "patients at risk" for developing diabetes / need for	Support identification of "patients at risk" for developing diabetes / need for insulin treatment in primary care (when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of	If a diabetic patient is not on insulin therapy, the platform shall be able to estimate the risk for the particular patient to become insulin-

			insulin treatment in primary care	risk.	dependent. Inpatient REACTION pilot decision support tool offers "patients at risk" calculator.
REACTION-219	Functional - Inpatient pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state. In the first iteration step all patients will use the same threshold.
REACTION-255	Functional - Inpatient 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. Guessing for default values is not safe enough for a medical device.	Mandatory fields have to be filled in a safe and traceable manner!

3.2.3 Deleted Requirements

No requirements have been deleted.

3.3 Change Request and Re-Engineering Originating from WP8

The main outcomes from the 3 Lessons Learned collected in this WP are summarized here below. Once again more details about the explicit Lessons Learned can be found in the detailed analysis contained in ID2-8-2 “Change request and re-engineering report 1”.

- The actual glycaemic management of the Endocrinology and Cardiology wards at the Medical University of Graz was assessed. The results were compared with the current recommendations. The main outcome of the workflow analysis was that there is space for improvement of glycaemic control.
- The literature review has shown that there is no suitable protocol of glycaemic control available which can be directly applied at the two wards (workflow in the hospital does not fit to the procedures described in the literature). Therefore the best published practice has been adapted to the needs at the wards of the Medical University of Graz.
- To reduce the gap between practice and science, an educational programme for glycaemic management and in particular for the adapted best published practice is being established at the wards. Furthermore, a multidisciplinary (physicians, nurses, engineers) focus group was formed to discuss and to plan the development of the new technical solution: requirements were defined and a risk analysis was started. The multidisciplinary procedure is more time-consuming than expected, but is absolutely necessary for later acceptance of the innovation.
- In order to practice the new glycaemic management without the possible risk of device failure, the algorithm will be tested using a paper based protocol in 32 patients at the Endocrinology ward. The findings of the study will be implemented into the new device which will then be tested after completion of the paper based study. This stepwise approach has the advantage that the practitioners get familiar with new solution. Furthermore, difficulties and barriers of the innovation can be solved and improved at an early stage of the development. In parallel 32 patients at the Cardiology ward will serve as a control group in order to monitor the improvement of glycaemic management by adapting the new protocol (first paper based and then electronically).

The impact of these Lessons Learned on the requirements related to WP8 has been summarized in the following table.

Key	Summary	Priority	Suggestions for Changes
	Risk analysis	Major	A new requirement specifying that a risk analysis has to be started in the very early stage of the development should be added. The identified risks have to be identified and assessed.
REACTION-262	Improve productivity and efficiency, reducing cost	Major	Usability tests were performed in order to adjust specifications of the system. Questionnaires will be part of the first clinical trial to assess usability
REACTION-281	Clinical trials CE- certification OR certification that the device fulfils the MDD 93/42/EEC and subsequent amending directives like the directive 2007/47/EC	Major	Change of rationale and fit criterion in order to specify that also software as medical device should be compliant with the amended MDD

As a consequence it has bees been suggested that:

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

3.3.1 New Requirements

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-321	Non-functional - Operational	Major	Risk Analysis	Risk Analysis was started in the very early stage of the development. The identified risks were identified and assessed.	All risks must be in an acceptable range according to the assessment criteria

3.3.2 Updated Requirements

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 patient workflow and management	Qualitative or quantitative measurements of productivity, efficiency and cost shall be foreseen in the field trials in order to make a proper comparison between the performances before the introduction of the REACTION platform and after the introduction of the REACTION platform. Assessment in field trial will be based on questionnaire for evaluating productivity and efficiency and on cost-benefit analysis estimating the different performances before the introduction of the REACTION platform and after the introduction of the REACTION platform. Usability tests will be performed early in the life cycle in order to adjust

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

3.3.3 Deleted Requirements

No requirements have been deleted.

3.4 Change Request and Re-Engineering Originating from WP10

In the course of the first iteration a specific 'REACTION Glucose management System (In-hospital prototype)' JIRA project was created in the context of WP10 in order to support, as issue tracker, the development of the in-hospital prototype (first release was due at M12). This project currently consists of 101 issues from GMSIP-1 to GMSIP-101, but all these issues, including tasks and potential bugs, as specified above, were inserted for the support of the development phase. The scope of this document is not to analyze the changes in this development-support JIRA project, but only in the primary 'REACTION requirements' JIRA project.

Based on the detailed specifications produced for the in-hospital prototype and the first iteration providing the realisation of the first-year in-hospital prototype, 8 Lessons Learned were collected in WP10 highlighting the following main elements:

- HbA1c data field is currently not foreseen for the in-hospital prototype.
- Detailed nutrition information in not needed for the in-hospital insulin dosing protocol (only whether or not the patient will eat before insulin administration).
- Some additional data (weight/BMI/waist to hip ratio, infection, diarrhoea, vomiting, limited renal/hepatic function, pancreas operation, co-morbidities, fever, temperature, other vital signs, insulin sensitivity, interfering drugs (systemic or analytical), diminished/absence of appetite, special conditions related to nutrition, meal composition, insulin deliver type, planned examinations/treatments) that in the initial requirements were expressed as desired are not important anymore, for the in-hospital prototype. That implies some requirements should have their rationale reviewed since they should not express a clear need for those data anymore. In some other cases priority, customer satisfaction and customer dissatisfaction should be lowered.
- Smart "guessing" for default values is not safe enough for a medical device; this requirement will not be implemented.
- In some requirements (general for the REACTION platform and not specific for one environment) data that are not strictly required anymore in the in-hospital environment are mentioned. Probably these requirements should now be referred only to the primary care application.
- When the 'fever/sugar chart' of the in-hospital environment is referred to, it is understood as the graphical display of the relevant information for the glucose management.

The impact of the above issues on the requirements related to WP10 has been summarized in the following table.

Key	Summary	Priority	Suggestions for Changes
REACTION-153	Symptoms of diabetes or hyperglycaemia	Major	This requirement should address only the primary care pilot application
REACTION-154	Comorbidities have to be registered	Major	This requirement should address only the primary care pilot application
REACTION-171	Data input application for inpatient glucose control	Major	Modify the clinical data listing only the ones which have been considered important for the in-hospital environment. The concept of guessing data has to be deleted.
REACTION-235	Therapy scheme in Inpatient environment registered immediately after the patient enrolment	Major	Modify the clinical data listing only the ones which have been considered important for the therapy scheme in the in-hospital environment.
REACTION-240	Intravenous insulin	Major	In hospital (non ICU) it is very rare that insulin will be delivered IV. It is always delivered subcutaneously. Thus, priority of this requirement should be lowered to Trivial.
REACTION-243	Nutrition has to be taken into account in the calculation of the drug dosage	Major	Nutrition in hospital is usually stored as a yes/no variable. Thus, such details for the nutrition should not be so important in hospitals and priority should be lowered to Trivial.
REACTION-244	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.	Major	Drug interference is not so primary in hospitals. The priority has to be reduced to Minor.
REACTION-245	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation	Major	Impact of fever and infections in the insulin dosage is secondary and priority should be reduced to Trivial.
REACTION-246	Multi-user availability and display of the fever chart	Major	Modify the clinical data listing only the ones which have been considered important for the in-hospital environment (e.g. temperature and vital signs are not important for the daily glucose management).
REACTION-255	Management of missing data	Major	Reduce the priority and specify that missing data have not to be guessed.
REACTION-285	User interface for the clinical data stored in the inpatient environment	Major	Modify the clinical data listing only the ones which have been considered important (at the enrolment and measured in the in-hospital workflow) for the in-hospital environment.

As a consequence it has bees been suggested that 11 requirements should be updated without adding or deleting any requirement.

3.4.1 New Requirements

No new requirements have been added.

3.4.2 Updated Requirements

Requirements REACTION-171, REACTION-235, REACTION-240, REACTION-243, REACTION-244, REACTION-245, REACTION-246 and REACTION-285 have been reviewed because they refer to the use of data that are not very important in the in-hospital environment. In some cases the rationale has been modified to exclude mentioning of these data and in other cases the priority, customer satisfaction and customer dissatisfaction have been lowered.

Requirements REACTION-255 has not been deleted but put at the lowest priority because it refers to "value guessing" which cannot be applied without generating potential harm for the patient in any medical device. For the same reason in REACTION-171 any reference to guessed values has been deleted.

Requirements REACTION-153 and REACTION-154 referred the general REACTION platform but address data that are not very important in the in-hospital environment. The decision has been to change the "requirement type" addressing now only the primary care environment.

The list of modified requirements is shown below.

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-153	Functional - Outpatient pilot application	Major	Symptoms of diabetes or hyperglycaemia	At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).	Specific design in the user interfaces, ontologies and data management
REACTION-154	Functional - Outpatient 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
REACTION-171	Functional - Inpatient pilot application	Major	Data input application for inpatient glucose control	The system should ask for data entry of relevant parameters. Main parameters for documentation (once, at the enrolment) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight 4. classification of the patient regarding insulin sensitive/normal/resistant Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. hypoglycaemic and	Data entry system will be available for inpatient decision support system with devices (tablet PC)

				hyperglycaemic episodes	
REACTION-235	Functional - Inpatient pilot application	Major	Therapy scheme in Inpatient environment registered immediately after the patient enrolment	The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status, nutrition, insulin resistance. Eventual additional data might be added during the course of the project.	The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.
REACTION-240	Functional - Inpatient pilot application	Trivial	Intravenous insulin	In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.	The insulin administration shall allow also the IV way in the user interface
REACTION-243	Functional - Inpatient pilot application	Trivial	Nutrition has to be taken into account in the calculation of the drug dosage	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
REACTION-244	Functional - Inpatient pilot application	Minor	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose-interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.	The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.
REACTION-245	Functional - Inpatient 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 checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.
REACTION-246	Functional - Inpatient 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 patient stay in the hospital ward (blood glucose level, information about the actual status of the patients, drug	Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.

				administration, nutrition, relevant events, etc.). Other eventual parameters could be considered during the overall life cycle of the development.	
REACTION-255	Functional - Inpatient pilot application	Trivial	Management of missing data	Mandatory fields have to be filled otherwise the user cannot go on the workflow of the inpatient prototype. Guessing for default values is not safe enough for a medical device.	Mandatory fields have to be filled in a safe and traceable manner!
REACTION-285	Functional - Inpatient pilot application	Major	User interface for the clinical data stored in the inpatient environment	The user interface shall allow the insertion, modification and visualization of the clinical data registered at the patient enrolment and of the clinical data acquired more frequently. The main data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight, therapy scheme, estimation of insulin resistance. Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, hypoglycaemia and hyperglycaemia. The possibility of adding further parameters at the enrolment or during daily acquisitions should be foreseen in the design.	There shall be a user interface which allows the insertion and the update of all the listed parameters.

3.4.3 Deleted Requirements

No requirements have been deleted.

4. The Next Iteration Cycle

4.1 High Level Management of the Requirements

It is important to notice that for an effective management of the REACTION requirements with JIRA from a high level, all requirements should be contained in a single comprehensive project.

The creation of additional projects should be deprecated.

In fact, the selected tool for requirement management (JIRA) does not make possible to perform requirements engineering across several projects. First of all, JIRA's workflow tool manages transitions between various states. It operates per issue in one project and cannot work synchronously on issues in several projects. So there is no automatic way for assuring that the requirements are totally synchronized in both the original project and the sub-projects (or clones).

JIRA has a well develop filtering system that allows making subset of requirements and it is possible to create the exact same functionality within the single requirement project and still maintain the overall high level manageability.

For this reason during the second year all the existing requirements of the two sub-projects "REACTION data management model requirements" and "REACTION Security Requirements" will be individually analyzed and eventually new requirements will be added to the main "REACTION requirements" project or some requirement will be updated or deleted.

4.2 Optimization of the Requirement Workflow

In order to have the overall control of the project requirements and of their progresses, there is the possibility in JIRA of enabling a workflow mechanism. At the beginning of the project, after examining different options of workflow schemes, the default workflow was selected and enabled as the most appropriate for the REACTION project.

A workflow in JIRA is composed of several status and each requirement during its life evolves (makes transitions) froma statuis to another till its finalization (status = Resolved and then Closed).

The default workflow mechanism of JIRA allows changing and tracking the status of each requirement during its lifecycle (see Figure 13). The status of each requirement has specific transitions or next steps that define its progress. For example, when a requirement is in the "In progress" status the next steps are "Resolve" or "Close", but it is also possible to go back to its initial status ("Open").

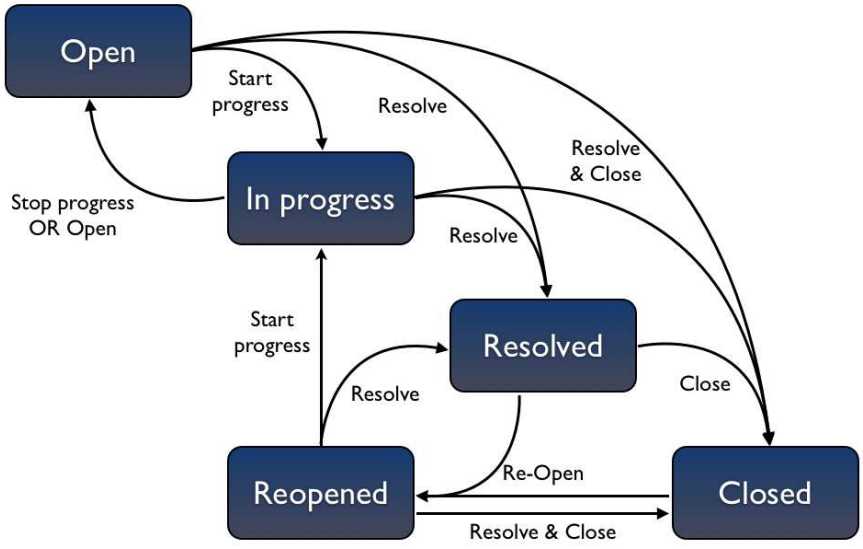

Figure 13: Default workflow scheme.

Resolutions have been used during the first year as a tag for further specifying the characteristics of the requirement in specific statuses (not only the Resolved status). During the first year some further resolutions were added to the default ones in order to tag the requirements during their lifecycle and to identify more clearly their evolution.

The current complete list of available resolutions is listed in the following table, where the resolutions in black are the predefined ones in JIRA while the resolutions in red have been added for the purposes of the REACTION requirement management:

Part of specification (Default)	The requirement can be assigned and progressed
QC passed	The requirement has been passed through quality gateway
Out of scope	The requirement is outside the scope of the project
Duplicate	The problem is a duplicate of an existing issue.
Incomplete Specification	The problem is not completely described.
Working on	Development has been started and under progress for implementing the requirement
Implemented	The requirement has been implemented
Validated	Testing confirms that the requirement has been satisfied
Incomplete or Not Satisfactory Implementation	The requirement has not been properly implemented and validation failed
Fixed	A fix for this issue is checked into the tree and tested.
Won't Fix	The problem described is an issue which will never be fixed.
Cannot Reproduce	All attempts at reproducing this issue failed, or not enough information was available to reproduce the issue. Reading the code produces no clues as to why this behavior would occur. If more information appears later, please reopen the issue.

However, it has to be noticed that JIRA has the flexibility of adding or editing existing workflow schemes to satisfy the project needs for tracking requirements (customizing the statuses and transitions according to the project needs).

During the second iteration cycle the design of an optimized workflow for the REACTION project has been started. The plan is that, after an evaluation phase on a test project and the agreement of all consortium partners, the new workflow will be applied to the main “REACTION requirements” project with the purpose to assure a simpler and more effective management of the REACTION requirements.

The basic ideas are:

- Execute reasonable changes to the statuses of the default workflow.
- 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 for explaining the reason for which a requirement was resolved. Thus, each requirement will be with “UNRESOLVED” resolution till when it will be moved in the “Resolved” status.
- Customize adequately the set of the available resolutions for resolving the requirements.

A first draft of the new workflow has been already designed and it is shown in Figure 14, 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.

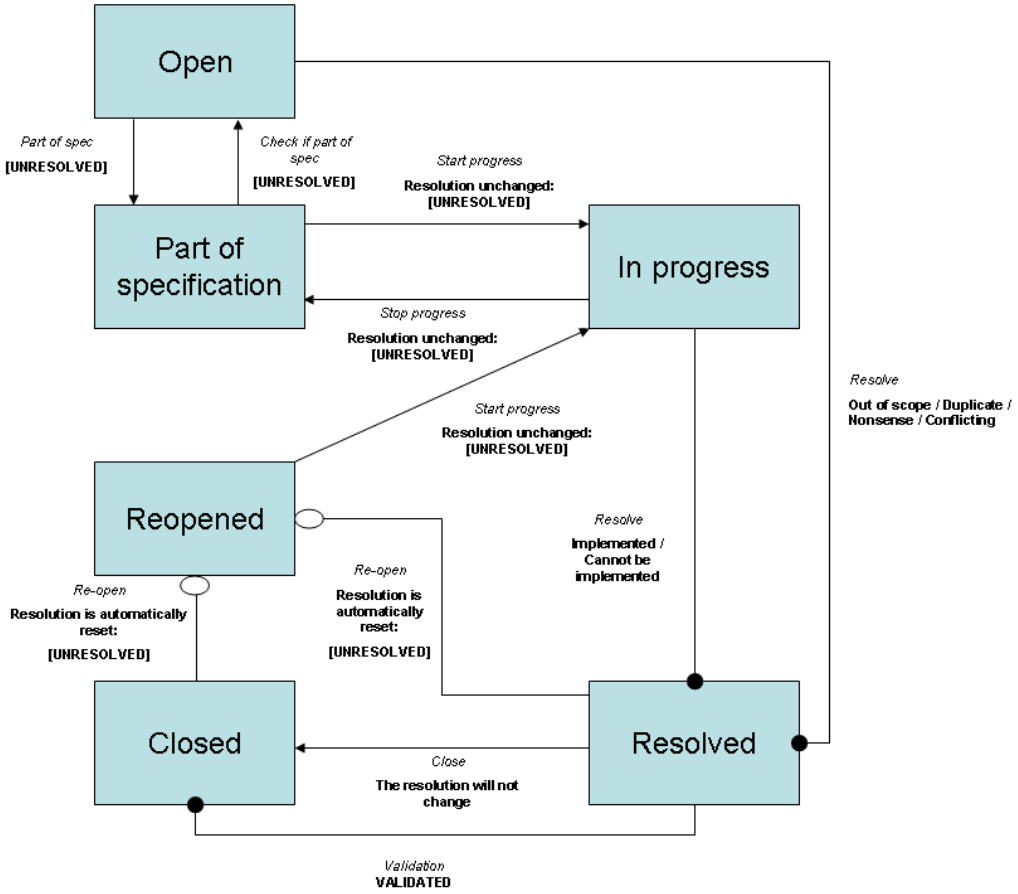

Figure 14: The new proposed workflow.

In the requirement lifecycle the Reporter is the person who created first the requirement, while the Assignee is the person who will be in charge of implementing the requirement once it has been agreed this requirement is Part of specification. Reporter will have also the responsibility of verifying the requirement was properly implemented and then closing it. In this case the Reporter will operate the Validation transition from the Resolved status with resolution = Implemented to the Closed status.

4.3 Impact of the Platform Architecture in the Requirements

It is important to notice that 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 iteration cycle and mainly after the production of the detailed specifications for the in-hospital prototype several architectural schemas were proposed and further refined.

This process will continue also during the second iteration cycle where the detailed specifications of the primary care prototypes will be produced. Based on the detailed specifications of the two environments which have to be addressed by the REACTION platform, it will be possible to make the final design of the platform architecture.

It has to be noticed that, once the final architecture will be produced, then a complete list of the logical and/or physical components or building blocks will be available. At that time all the requirements will have to be re-assigned to the components or building blocks of the new architecture.

Currently the list of components is still the one which was identified during the initial phase of the project:

- 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)

This task will be performed during the second iteration cycle or just at the end of the second iteration cycle when the new Lessons Learned will be collected, change requests will be produced and requirements will have to be added, updated or deleted.

5. Conclusions

Lessons Learned and watch reports have induced very few changes in the initial requirements which have been resulted in 1 new requirement and 22 updated requirements (no requirement was deleted). These few changes can raise some doubts about the effectiveness of the Lessons Learned process and the consortium has to consider if it will be necessary to optimize this process during the next iteration cycles.

The work performed during the first year has been mainly dedicated to the development of a prototype for the in-hospital environment and to architectural studies and general component development. No focused work was performed on the primary care prototypes since detailed specifications are still under development for the primary care environment. It is very likely that several requirements defined at the early beginning of the project and focused on this environment might need to be reviewed, once the detailed specifications of the primary care environment will be agreed among the REACTION consortium and finally delivered.

This is one of the main reasons because work has not started yet on 45% of the requirements, but this problem should be overcome during the second year. 7% of the requirements have been implemented during the first year even if in the detailed specifications for the in-hospital prototype a clear plan for the release of the different prototypes till the end of the project was delivered and the various requirements were distributed in the various prototypes scheduled at different years. 40% of the requirements are in progress and that make us optimistic about the implementation of many of them during the second iteration cycle.

Some problems have been put into evidence during the first year of requirement management.

The default JIRA workflow will be probably substituted by a more suitable workflow during the second iteration cycle and that should facilitate further the requirement management.

Another important point will be the final architecture review and component specification that will probably induce some changes in the component field of the requirements during the second iteration cycle. If this will be the case, that will be reported at the end of year 2.

6. The Requirements of the REACTION Platform after the First Year Revision

In this chapter the requirements of the REACTION platform after the first year revision are reported per WP and per component showing only the major fields like priority, summary, rationale and fit criterion. Duplicated requirements in the “Resolved” status (with resolution “Duplicate”) have not been listed. A complete list of the requirements after the first year revision (including the duplicates), which includes all the requirement fields and their current status in the selected JIRA workflow, is provided in the last chapter of this deliverable.

It has to be noticed that each requirement can have an impact on more than a single WP and on more than a single component. 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. It is a task of the Assignee to coordinate the work during the lifecycle of the REACTION project among different WPs or components in order to assure the requirement will be properly resolved. In order to give an effective view of the requirements and to avoid an excessive length for this deliverable, each requirement, even if with an impact on more than a single WP, has been listed only in the WP on which it has major impact. Furthermore, for the same reasons, only the requirements which have had some changes at the end of the first 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 first 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 but no work has been already started on them either because their specification has been considered incomplete or because the assignee is waiting for the detailed specifications of the primary care prototypes in order to evaluate if these “Open” requirements are really part of the specifications.

The main purpose of the tables shown below is to provide each WP leader with an immediate visual impact on the status and progresses of the requirements of her/his WP.

6.1 Requirements of WP3 – Sensors Monitoring and Contextualisation

6.1.1 Alarm and Subsystem

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

6.1.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-126	Functional - REACTION platform	Major	Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake)	*The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. …*	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device
REACTION-128	Functional - REACTION platform	Major	Portable device should allow the display of feedback to patient	*In mobile situation the only available device is the portable device and patient should be able to use it for uploading or downloading data. …*	*The portable user interface should be used also for displaying the clinician feedback to patients, graphical representation of the data acquired ….*
REACTION-129	Functional - REACTION platform	Major	Portable device should allow the notification of alarms & alerts	The use of the same device also for the reception of alarms and alerts simplifies and makes less expensive the overall solution	The reception of alarm and alerts will be checked on the portable device

6.1.3 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-40	Functional - REACTION platform	Critical	*The sensors/devices developed by the consortium which communicate with the platform wirelessly, must be able to connect swiftly to platform …*	*To guarantee the operation of the portable devices under any circumstances. Consortium developed wireless …*	*Multiple trials in a real life environment (not only in the fully controlled environment of the laboratory) using multiple WiFi and Bluetooth devices …*
REACTION-52	Non-functional - Usability	Minor	*If the portable touch device is not capable to connect wirelessly and send the data, then it should be able to connect via USB to a host …*	*If no wireless network is available at the user's home environment, then he/she must be given the opportunity to send the measurements from the …*	*Creation of a service for the home gateway that upon USB connection with the portable device, the service will transmit the cached data of the …*

REACTION-207	Functional	Major	ePatch communication	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.	*The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the …*

6.1.4 Data Management

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

6.1.5 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-126	Functional - REACTION platform	Major	Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake)	*The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. The possibility …*	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device
REACTION-204	Functional - REACTION platform	Critical	ePatch	*The ePatch is the preferred device and technology used to attached and connect sensors to the body. However, it should be possible that …*	Hardware fabricated.
REACTION-207	Functional	Major	ePatch communication	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.	*The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the …*
REACTION-236	Functional - Inpatient pilot application	Major	Blood glucose measurements in Inpatient environment	*PoC devices are currently used and will be used in Inpatient environment. The procedure is reliable and has been used since several years…*	*There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose …*

6.1.6 Portable Devices

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

REACTION-49	Non-functional - Usability	Major	The touch/tablet/phone device must allow the execution of processes in the background	*The applications developed for the portable devices should start and stop only when the user wants. If the portable device is a mobile phone …*	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-50	Non-functional - Usability	Major	The touch/tablet/phone device must support notification messages	*The portable device must have the ability to show alert messages to the user. This will allow the device to report promptly to the user if any …*	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-51	Functional - Outpatient pilot application	Critical	*If the touch/tablet/phone device is not able to send the data to the platform (lack of connectivity), it should store them locally and then send them …*	*It is likely that outside the home, the user will not have access to a wireless network. In such a case the mobile device will continue to take ...*	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-52	Non-functional - Usability	Minor	*If the portable touch device is not capable to connect wirelessly and send the data, then it should be able to connect via USB to a host …*	*If no wireless network is available at the user's home environment, then he/she must be given the opportunity to send the measurements from …*	*Creation of a service for the home gateway that upon USB connection with the portable device, the service will transmit the cached data of the …*
REACTION-53	Non-functional - Usability	Major	**The portable touch device must have at least the following connectivity options: WiFi (802.11g or 802.11n), Bluetooth, USB; *Also it must have …*	*The device must support the latest and most widespread communication protocols. The presence of specialized sensors like the accelerometer, and …*	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-55	Non-functional - Usability	Major	*The portable touch device must have a display of sufficient screen size & resolution (more than a 3,5" display, more than 320px*480px). If not a …*	*A device with smaller screen estate will compromise its usability, and will make the interaction with user an unattractive and difficult experience …*	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-56	Non-functional - Usability	Major	*The portable touch device must have a satisfactory operational time. The battery must be able to support the device for at least half a day. If the …*	*The portable device will have to be operated continuously. The small size and weight of the device allows the user to move freely, but the battery ...*	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-80	Non-functional - Usability	Major	Only one or max two categories of different mobile operating systems will be considered for the portable devices	*The large spread of existing operating systems does not allow developments on a large number of mobile operating system. The more effective solution …*	Internal test and field trials will be performed only using portable devices with one of the selected operating systems
REACTION-126	Functional - REACTION platform	Major	Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake)	*The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. The possibility ...*	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device
REACTION-128	Functional - REACTION platform	Major	Portable device should allow the display of feedback to patient	*In mobile situation the only available device is the portable device and patient should be able to use it for uploading or downloading data …*	*The portable user interface should be used also for displaying the clinician feedback to patients, graphical representation of the data acquired …*

REACTION-129	Functional - REACTION platform	Major	Portable device should allow the notification of alarms & alerts	The use of the same device also for the reception of alarms and alerts simplifies and makes less expensive the overall solution	The reception of alarm and alerts will be checked on the portable device
REACTION-236	Functional - Inpatient pilot application	Major	Blood glucose measurements in Inpatient environment	*PoC devices are currently used and will be used in Inpatient environment. The procedure is reliable and has been used since several years …*	*There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose …*

6.1.7 Portable User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-49	Non-functional - Usability	Major	The touch/tablet/phone device must allow the execution of processes in the background	*The applications developed for the portable devices should start and stop only when the user wants. If the portable device is a mobile phone …*	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-50	Non-functional - Usability	Major	The touch/tablet/phone device must support notification messages	*The portable device must have the ability to show alert messages to the user. This will allow the device to report promptly to the user if any …*	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-128	Functional - REACTION platform	Major	Portable device should allow the display of feedback to patient	*In mobile situation the only available device is the portable device and patient should be able to use it for uploading or downloading data …*	*The portable user interface should be used also for displaying the clinician feedback to patients, graphical representation of the data acquired …*

6.1.8 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-29	Functional - Outpatient pilot application	Critical	Accurate data acquirement	IR-absorption glucose spectra are strongly temperature dependent	Integration of temperature sensor in the sensor platform
REACTION-30	Functional - REACTION platform	Major	Power budget of wearable sensor platform	Depending on the measuring intervals (tbd) power must be available for autarkic operation of sensor platform	Definition of total power budget
REACTION-180	Functional - REACTION platform	Major	Measurement of glucose should be specific and the glucose sensor should be able to monitor glucose in complex media	*If the glucose monitoring is not specific, detection could be disturbed by other components of the ISF or the blood, influencing the accuracy of …*	Sensor should exhibit a high accuracy even if other media are in contact with the sensor area.

REACTION-183	**Functional - REACTION platform**	**Major**	**The sensitivity of the glucose sensor should be high, the SNR must be large and changes of glucose concentration in the range 1-15 mM must be detectable**	**For AGC the accuracy should be +/- 5% of the measured value in the specified range. For a closed loop sensor system (glucose measurement + insulin dosage) especially in the lower concentration range of about 3-4 mM or less a high accuracy is required to avoid mistreatments in the hyperglycaemic range.**	**Performance of reference measurements on defined samples.**
REACTION-186	Functional - Outpatient pilot application	Major	The sensor platform should be robust and simple to be used, enabling the device to be operated by the patient himself	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. However, it should be possible that …*	Hardware fabricated.
REACTION-205	Functional - REACTION platform	Minor	Docking station for the ePatch	Charging of the reusable sensor in the ePatch	Hardware fabricated.
REACTION-206	Functional	Major	ePatch reusable sensor	*The ePatch reusable sensor contains the optical and electrical sensor components, electronics, radio, antenna, and battery. Eventually …*	Hardware fabricated.
REACTION-207	Functional	Major	ePatch communication	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.	*The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the …*
REACTION-208	Functional	Major	ePatch adhesive base	*The adhesive base forms the contact between the ePatch sensor and the skin surface of a human. Sensors measuring physiological data …*	ePatch can stick to the skin and sensor can measure physiologic data.
REACTION-209	Functional	Major	ePatch adhesive base has unique physical properties	*The ePatch adhesive base contains 3 gel electrodes with impedance matched to the skin. The gel or part of the gel is optical transparent in the …*	ePatch can stick to the skin and optical or NIR sensor (if required) can measure physiologic data.
REACTION-210	Functional	Major	ePatch adhesive base has unique adhesive properties	*The ePatch adhesive base contains at least two type of adhesive materials: 1) One with good skin adhesive properties 2) An adhesive gel or …*	Adhesive can stick to skin and sensors can measure.

REACTION-214	Functional - REACTION platform	Major	Activity parameters must be measured (e.g. pulse frequency, body temperature) by sensors	*For input to the AGC algorithm to make prediction of glucose levels activity parameters are required. Which ones are still tbd but heart …*	Activity parameter sensors must be integrated into the REACTION e-patch.
REACTION-236	Functional - Inpatient pilot application	Major	Blood glucose measurements in Inpatient environment	*PoC devices are currently used and will be used in Inpatient environment. The procedure is reliable and has been used since several years ...*	*There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose …*
REACTION-265	Functional - REACTION platform	Major	The clinical parameters to be measured must be specified	For sensor development the type of clinical parameter must be specified to adapt sensor properties to the specific parameter.	Clinical parameters given by the clinicians, but also parameters that are necessary for running the physiological model
REACTION-266	Functional - REACTION platform	Major	Type of sensor/signal should be specified	*Type of sensor/signal, whether chemical, electrical, optical, etc. is important for integration in e-patch and sensor platform and for the …*	Type of sensor specified by the sensor manufacturers.
REACTION-267	Functional - REACTION platform	Major	Accuracy/precision of sensors should be specified	*For all types of sensors the accuracy/precision has to be known. In some sensors a high accuracy can be required, as, for example, for …*	The accuracy/precision should be specified by the sensor manufacturers.
REACTION-268	Functional - REACTION platform	Major	Response time and drift of the sensors should be specified	*Response time of the sensor is important for online monitoring and it may not be too long, drift could influence the accuracy and could …*	Response time and drift should be specified by the sensor manufacturers.
REACTION-269	Functional - REACTION platform	Major	Working range of sensors should be specified (linearity and detection limit)	*The working range of the sensors should cover the required ranges as defined by the clinicians and ideally should be linear, the detection limit …*	Working range of the different sensors should be specified by the sensor manufacturers.
REACTION-270	Functional - REACTION platform	Major	Operating temperature of sensors should be specified	The temperature might influence the result of the measurement and its accuracy.	*Either sensor manufacturers should specify the operating temperature of the sensors or the device should be able to adjust the measurement …*
REACTION-271	Functional - REACTION platform	Major	The calibration of the sensors should be specified (strategy, intervals, reference, algorithms)	*The sensor must be calibrated before usage and might be re-calibrated after a certain time, also might the calibration required to be individual …*	Calibration routines of the sensors should be specified by the sensor manufacturers.
REACTION-272	Functional - REACTION platform	Major	The body interface of the sensors should be specified	*The body interface of the sensors determines whether it is invasive or non-invasive, it probably influences the accuracy and operating time of …*	The body interface should be specified by the sensor manufacturers.

REACTION-273	Functional - REACTION platform	Major	The sensor safety should follow the device directive 93/42/EEC and subsequent amending directives like the directive 2007/47/EC	*The safety directive is essential for sensors being operated on patients. The off-the-shelf sensors/devices and the consortium-designed …*	Sensors should be designed in a way that the directive 93/42/EEC is fulfilled.
REACTION-274	**Functional - REACTION platform**	**Major**	**The cost of the sensor should be specified**	**The cost of the sensor determines its later potential for a certain application (outpatient or inpatient use) and is influenced by its production effort.**	**The cost of the sensor should be specified by the sensor manufacturers and be as low as possible. The cost of the sensor should be specified and the cost should not exceed tbd EUR for inpatient application, tbd EUR for primary care, tbd EUR for AGC.**
REACTION-280	Non-functional - Legal	Major	Device manual for clinical trials	For clinical trials a sensor device manual must be available.	Manual available for clinical trials.

6.2 Requirements of WP4 – Data Management and Service Orchestration

6.2.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-161	Functional - Inpatient pilot application	Major	Alarm system- reminder to perform measurements	*The system should remind caregivers to perform measurements.* *A decision was taken not being too …*	*Alarm system- reminder to perform measurements is available within the inpatient platform* *…*
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	*When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, …*	Check the overall procedure in case of acquired measurements in the alarm range.

6.2.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-3	Functional	Major	Support for IEEE medical device standards	To support a wide variety of medical devices, the selected subsets of the IEEE medical device standards should be supported.	Show that REACTION device proxies can be developed for at least 2 different devices from different manufacturers.
REACTION-6	Functional	Major	Any REACTION device should have an associated semantic model (description)	To facilitate device discovery and application development, a device ontology should be part of the architecture.	New devices can be matched against descriptions in the device ontology.
REACTION-14	Functional	Major	Persistent local/global data storage	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).	At least global storage is supported.
REACTION-16	Functional	Major	Individualized targets for patients needs to be stored and retrieved	Needed to determine the effectiveness of different therapies.	Possible to store targets.
REACTION-21	Functional	Major	Change log for feedback model	It must be possible to track changes in the feedback model, i.e. which data has been collected at certain times.	All changes to the feedback model are stored in a change log.

REACTION-22	Functional	Major	Local feedback on measured values	It should be possible to provide feedback on measured values, e.g. graphical representations, to those patients that request it.	Patient able to select requested feedback values.
REACTION-24	Non-functional - Maintainability and portability	Critical	Logging of events from components	*All software components shall keep a detailed activity log, which will support the tracing and debugging of possible functioning errors, security holes, …*	A log file will be available for each component, containing data which will be defined by the design process.
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
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-42	Non-functional - Maintainability and portability	Major	The technical interfaces to the platform must be documented and in such a way that the stakeholders can understand it and use it for integration.	Developers can develop better applications faster. The platform thus could also provide easy access to third party developers.	Writing sufficient documentation for the technical interfaces and also by providing examples and if available simulators.
REACTION-68	Functional - REACTION platform	Major	Component Versioning	In order to have a good development practice	The test facility will take into account also the version of components

REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-76	Non-functional - Usability	Major	Portability	*All components should have the capability of running at least under two of the most common operating systems (e.g. Linux and Windows 7 …*	Specific test has to be done on each component
REACTION-134	Non-functional - Performance	Major	*Any interface between an end-user and the platform shall have a reasonable maximum response time in condition of public network …*	Response time should be quick enough except for reasons independent from the technical design of the platform	*The platform when the public network is perfectly working at the max speed shall respond in less than 5 sec in 90% of functions activated by the …*
REACTION-136	Non-functional - Performance	Major	The platform shall cater for 20 simultaneous users in the field trials. In the end product this number is expected to grow to 100.	*A maximum number of simultaneous users has to be fixed. These numbers are very reasonable considering the number of potential end-users at …*	*The platform will be tested with the max number of simultaneous users verifying that the response time for the most common operations are …*

REACTION-137	Non-functional - Performance	Major	*The platform should be able to process the existing end users of the outpatient and inpatient field trials. 300 end-users should be enough. In the …*	In the workshops the maximum number of users in the outpatient and inpatient field trials has been estimated.	The possibility of creating such number of end-users will be tested.
REACTION-154	**Functional - Outpatient 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**
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	*Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the …*	The inpatient pilot application stores data records/charts
REACTION-156	Functional - Inpatient pilot application	Major	Regular backup of data	Inpatient pilot application offers backup system	Regular backup of data
REACTION-157	Functional - Outpatient pilot application	Major	Annual clinical checks	*The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of …*	*Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt thesefields (e.g. …*
REACTION-158	Functional - Outpatient pilot application	Major	6-month clinical checks	*Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, …*	*Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt …*
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-161	Functional - Inpatient pilot application	Major	Alarm system- reminder to perform measurements	*The system should remind caregivers to perform measurements.* *A decision was taken not being too …*	*Alarm system- reminder to perform measurements is available within the inpatient platform* *…*
REACTION-163	Functional - Inpatient 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
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	*The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until …*	Specific fields have to be foreseen in data management, ontologies and user interfaces.

REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	*Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always …*	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-195	Functional - Outpatient pilot application	Major	Data management should handle different types of complications for the diabetic patients in the outpatient environment	*The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management …*	In the ontology, user interfaces and applications these complications have to be present
REACTION-201	Functional - Outpatient pilot application	Major	Record baseline physiological measurements at the first visit	*At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the …*	*The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological …*
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	*At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to …*	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-211	Functional - Outpatient pilot application	Major	*Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at …*	*A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and …*	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	*Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of …*	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up
REACTION-213	Functional - Outpatient pilot application	Major	*Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and …*	*The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM …*	*The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and …*
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	*When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, …*	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-218	Functional - Outpatient pilot application	Major	Patient monitor either manual or through the RPM	*In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient …*	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.

REACTION-219	**Functional - Inpatient pilot application**	**Major**	**Safe Glycaemic Control (SGC)**	**Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.**	**Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.** **In the first iteration step all patients will use the same threshold.**
REACTION-227	Functional - Inpatient pilot application	Major	Initialization of the fever/sugar chart	*Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be …*	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient
REACTION-229	Functional - Inpatient pilot application	Major	Decision on therapy in Inpatient environment	*Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history …*	*Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the …*
REACTION-232	Functional - REACTION platform	Major	Continua Manager emulation	*The integration of Continua devices requires a Continua Manager component as part of the architecture. In the absence of such a manager, …*	A Continua Manager stub exists allowing simulated access to a Continua device.
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	*Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values …*	*The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored …*
REACTION-264	Non-functional - Performance	Major	Increase accuracy and reduce errors	*The registration of all relevant data (vital sign and environmental measurements, nutrition and lifestyle, drugs/insulin administration, …*	*Qualitative and quantitative criteria shall be present in the field trial evaluations in order to measure the reduction of errors compared to the …*

6.2.3 Backend Middleware

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-66	Functional - REACTION platform	Major	Component Interface	Interoperability among components should be guaranteed by the use of standard interfaces.	The test facility will be based on the implemented standard

REACTION-68	Functional - REACTION platform	Major	Component Versioning	In order to have a good development practice	The test facility will take into account also the version of components
REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-76	Non-functional - Usability	Major	Portability	*All components should have the capability of running at least under two of the most common operating systems (e.g. Linux and Windows 7 …*	Specific test has to be done on each component
REACTION-156	Functional - Inpatient pilot application	Major	Regular backup of data	Inpatient pilot application offers backup system	Regular backup of data
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform

REACTION-163	Functional - Inpatient pilot application	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
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification
REACTION-211	Functional - Outpatient pilot application	Major	*Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at …*	*A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and …*	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	*Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of …*	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up
REACTION-213	Functional - Outpatient pilot application	Major	*Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and …*	*The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM …*	*The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and …*
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	*When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, …*	Check the overall procedure in case of acquired measurements in the alarm range.

6.2.4 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-3	Functional	Major	Support for IEEE medical device standards	To support a wide variety of medical devices, the selected subsets of the IEEE medical device standards should be supported.	Show that REACTION device proxies can be developed for at least 2 different devices from different manufacturers.
REACTION-17	Functional	Major	Configurable data transfer frequency	Possibility to configure the periodical transfer of the collected sensor data to external services such as WAN devices.	Lowest periodical transfer is once per day.
REACTION-22	Functional	Major	Local feedback on measured values	It should be possible to provide feedback on measured values, e.g. graphical representations, to those patients that request it.	Patient able to select requested feedback values.

REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-28	Functional - REACTION platform	Major	Network interoperability	The communication between applications running in different devices will be based on SOAP messages.	Communication with a service should be feasible by SOAP tools and standards, based on a service's published interface.
REACTION-32	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-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality

REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-161	Functional - Inpatient pilot application	Major	Alarm system- reminder to perform measurements	*The system should remind caregivers to perform measurements.* *A decision was taken not being too …*	*Alarm system- reminder to perform measurements is available within the inpatient platform* *…*
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification

6.2.5 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-12	Functional	Major	Automatic update on lifestyle data	*Automatic update of lifestyle data based on sensors such as pedometers but also retrieval from health and lifestyle services and …*	At least one external service is supported.
REACTION-14	Functional	Major	Persistent local/global data storage	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).	At least global storage is supported.
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*

REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	*Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the …*	The inpatient pilot application stores data records/charts
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-161	Functional - Inpatient pilot application	Major	Alarm system- reminder to perform measurements	*The system should remind caregivers to perform measurements.* *A decision was taken not being too …*	*Alarm system- reminder to perform measurements is available within the inpatient platform* *…*

REACTION-167	Functional - REACTION platform	Major	Use of contextualized data at medical decision and predictive models	*Medical decision and predictive models have to use contextualized data in such a way that measurements will be annotated with context …*	Data for medical decision and predictive models.
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification
REACTION-228	Functional - Inpatient pilot application	Major	Blood glucose measurements have to be contextualized (e.g. before/after meal)	The availability of the blood glucose measurements shall be accompanied also by the context of the measurements	Measurements before any usage have to be contextualized
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	*In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in …*	*The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different …*
REACTION-239	Functional - Inpatient pilot application	Major	Special examinations/treatments to be registered in fever chart	*For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases …*	*These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the …*
REACTION-246	**Functional - Inpatient 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 patient stay in the hospital ward (blood glucose level, information about the actual status of the patients, drug administration, nutrition, relevant events, etc.). Other eventual parameters could be considered during the overall life cycle of the development.**	**Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.**
REACTION-284	Functional - Inpatient pilot application	Major	Clinical data to be stored in the Inpatient environment	*The data management shall be design in order to allow the storage of the clinical data to be registered at the patient enrolment and other clinical …*	The data management shall allow the insertion and the update of all the listed clinical parameters.

6.2.6 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*

REACTION-39	Non-functional - Security	Critical	Platform Integrity (integrity checks for the stored data)	To guarantee the integrity of the stored data in the case of an unwanted happening.	Use of adequate methods like e.g. Hash keys or redundancy codes for the data stored.
REACTION-62	Functional - REACTION platform	Major	Semantics based data management	*According to the DoW the monitoring and other data need to be properly annotated with ontological descriptions in order to achieve …*	Relevant entries in the REACTION's databases are annoted with semantic concepts
REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-154	**Functional - Outpatient 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**

REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	*Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the …*	The inpatient pilot application stores data records/charts
REACTION-157	Functional - Outpatient pilot application	Major	Annual clinical checks	*The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of …*	*Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt thesefields (e.g. …*
REACTION-158	Functional - Outpatient pilot application	Major	6-month clinical checks	*Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, …*	*Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt …*
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-161	Functional - Inpatient pilot application	Major	Alarm system- reminder to perform measurements	*The system should remind caregivers to perform measurements.* *A decision was taken not being too …*	*Alarm system- reminder to perform measurements is available within the inpatient platform* *…*
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	*The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until …*	Specific fields have to be foreseen in data management, ontologies and user interfaces.
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	*Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always …*	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-195	Functional - Outpatient pilot application	Major	Data management should handle different types of complications for the diabetic patients in the outpatient environment	*The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management …*	In the ontology, user interfaces and applications these complications have to be present
REACTION-201	Functional - Outpatient pilot application	Major	Record baseline physiological measurements at the first visit	*At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the …*	*The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological …*
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	*At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to …*	An enrolled patient can be assigned to a configurable RPM scheme

REACTION-211	Functional - Outpatient pilot application	Major	*Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at …*	*A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and …*	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	*Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of …*	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up
REACTION-213	Functional - Outpatient pilot application	Major	*Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and …*	*The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM …*	*The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and …*
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	*When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, …*	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-218	Functional - Outpatient pilot application	Major	Patient monitor either manual or through the RPM	*In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient …*	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.
REACTION-219	**Functional - Inpatient pilot application**	**Major**	**Safe Glycaemic Control (SGC)**	**Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.**	**Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.** **In the first iteration step all patients will use the same threshold.**
REACTION-227	Functional - Inpatient pilot application	Major	Initialization of the fever/sugar chart	*Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be …*	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient
REACTION-228	Functional - Inpatient pilot application	Major	Blood glucose measurements have to be contextualized (e.g. before/after meal)	The availability of the blood glucose measurements shall be accompanied also by the context of the measurements	Measurements before any usage have to be contextualized
REACTION-229	Functional - Inpatient pilot application	Major	Decision on therapy in Inpatient environment	*Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history …*	*Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the …*

REACTION-232	Functional - REACTION platform	Major	Continua Manager emulation	*The integration of Continua devices requires a Continua Manager component as part of the architecture. In the absence of such a manager, …*	A Continua Manager stub exists allowing simulated access to a Continua device.
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	*In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in …*	*The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different …*
REACTION-238	Functional - Inpatient pilot application	Major	Update and entering of drug administration (OAD and/or insulin) data	*Drug administration (time, type, dosage and other relevant information) has to be immediately annotated in the fever chart by the …*	*The nurse through an appropriate user interface can check the last drug administration and insert the relevant data related to the drug …*
REACTION-239	Functional - Inpatient pilot application	Major	Special examinations/treatments to be registered in fever chart	*For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases …*	*These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the …*
REACTION-246	**Functional - Inpatient 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 patient stay in the hospital ward (blood glucose level, information about the actual status of the patients, drug administration, nutrition, relevant events, etc.). Other eventual parameters could be considered during the overall life cycle of the development.**	**Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.**
REACTION-248	Functional - Inpatient pilot application	Major	*Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, …*	*Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the …*	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	*Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values …*	*The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored …*
REACTION-284	Functional - Inpatient pilot application	Major	Clinical data to be stored in the Inpatient environment	*The data management shall be design in order to allow the storage of the clinical data to be registered at the patient enrolment and other clinical …*	The data management shall allow the insertion and the update of all the listed clinical parameters.

6.2.7 Glucose Control Algorithms

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-219	**Functional - Inpatient pilot application**	**Major**	**Safe Glycaemic Control (SGC)**	**Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.**	**Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.** **In the first iteration step all patients will use the same threshold.**
REACTION-251	Functional - Inpatient pilot application	Major	Creation of electronic decision support rules shall be supported	*An electronic decision support system with standardised instructions and decisions (e.g. evidence based medicine, support identification of …*	*Suggestions on treatments shall be available in order to facilitate the clinical decision. An available protocol from literature (e.g. RABBIT II trial) …*

6.2.8 Interfaces with HIS/EPR

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*

REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-154	**Functional - Outpatient 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**
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	*Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the …*	The inpatient pilot application stores data records/charts
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification

REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	*In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in …*	*The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different …*
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	*Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values …*	*The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored …*

6.2.9 Networking

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-28	Functional - REACTION platform	Major	Network interoperability	The communication between applications running in different devices will be based on SOAP messages.	Communication with a service should be feasible by SOAP tools and standards, based on a service's published interface.

REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	*Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the …*	The inpatient pilot application stores data records/charts
REACTION-175	Functional - Inpatient pilot application	Major	Automated identification of users (caregivers) working with REACTION front-end in the hospital	Automated identification of users (caregivers) working with REACTION front-end in the hospital (e.g. RFID)	Automated user identification

6.2.10 Ontology Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-154	**Functional - Outpatient 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**

REACTION-157	Functional - Outpatient pilot application	Major	Annual clinical checks	*The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of …*	*Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt thesefields (e.g. …*
REACTION-158	Functional - Outpatient pilot application	Major	6-month clinical checks	*Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, …*	*Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt …*
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	*The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until …*	Specific fields have to be foreseen in data management, ontologies and user interfaces.
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	*Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always …*	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-195	Functional - Outpatient pilot application	Major	Data management should handle different types of complications for the diabetic patients in the outpatient environment	*The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management …*	In the ontology, user interfaces and applications these complications have to be present
REACTION-201	Functional - Outpatient pilot application	Major	Record baseline physiological measurements at the first visit	*At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in the …*	*The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological …*
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	*At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to …*	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-211	Functional - Outpatient pilot application	Major	*Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at …*	*A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and …*	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	*Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of …*	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up
REACTION-213	Functional - Outpatient pilot application	Major	*Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and …*	*The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM …*	*The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and …*

REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	*When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, …*	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-218	Functional - Outpatient pilot application	Major	Patient monitor either manual or through the RPM	*In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient …*	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.
REACTION-219	**Functional - Inpatient pilot application**	**Major**	**Safe Glycaemic Control (SGC)**	**Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.**	**Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.** **In the first iteration step all patients will use the same threshold.**
REACTION-231	Functional - Inpatient pilot application	Major	End of process for the diabetic patient in the inpatient environment	*The workflows in the Inpatient glycaemic control management ends with the patient discharge from the department. However, there should …*	At the patient discharge from the department, the workflow related to the patient has to be terminated
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	*In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in …*	*The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different …*
REACTION-239	Functional - Inpatient pilot application	Major	Special examinations/treatments to be registered in fever chart	*For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases …*	*These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the …*
REACTION-248	Functional - Inpatient pilot application	Major	*Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, …*	*Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the …*	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.

6.2.11 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*

REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	*At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to …*	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	*Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values …*	*The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored …*

6.2.12 Physiology Models

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality

REACTION-219	**Functional - Inpatient pilot application**	**Major**	**Safe Glycaemic Control (SGC)**	**Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.**	**Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.** **In the first iteration step all patients will use the same threshold.**

6.2.13 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-6	Functional	Major	Any REACTION device should have an associated semantic model (description)	To facilitate device discovery and application development, a device ontology should be part of the architecture.	New devices can be matched against descriptions in the device ontology.
REACTION-9	Functional	Major	Formalized feedback model	A model describing which parameters to be collected, the frequency of collection, and target users of the data	System is able to provide feedback in satisfactory time
REACTION-10	Functional	Major	Data fusion model	A description of how different data values are combined into medical data	The system can provide automatic aggregation of data values from at least two different sensors.
REACTION-11	Functional - Outpatient pilot application	Major	Life style baseline data	The system needs to store a set of baseline data regarding life style for each patient.	Life style data can be retrieved and updated per patient
REACTION-14	Functional	Major	Persistent local/global data storage	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).	At least global storage is supported.
REACTION-16	Functional	Major	Individualized targets for patients needs to be stored and retrieved	Needed to determine the effectiveness of different therapies.	Possible to store targets.
REACTION-21	Functional	Major	Change log for feedback model	It must be possible to track changes in the feedback model, i.e. which data has been collected at certain times.	All changes to the feedback model are stored in a change log.
REACTION-22	Functional	Major	Local feedback on measured values	It should be possible to provide feedback on measured values, e.g. graphical representations, to those patients that request it.	Patient able to select requested feedback values.

REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration. …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	*At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to …*	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	*Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values …*	*The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored …*

6.2.14 Portable User interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-164	Functional - REACTION platform	Major	Common schema for data exchange between user interface (Health Status Profile) and integrated modules within WP6	It is essential to define and set schemas for the communication and interaction between modules within the Health Status Profile system.	Standardises Interfaces
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	*Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always …*	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	*Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values …*	*The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored …*

6.2.15 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*

REACTION-70	**Functional - REACTION platform**	**Blocker**	**Processing of multi-parametric clinical and non-clinical data from different sources**	**The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.** **Four different applications have been identified in ID6-5 of WP6:** **1) Decision Support for Insulin Dosing in Hospital** **a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes** **b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes** **2) Primary Care Risk Assessment Applications** **a. Long-term risk assessment application** **b. Short-term risk assessment application** **Details of the applications can be found in ID6-5.**	**Platform flexibly supports processing of data from multiple sources**
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-159	Functional - REACTION platform	Major	Logging mechanisms	Using logging from all components within Health Status Profile it's easier to integrate and control the system.	A logging mechanism is implemented in the REACTION platform
REACTION-164	Functional - REACTION platform	Major	Common schema for data exchange between user interface (Health Status Profile) and integrated modules within WP6	It is essential to define and set schemas for the communication and interaction between modules within the Health Status Profile system.	Standardises Interfaces
REACTION-167	Functional - REACTION platform	Major	Use of contextualized data at medical decision and predictive models	*Medical decision and predictive models have to use contextualized data in such a way that measurements will be annotated with context …*	Data for medical decision and predictive models.

REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	*The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until …*	Specific fields have to be foreseen in data management, ontologies and user interfaces.
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	*Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always …*	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	*When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, …*	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-219	**Functional - Inpatient pilot application**	**Major**	**Safe Glycaemic Control (SGC)**	**Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.**	**Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.** **In the first iteration step all patients will use the same threshold.**
REACTION-251	Functional - Inpatient pilot application	Major	Creation of electronic decision support rules shall be supported	*An electronic decision support system with standardised instructions and decisions (e.g. evidence based medicine, support identification of …*	*Suggestions on treatments shall be available in order to facilitate the clinical decision. An available protocol from literature (e.g. RABBIT II trial) …*

6.2.16 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-39	Non-functional - Security	Critical	Platform Integrity (integrity checks for the stored data)	To guarantee the integrity of the stored data in the case of an unwanted happening.	Use of adequate methods like e.g. Hash keys or redundancy codes for the data stored.
REACTION-43	Non-functional - Security	Critical	*Protection against data loss System must protect against: *Loss or replication of data transferred between two systems; *Concurrency …*	*Data integrity has to be guaranteed. *Loss or replication of data transferred between two systems (e.g. system shutdown); *Concurrency problems …*	The functional test should include specific tests in order to verify such circumstances

REACTION-93	Non-functional - Security	Major	Confidentiality: Sensitive information must not be readable by unauthorised persons	*Various stakeholders exchange information over the REACTION platform which, without any safeguards, would allow third …*	Availability of a mechanism for ensuring data confidentiality
REACTION-155	Functional - Inpatient pilot application	Major	Electronic paperless data record	*Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the …*	The inpatient pilot application stores data records/charts

6.2.17 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	*The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further …*	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	*At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to …*	An enrolled patient can be assigned to a configurable RPM scheme
REACTION-237	Functional - Inpatient pilot application	Major	Annotation of blood glucose values, especially in inpatient environment	*In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in …*	*The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different …*
REACTION-257	Functional - Inpatient pilot application	Major	Automated transfer of measured and relevant data to the patient's record	*Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values …*	*The acquired measurements are currently automatically sent to the HIS. Through an HL7 interface they can be retrieved and automatically stored …*

6.2.18 Web User Interface

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-27	Non-functional - Look and feel	Minor	Seamless integration	*All software components shall use a common ontology to refer to data, metadata, interfaces and models, to facilitate their seamless integration …*	*All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies …*

REACTION-154	**Functional - Outpatient 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**
REACTION-157	Functional - Outpatient pilot application	Major	Annual clinical checks	*The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of …*	*Specific fields have to be present in ontologies, data management and web user interfaces. It should be possible to adapt thesefields (e.g. …*
REACTION-158	Functional - Outpatient pilot application	Major	6-month clinical checks	*Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, …*	*Specific fields (entries) have to be foreseen in the data management, ontologies and web user interfaces. It should be possible to adapt …*
REACTION-161	Functional - Inpatient pilot application	Major	Alarm system- reminder to perform measurements	*The system should remind caregivers to perform measurements.* *A decision was taken not being too …*	*Alarm system- reminder to perform measurements is available within the inpatient platform* *…*
REACTION-164	Functional - REACTION platform	Major	Common schema for data exchange between user interface (Health Status Profile) and integrated modules within WP6	It is essential to define and set schemas for the communication and interaction between modules within the Health Status Profile system.	Standardises Interfaces
REACTION-182	Functional - Outpatient pilot application	Major	Measurement of HbA1c	*The risk of developing diabetic complications is strongly mirrored by HbA1c. This parameter has to be measured every 2-6 months until …*	Specific fields have to be foreseen in data management, ontologies and user interfaces.
REACTION-187	Functional - Outpatient pilot application	Major	Storage of administered insulin	*Insulin administered to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always …*	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable)
REACTION-195	Functional - Outpatient pilot application	Major	Data management should handle different types of complications for the diabetic patients in the outpatient environment	*The complications considered for the diabetic patient in the outpatient environment are: cardiovascular, renal, ophthalmology, management …*	In the ontology, user interfaces and applications these complications have to be present
REACTION-201	Functional - Outpatient pilot application	Major	Record baseline physiological measurements at the first visit	*At the first visit baseline physiological measurements (the set of measurements must be exactly defined) have to be inserted in …*	*The design of the web user interface and of the data management shall foresee the possibility of introducing the baseline physiological …*
REACTION-202	Functional - Outpatient pilot application	Major	Setup remote patient monitoring scheme	*At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to …*	An enrolled patient can be assigned to a configurable RPM scheme

REACTION-211	Functional - Outpatient pilot application	Major	*Disease management plan, risk management plan and lifestyle plan should be part of the personalized care plan. It has to be defined at …*	*A personalized care plan is a complex plan that consists of 3 main components: disease management plan, risk management plan and …*	These 3 components should be part of the care management for any diabetic patient
REACTION-212	Functional - Outpatient pilot application	Major	Clinical case conference has to be set-up whenever the acquired data are outside some thresholds fixed by the Map of Medicine	*Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of …*	In case the acquired values are outside a fixed range a case conference with the help of e.g. video-conference shall be set-up
REACTION-213	Functional - Outpatient pilot application	Major	*Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and …*	*The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM …*	*The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and …*
REACTION-217	Functional - Outpatient pilot application	Major	Acquired values in the alarm range	*When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, …*	Check the overall procedure in case of acquired measurements in the alarm range.
REACTION-218	Functional - Outpatient pilot application	Major	Patient monitor either manual or through the RPM	*In case patient has to be assessed or he has a high risk, the patient monitoring shall be performed using the RPM. Otherwise, the patient …*	Two different monitorings have to be allowed by the REACTION platform. daily check will be allowed only using the RPM.
REACTION-219	**Functional - Inpatient pilot application**	**Major**	**Safe Glycaemic Control (SGC)**	**Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.**	**Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state.** **In the first iteration step all patients will use the same threshold.**
REACTION-227	Functional - Inpatient pilot application	Major	Initialization of the fever/sugar chart	*Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be …*	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient
REACTION-229	Functional - Inpatient pilot application	Major	Decision on therapy in Inpatient environment	*Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history …*	*Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the …*
REACTION-231	Functional - Inpatient pilot application	Major	End of process for the diabetic patient in the inpatient environment	*The workflows in the Inpatient glycaemic control management ends with the patient discharge from the department. However, there should …*	At the patient discharge from the department, the workflow related to the patient has to be terminated

REACTION-238	Functional - Inpatient pilot application	Major	Update and entering of drug administration (OAD and/or insulin) data	*Drug administration (time, type, dosage and other relevant information) has to be immediately annotated in the fever chart by the …*	*The nurse through an appropriate user interface can check the last drug administration and insert the relevant data related to the drug …*
REACTION-239	Functional - Inpatient pilot application	Major	Special examinations/treatments to be registered in fever chart	*For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore, in such cases …*	*These events (special examination/treatments) have to be registered in the fever chart together with the adopted changes in the …*
REACTION-246	**Functional - Inpatient 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 patient stay in the hospital ward (blood glucose level, information about the actual status of the patients, drug administration, nutrition, relevant events, etc.). Other eventual parameters could be considered during the overall life cycle of the development.**	**Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.**

6.3 Requirements of WP5 – Network Management and Service Execution

6.3.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	*All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing …*	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database
REACTION-88	Functional - Outpatient pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None
REACTION-160	Functional - Outpatient pilot application	Major	Alerts for the annual and 6-month clinical checks	*When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the …*	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency
REACTION-252	Functional - Inpatient pilot application	Major	When some measurements are missing the system shall remind it through an active alarm reminder	*Sometimes nurses forget to perform measurements. An active alarm system shall remind to perform the missing measurements. Regular …*	*When a configurable time after the expected measurement acquisition time is elapsed, the system should send (at regular intervals) an alert …*

6.3.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-19	Non-functional - Maintainability and portability	Major	Necessity of a mobile solution for the outpatient sphere	People tend to be moving and travelling.	Same service everywhere.
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	*All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing …*	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database

REACTION-87	Non-functional - Operational	Major	Define network architectural model	*Handle resources and services in heterogeneous networks (define heterogeneous networks) and dynamically change performance …*	None
REACTION-124	Functional - REACTION platform	Major	Portable device should collect all the relevant vital signs measured on the patient	A portable with adequate features/performances should collect all the relevant vital signs measured on the patient realizing the BAN	A commercial portable device will be selected in order to perform the internal tests and the field trials
REACTION-125	Functional - REACTION platform	Major	Portable device should collect also additional environmental measurements	*The same portable device used for the BAN integration will be used also for the PAN integration collecting also relevant environmental …*	*BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium …*
REACTION-127	Functional - REACTION platform	Major	Home and mobile gateway	*The portable device should be able to act as home and mobile gateway. When connection to the public wireless network is not available at …*	Specific tests have to be performed when public wireless network is not available at home.
REACTION-160	Functional - Outpatient pilot application	Major	Alerts for the annual and 6-month clinical checks	*When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the …*	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	*RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other …*	RPM module has to be present in the Outpatient field trials
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	*The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in …*	Achieving location independence and multi-user support
REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	*In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by …*	*Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the …*

6.3.3 Backend Middleware

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	*All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing …*	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.

REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database
REACTION-88	Functional - Outpatient pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	*The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in …*	Achieving location independence and multi-user support
REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	*In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by …*	*Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the …*

6.3.4 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-1	Functional - Outpatient pilot application	Major	Internet communication between patient home and primary/secondary healthcare structures based on public wired or wireless network	A basic communication infrastructure has to be assumed	Tests will be based on this assumption
REACTION-18	Functional	Major	Monitoring devices must be discoverable by existing network infrastructure	Device must be discovered in order to be able to communicate with other devices and platforms.	At least to automatically discover devices using protocols supported in the Hydra middleware such as BT, ZigBee etc.
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	*All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing …*	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-34	Functional - Outpatient pilot application	Major	Define "black box" to be used at outpatient environment	*Define the hardware to be used at the outpatient environment for acquiring and transmitting sensor data to the REACTION middleware (use a …*	None
REACTION-54	Functional	Major	Network & system monitoring	*Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements …*	none

REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database
REACTION-87	Non-functional - Operational	Major	Define network architectural model	*Handle resources and services in heterogeneous networks (define heterogeneous networks) and dynamically change performance …*	None
REACTION-88	Functional - Outpatient pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None
REACTION-89	Functional - REACTION platform	Major	Network management subsets	*Define network management subsets for data traffic management between Patient's sphere and Carer's sphere communication. Integration and …*	None
REACTION-123	Functional - REACTION platform	Critical	Define components and services	Define the necessary components, services and orchestration methods under a Service Oriented Architecture perspective.	none
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	*The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in …*	Achieving location independence and multi-user support

6.3.5 Context Management

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

6.3.6 Data Management

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

6.3.7 Glucose Control Algorithms

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

6.3.8 Networking

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	*All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing …*	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-34	Functional - Outpatient pilot application	Major	Define "black box" to be used at outpatient environment	*Define the hardware to be used at the outpatient environment for acquiring and transmitting sensor data to the REACTION middleware (use a …*	None
REACTION-54	Functional	Major	Network & system monitoring	*Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements …*	none
REACTION-87	Non-functional - Operational	Major	Define network architectural model	*Handle resources and services in heterogeneous networks (define heterogeneous networks) and dynamically change performance …*	None
REACTION-89	Functional - REACTION platform	Major	Network management subsets	*Define network management subsets for data traffic management between Patient's sphere and Carer's sphere communication. Integration and …*	None
REACTION-123	Functional - REACTION platform	Critical	Define components and services	Define the necessary components, services and orchestration methods under a Service Oriented Architecture perspective.	none
REACTION-173	Functional - Inpatient pilot application	Major	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	*The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in …*	Achieving location independence and multi-user support

6.3.9 Ontology/Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-160	Functional - Outpatient pilot application	Major	Alerts for the annual and 6-month clinical checks	*When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the …*	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency

REACTION-220	Functional - Inpatient pilot application	Major	Healthcare physicians and/or nurses perform the safe glycaemic control in Inpatient environment (not self-management)	*In Inpatient environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by …*	*Measurements of blood glucose and insulin injections are tasks performed by clinicians an/or nurses. They have to store the relevant data in the …*

6.3.10 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	*All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing …*	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database
REACTION-89	Functional - REACTION platform	Major	Network management subsets	*Define network management subsets for data traffic management between Patient's sphere and Carer's sphere communication. Integration and …*	None
REACTION-124	Functional - REACTION platform	Major	Portable device should collect all the relevant vital signs measured on the patient	A portable with adequate features/performances should collect all the relevant vital signs measured on the patient realizing the BAN	A commercial portable device will be selected in order to perform the internal tests and the field trials
REACTION-125	Functional - REACTION platform	Major	Portable device should collect also additional environmental measurements	*The same portable device used for the BAN integration will be used also for the PAN integration collecting also relevant environmental …*	*BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium …*
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	*RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other …*	RPM module has to be present in the Outpatient field trials

6.3.11 Physiology Models

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database

6.3.12 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-34	Functional - Outpatient pilot application	Major	Define "black box" to be used at outpatient environment	*Define the hardware to be used at the outpatient environment for acquiring and transmitting sensor data to the REACTION middleware (use a …*	None
REACTION-54	Functional	Major	Network & system monitoring	*Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements …*	none
REACTION-79	Constraint - Off-the-Shelf Sensors & Devices	Major	Off-the-Shelf Devices	*Non standard communication protocols imply a significant development effort. Such development effort can be very huge and very …*	*The commercial devices not developed by the consortium have to be compliant with relevant communication standard or, only in …*
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; …*	Data will be available shortly after measurement in the REACTION database
REACTION-88	Functional - Outpatient pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None
REACTION-124	Functional - REACTION platform	Major	Portable device should collect all the relevant vital signs measured on the patient	A portable with adequate features/performances should collect all the relevant vital signs measured on the patient realizing the BAN	A commercial portable device will be selected in order to perform the internal tests and the field trials
REACTION-125	Functional - REACTION platform	Major	Portable device should collect also additional environmental measurements	*The same portable device used for the BAN integration will be used also for the PAN integration collecting also relevant environmental …*	*BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium …*
REACTION-127	Functional - REACTION platform	Major	Home and mobile gateway	*The portable device should be able to act as home and mobile gateway. When connection to the public wireless network is not available at …*	Specific tests have to be performed when public wireless network is not available at home.
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	*RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other …*	RPM module has to be present in the Outpatient field trials

6.3.13 Portable User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	*RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other …*	RPM module has to be present in the Outpatient field trials

6.3.14 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database

6.3.15 Security

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

6.3.16 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-79	Constraint - Off-the-Shelf Sensors & Devices	Major	Off-the-Shelf Devices	*Non standard communication protocols imply a significant development effort. Such development effort can be very huge and very …*	*The commercial devices not developed by the consortium have to be compliant with relevant communication standard or, only in …*
REACTION-83	Functional - Inpatient pilot application	Major	Interface to clinical data from "near" real-time observations for decision support	*"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in outpatient care; the …*	Data will be available shortly after measurement in the REACTION database
REACTION-168	Functional - Outpatient pilot application	Major	Remote Patient Monitoring (RPM)	*RPM has to be used in the Outpatient Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other …*	RPM module has to be present in the Outpatient field trials

6.3.17 Web User Interfaces

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

6.4 Requirements of WP6 – Integrative Risk Assessment and Feedback

6.4.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool
REACTION-184	Functional - Outpatient pilot application	Major	Risk values for HbA1c	*Maintaining glycated haemoglobin (HbA1c) below 7.5% is likely to minimize risk of developing diabetic complications. If there is evidence …*	Thresholds have to be foreseen in the risk assessment module and advices have to be sent to patients.
REACTION-192	Functional - REACTION platform	Major	Thresholds for hypoglycaemia and hyperglycaemia	Different configurable thresholds shall be present for the detection of serious and life-threatening hypoglycaemic and hyperglycaemic episodes	*Once made sure the blood glucose level was correctly measured, values under specific thresholds (hypoglycaemia) or over specific …*
REACTION-193	Functional - Outpatient pilot application	Major	Alarm & alert generation	*The alerts and alarms should not be generated too often in such a way the system will be considered too intrusive for the patient himself. However …*	*Some serious or life-threatening situations can be simulated in the integration environment and the production of adequate alarms can …*

6.4.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool

6.4.3 Backend Middlware

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**

REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)

6.4.4 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)

6.4.5 Context Management

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

REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-101	Functional - Outpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	*Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence …*	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-222	Functional - Inpatient pilot application	Major	Insulin evaluation in Inpatient environment	*The data used for the insulin evaluation have to be contextualized before their usage and then passed to mathematical algorithms for the …*	The glucose control algorithms have to evaluate the insulin based on the parameters described above.
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	*Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters …*	*Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion …*
REACTION-243	**Functional - Inpatient pilot application**	**Trivial**	**Nutrition has to be taken into account in the calculation of the drug dosage**	**Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).**	**The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.**

REACTION-244	**Functional - Inpatient pilot application**	**Minor**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**	**Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**
REACTION-255	**Functional - Inpatient 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. Guessing for default values is not safe enough for a medical device.**	**Mandatory fields have to be filled in a safe and traceable manner!**

6.4.6 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	*The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services …*	Mechanistic physiology-based models are available within the REACTION platform

REACTION-81	Functional - Outpatient pilot application	Major	Long-term risk calculation and patient-oriented presentation	*Calculate long-term risk based on patient health profile and:* *- visualize in a patient-oriented form* *- present risk-reduction strategies …*	The REACTION platform offers a service to calculate diabetes dependent long-term risks
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-222	Functional - Inpatient pilot application	Major	Insulin evaluation in Inpatient environment	*The data used for the insulin evaluation have to be contextualized before their usage and then passed to mathematical algorithms for the …*	The glucose control algorithms have to evaluate the insulin based on the parameters described above.
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	*Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters …*	*Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion …*
REACTION-243	**Functional - Inpatient pilot application**	**Trivial**	**Nutrition has to be taken into account in the calculation of the drug dosage**	**Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).**	**The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.**
REACTION-244	**Functional - Inpatient pilot application**	**Minor**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**	**Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference).** **These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**

REACTION-255	**Functional - Inpatient 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.** **Guessing for default values is not safe enough for a medical device.**	**Mandatory fields have to be filled in a safe and traceable manner!**

6.4.7 Glucose Control Algorithm

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented:** **1) Adaptive long-term risk predication for risk communication (FORTH-ICS)** **2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	*The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services …*	Mechanistic physiology-based models are available within the REACTION platform
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-101	Functional - Outpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	*Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence …*	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-185	Constraint - Solution	Major	Diabetic management for type I diabetic patients	Type I diabetic patients will always be on insulin treatment	Glucose management has to be performed only with insulin (and not OAD) to type I diabetic patients

REACTION-222	Functional - Inpatient pilot application	Major	Insulin evaluation in Inpatient environment	*The data used for the insulin evaluation have to be contextualized before their usage and then passed to mathematical algorithms for the …*	The glucose control algorithms have to evaluate the insulin based on the parameters described above.
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	*Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters …*	*Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion …*
REACTION-243	**Functional - Inpatient pilot application**	**Trivial**	**Nutrition has to be taken into account in the calculation of the drug dosage**	**Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).**	**The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.**
REACTION-244	**Functional - Inpatient pilot application**	**Minor**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**	**Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**

6.4.8 Interfaces with HIS/EPR

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

REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	*The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services …*	Mechanistic physiology-based models are available within the REACTION platform
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)

6.4.9 Networking

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**

6.4.10 Ontology/Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-101	Functional - Outpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	*Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence …*	Decision support systems implements a module to link relevant literature to help clinicians in decision making
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	*Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters …*	*Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion …*

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

6.4.11 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**

6.4.12 Physiology Models

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**

REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	*The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services …*	Mechanistic physiology-based models are available within the REACTION platform
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	*Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters …*	*Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion …*

6.4.13 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	*The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services …*	Mechanistic physiology-based models are available within the REACTION platform
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-162	Non-functional - Usability	Major	Documentation of user interfaces	Documentation for User Interface of all frontend applications.	User manual for all frontend applications

6.4.14 Portable User Interface

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool
REACTION-98	**Functional - Outpatient pilot application**	**Minor**	**Support identification of "patients at risk" for developing diabetes / need for insulin treatment in primary care**	**Support identification of "patients at risk" for developing diabetes / need for insulin treatment in primary care (when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of risk.**	**If a diabetic patient is not on insulin therapy, the platform shall be able to estimate the risk for the particular patient to become insulin-dependent. Inpatient REACTION pilot decision support tool offers "patients at risk" calculator.**
REACTION-101	Functional - Outpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	*Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence …*	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

6.4.15 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-74	Functional - REACTION platform	Critical	Formalization of pre-existing clinical data (semantic structure)	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS	External data from EPR/HIS are available in a formalized manner
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	*The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services …*	Mechanistic physiology-based models are available within the REACTION platform
REACTION-81	Functional - Outpatient pilot application	Major	Long-term risk calculation and patient-oriented presentation	*Calculate long-term risk based on patient health profile and: - visualize in a patient-oriented form - present risk-reduction strategies …*	The REACTION platform offers a service to calculate diabetes dependent long-term risks
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-86	Functional - Outpatient pilot application	Major	Estimate short- and mid-term risk and identify successful therapy schemes for patient groups	*For the REACTION project data mining methods and heuristic algorithms should be used in order to identify: …*	*Health risk profiles (short- and mid-term) are available for risk profiling and knowledge discovery within the data sets can be conducted. Based …*
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool

REACTION-98	**Functional - Outpatient pilot application**	**Minor**	**Support identification of "patients at risk" for developing diabetes / need for insulin treatment in primary care**	**Support identification of "patients at risk" for developing diabetes / need for insulin treatment in primary care (when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of risk.**	**If a diabetic patient is not on insulin therapy, the platform shall be able to estimate the risk for the particular patient to become insulin-dependent. Inpatient REACTION pilot decision support tool offers "patients at risk" calculator.**
REACTION-101	Functional - Outpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	*Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence …*	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-165	Functional - REACTION platform	Major	Error Messages	Error messages for every component within the application have to be foreseen so that they are helpful for the end user.	Services and feedback to user.
REACTION-184	Functional - Outpatient pilot application	Major	Risk values for HbA1c	*Maintaining glycated haemoglobin (HbA1c) below 7.5% is likely to minimize risk of developing diabetic complications. If there is evidence …*	Thresholds have to be foreseen in the risk assessment module and advices have to be sent to patients.
REACTION-192	Functional - REACTION platform	Major	Thresholds for hypoglycaemia and hyperglycaemia	Different configurable thresholds shall be present for the detection of serious and life-threatening hypoglycaemic and hyperglycaemic episodes	*Once made sure the blood glucose level was correctly measured, values under specific thresholds (hypoglycaemia) or over specific …*
REACTION-193	Functional - Outpatient pilot application	Major	Alarm & alert generation	*The alerts and alarms should not be generated too often in such a way the system will be considered too intrusive for the patient himself. However …*	*Some serious or life-threatening situations can be simulated in the integration environment and the production of adequate alarms can …*
REACTION-200	Functional - Outpatient pilot application	Major	eQual & Mental Health Score	*These scores have to be evaluated after the insertion of the baseline and clinical history and to be presented to the clinicians and saved in the …*	These scores have to be implemented in the risk assessment component
REACTION-233	Functional - Inpatient pilot application	Major	Insulin sensitivity and insulin resistance	*Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters …*	*Glucose control algorithm and physiology models should use these two parameters and an appropriate user interface for their insertion …*

REACTION-243	**Functional - Inpatient pilot application**	**Trivial**	**Nutrition has to be taken into account in the calculation of the drug dosage**	**Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).**	**The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.**
REACTION-244	**Functional - Inpatient pilot application**	**Minor**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**	**Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**

6.4.16 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**

6.4.17 Sensors

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

6.4.18 Web User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-72	Functional - Inpatient pilot application	Critical	Provide decision support for insulin dosing for clinicians (in-hospital)	*Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters …*	eDSS is available for the REACTION platform
REACTION-73	**Functional - Outpatient pilot application**	**Major**	**Provide decision support for insulin dosing for physicians and/or patients (outpatient)**	**Primary care applications have been refined. Following 2 applications will be implemented: 1) Adaptive long-term risk predication for risk communication (FORTH-ICS) 2) Recognition of short-term patterns; Risk classification of diabetic patients at risk for bad glucose control (ALL)**	**Suggestion system will be available for patients and/or caregivers in the outpatient pilot application; revision based on ID6-5**
REACTION-81	Functional - Outpatient pilot application	Major	Long-term risk calculation and patient-oriented presentation	*Calculate long-term risk based on patient health profile and: - visualize in a patient-oriented form - present risk-reduction strategies …*	The REACTION platform offers a service to calculate diabetes dependent long-term risks
REACTION-82	Functional - REACTION platform	Major	Contextualized and personalized feedback to patients and carers	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)
REACTION-97	Functional - Inpatient pilot application	Minor	Quality analysis for ward personnel	Time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)	Inpatient REACTION pilot offers quality tool

REACTION-98	**Functional - Outpatient pilot application**	**Minor**	**Support identification of "patients at risk" for developing diabetes / need for insulin treatment in primary care**	**Support identification of "patients at risk" for developing diabetes / need for insulin treatment in primary care (when they are not on insulin when coming in). The risk management component shall be able to evaluate this kind of risk.**	**If a diabetic patient is not on insulin therapy, the platform shall be able to estimate the risk for the particular patient to become insulin-dependent. Inpatient REACTION pilot decision support tool offers "patients at risk" calculator.**
REACTION-101	Functional - Outpatient pilot application	Minor	Display / link to evidence based medicine information for decision support	*Use of NLP-technologies to link relevant (e.g. based on actual diagnosis of, treatment suggestions for individual patient) evidence …*	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-243	**Functional - Inpatient pilot application**	**Trivial**	**Nutrition has to be taken into account in the calculation of the drug dosage**	**Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation. Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).**	**The data management and the user interface shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.**
REACTION-244	**Functional - Inpatient pilot application**	**Minor**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**	**Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), Analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference). These facts will be considered by the physician when defining the treatment and evaluating the insulin dosage.**	**The data management and the user interface shall allow the insertion of specific interfering drugs (including their dosage). The dosage of insulin shall vary with these drugs.**

6.5 Requirements of WP7 – Security, Privacy and Safety

6.5.1 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-104	Non-functional - Security	Major	Need-to-know Basis: Stakeholders processing information should only learn what is necessary to carry out their specific task	*In an information processing chain, several stakeholders might be involved but it might not be necessary for every stakeholder to know …*	Process design takes into account the need-to-know principle
REACTION-114	Non-functional - Maintainability and portability	Major	Modularity: the system has to be divided into components	It is easier to implement, exchange, and integrate the modules.	REACTION platform should be modular
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	*Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and …*	Each member of the care space will have specific roles and tasks in the patient's care.
REACTION-259	Functional - Inpatient pilot application	Major	Automated patient identification	*Automated patient identification to avoid identification mistakes. Risks of wrong patient identification have to be negligible. The REACTION …*	*An effective, proper and easy-to-use way for automated patient identification, when mobile device is close to the patient (RFID, NFC?) …*

6.5.2 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	*Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and …*	Each member of the care space will have specific roles and tasks in the patient's care.

6.5.3 Context Management

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

6.5.4 Data Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	*Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and …*	Each member of the care space will have specific roles and tasks in the patient's care.
REACTION-198	Functional - REACTION platform	Major	Information related to informed consent have to be stored in the REACTION platform	*An ethical approved informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION …*	*The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the paper form signed …*

6.5.5 Interfaces with HIS/EPR

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	*Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and …*	Each member of the care space will have specific roles and tasks in the patient's care.

6.5.6 Ontology Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	*Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and …*	Each member of the care space will have specific roles and tasks in the patient's care.

6.5.7 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-45	Non-functional - Security	Critical	Protection against threats	*Medical data are sensible data and protection against threats and and unauthorized access should be provided. The system must protect …*	The functional test should include specific tests in order to verify such circumstances
REACTION-63	Functional - REACTION platform	Major	Security and privacy related to patient data	*Privacy concerns are of utmost importance. The patient data should be transfer and maintained in a secure way while any access to them …*	Verify that any access to patient data is logged and is performed in a secure way

REACTION-90	Non-functional - Security	Major	Identifiability: Recipients and senders of information must be identifiable, though not necessarily personally identifiable	Reports/measurements must be assignable to the 'right' patient file/device	Recipients and senders must have unique identifiers
REACTION-91	Non-functional - Security	Major	Authenticity: Processors of information should be able to determine whether the data being processed is authentic	*Medical personnel should know if information relating to their patient originates from a known/trusted source, e.g., the patient's blood …*	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 during transport	Any kind of undetectable changes in patient's data may give rise to wrong treatment and harm patients	Availability of a mechanism for ensuring data integrity
REACTION-95	Non-functional - Legal	Major	Accountability: Stakeholders should be held accountable for relevant actions	*Certain actions or decisions will have an impact on the person making the decision or on the person affected by it, thus it should be clear, e.g., who …*	Availability of a procedure or mechanism allowing to review relevant actions of stakeholders
REACTION-99	Non-functional - Security	Major	Authorisation: Stakeholders must be authorised before they are allowed to perform relevant actions	Certain actions are not permitted for everybody but may only be carried out by authorised personnel	Availability of a procedure or mechanism allowing to authorise relevant actions
REACTION-100	Non-functional - Security	Major	Access control: Access to sensitive information should only by given to authorised personnel	Sharing patient data is necessary in health care to treat patients but access should only be given to persons involved in the treatment	Availability of a mechanism allowing to control access to sensitive data
REACTION-102	Non-functional - Legal	Major	Notice: Natural persons should be notified when, how, and to what extent their personal data are communicated to others	Handling of personal data has to conform to privacy laws	Process design takes into account the fair-processing principle
REACTION-103	Non-functional - Legal	Major	Data reduction and data economy: Personal data shall be collected, processed and used as little as possible.	*Handling personal data has to conform to privacy laws. In particular, personal data shall be rendered anonymous or pseudonymous as …*	*Processes are designed such that personal data are only collected when necessary and anonymisation/pseudonymisation …*
REACTION-104	Non-functional - Security	Major	Need-to-know Basis: Stakeholders processing information should only learn what is necessary to carry out their specific task	*In an information processing chain, several stakeholders might be involved but it might not be necessary for every stakeholder to know …*	Process design takes into account the need-to-know principle
REACTION-109	Non-functional - Performance	Major	Scalability: the security must not materially impact the performance of the system	the security resources have to scale well with the overall architecture	Security does not significantly impact overall latency of the system
REACTION-114	Non-functional - Maintainability and portability	Major	Modularity: the system has to be divided into components	It is easier to implement, exchange, and integrate the modules.	REACTION platform should be modular

REACTION-115	Non-functional - Usability	Major	Transparency: Security configuration should be hidden from the user as far as possible	Users usually do not have the expertise to choose the 'right' security options.	No, or as few as possible, additional user interactions for security.
REACTION-116	Non-functional - Maintainability and portability	Major	Availability of security mechanisms to manage sensitive data	In REACTION, we are dealing with sensitive data, thus security must be available on all platforms.	Security mechanisms are available for all target platforms of REACTION.
REACTION-118	Non-functional - Legal	Major	Assurance: the architecture and its implementation must provide assurance that it delivers the security and compliance properties it promises	If allegedly secure functions do not live up to their expected functionality, the whole platform could be compromised.	Successful review of expected security functionality.
REACTION-198	Functional - REACTION platform	Major	Information related to informed consent have to be stored in the REACTION platform	*An ethical approved informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION …*	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the paper form signed …
REACTION-259	Functional - Inpatient pilot application	Major	Automated patient identification	*Automated patient identification to avoid identification mistakes. Risks of wrong patient identification have to be negligible. The REACTION …*	*An effective, proper and easy-to-use way for automated patient identification, when mobile device is close to the patient (RFID, NFC?) …*

6.5.8 Sensors

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

6.5.9 Web User Interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-197	Functional - Outpatient pilot application	Major	Care spaces in the outpatient environment	*Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and …*	Each member of the care space will have specific roles and tasks in the patient's care.

6.6 Requirements of WP8 –Clinical Practise and Field Trials

6.6.1 Architecture

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

REACTION-262	**Non-functional - Performance**	**Major**	**Improve productivity and efficiency, reducing cost**	**The platform shall improve productivity and efficiency and at the same time shall reduce the cost of the diabetic patient workflow and management**	**Qualitative or quantitative measurements of productivity, efficiency and cost shall be foreseen in the field trials in order to make a proper comparison between the performances before the introduction of the REACTION platform and after the introduction of the REACTION platform. Assessment in field trial will be based on questionnaire for evaluating productivity and efficiency and on cost-benefit analysis estimating the different performances before the introduction of the REACTION platform and after the introduction of the REACTION platform. Usability tests will be performed early in the life cycle in order to adjust specifications of the system. Questionnaires will be part of the first clinical trial to assess usability.**
REACTION-263	Functional - Inpatient pilot application	Major	Improve documentation quality and streamlined access to information	*The registration of all measurements, additional information, decision on treatments, drug administration will improve the quality of …*	*The platform shall allow the registration of all relevant information and its contextualized retrieval. In the questionnaires used in the …*

6.6.2 Glucose Control Algorithm

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 identified and assessed.**	**All risks must be in an acceptable range according to the assessment criteria.**

6.6.3 Interfaces with HIS/EPR

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

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.

6.6.4 Physiology Models

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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 identified and assessed.**	**All risks must be in an acceptable range according to the assessment criteria.**

6.6.5 Portable User Interface

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 additional workload has not to be …*	*Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work they have to do and …*

6.6.6 Risk Assessment

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-275	Non-functional - Legal	Major	Clinical trials, formal application	A formal application is required for clinical trials.	Formal application must be made before clinical trials.
REACTION-276	Non-functional - Legal	Major	Clinical trials, patient's information sheet including informed consent	Patient's information sheet including informed consent is needed for clinical trials.	Patient's information sheet including informed consent must be given before clinical trials.
REACTION-277	Non-functional - Legal	Major	Clinical trials study protocol	A study protocol must be written during clinical trials.	Study protocol must be available after clinical trials. The protocol should fulfil EN ISO 14155-1 and EN ISO 14155-2

REACTION-278	Non-functional - Legal	Major	Clinical trials case report form	For clinical trials a case report form has to be generated.	Case report form was generated for clinical trials.
REACTION-279	Non-functional - Legal	Major	Clinical trials investigators brochure	It is important to create an investigators brochure (sensor development) for clinical trials.	Investigators brochure present for clinical trials.
REACTION-282	Non-functional - Legal	Major	Insurance for clinical trials must be made	Insurance is required for clinical trials otherwise it can not be performed.	Insurance made before clinical trials.
REACTION-283	Non-functional - Legal	Major	Qualification of the investigator for clinical trials	Qualification of investigator must be given for clinical trials.	Qualification of investigator given in advance of clinical trials.

6.6.7 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-279	Non-functional - Legal	Major	Clinical trials investigators brochure	It is important to create an investigators brochure (sensor development) for clinical trials.	Investigators brochure present for clinical trials.
REACTION-281	**Non-functional - Legal**	**Major**	**Clinical trials CE- certification OR certification that the medical device fulfils the MDD 93/42/EEC and subsequent amending directives like the directive 2007/47/EC**	**For clinical trials applied sensors, devices or software (as medical device) must fulfil the medical device directive (MDD). The clinical sites have to check the requirements (also on sensors/devices/software which will be used) for starting the clinical trials.**	**Sensors/devices/software (as medical device) applied in clinical trials fulfil the MDD.**

6.6.8 Web User Interface

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 additional workload has not to be …*	*Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work they have to do and …*

6.7 Requirements of WP9 – Socio-Economic Framework

6.7.1 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-131	Non-functional - Look and feel	Major	The platform shall appear authoritative	Trust of end-users is paramount	After their first encounter with the product, 2/3 of representative end-users shall agree they feel they can trust the platform and its services
REACTION-146	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings	*To increase the adoption of REACTION technologies within different social groups, it must adapt were possible to social conventions …*	*The application should cater for configuring at least:* *- language settings* *- different sets of symbols and …*
REACTION-148	Non-functional - Security	Major	The user should be able to trust the application infrastructure	*ICT components have to be trustworthy, because otherwise they pose the same risks they try to protect the user from. The application …*	*Does the application provide information about its trustworthiness?* *Does the application provide information the infrastructure …*
REACTION-149	Non-functional - Cultural and political	Major	The user should be able to trust the operators involved in the application	*The application should provide means to strengthen/restore this trust.* *The application can contribute to trust by: …*	*Does the application provide ways to establish the trustworthiness of the operators?* *Does the application provide ways …*
REACTION-150	Non-functional - Economical and business	Major	The user should be able to obtain and use the application at reasonable cost	*The design and/or business model of the application should minimise the costs for acquisition, installation and exploitation/use (both in money and …*	Does the application have a reasonable cost? Is the application easy to install and maintain?

6.7.2 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-143	Non-functional - Ethical	Major	The user should be aware of the essential events, processes, stakeholders and attributes of the collection and use of personal data	*In order for data collection and use to be fair (see for instance, preamble 38 Directive 95/46/EC), users have to be aware that their data is requested …*	*The user should be aware of:* *- when data collection occurs* *- who collects the (personal) data* *- for which purpose the data is …*
REACTION-144	Non-functional - Ethical	Major	The user should understand how personal data is handled by the service provider	*In order for users to be in control of their personal data, they have to understand what happens with their data if they are disclosed to the …*	*Users should be able to understand:* *• how their personal data is collected and used* *• for which purpose the data is …*

6.7.3 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-147	Non-functional - Cultural and political	Major	The user should be able to use the application with a minimal amount of training	*To limit social divides resulting from having access and being able to use the technology, the application should be as easy to use as possible …*	*Does the application provide a set of default settings that cover the needs of the majority of users?* *Does the application provide a …*

6.7.4 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. Choice is also mandated by …*	*Offering the user opt-in and opt-out choices for particular uses of collected data is an element of choice. When there is a choice to provide the ...*
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 and to whom. Of course …*	*The fact that consent is instrumental to a number of fundamental values, means that it has to be revocable when it turns out that the effects of …*
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 service providers alike …*	*Levels of ex-post user control that can be distinguished are:* *- rectify: the power to change or …*

6.7.5 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-142	Non-functional - Ethical	Major	The user should have a certain level of control over information relating to him/her	*Users are taken to be individuals who can make autonomous choices about their life. Although they can not be said to own their personal data in a …*	*User control means that the user should be able to:* *- control of how personal data is handled …*

6.8 Requirements of WP10 – Platform Integration and Implementation

6.8.1 Alarm & Alert Subsystem

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	*The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose ...*	*A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant …*
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	*In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered …*	*A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the …*

6.8.2 Architecture

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-13	Functional	Major	To update EPRs with collected data	Provide an interface for updating EPRs.	Support at least IHE-PCD01.
REACTION-23	Functional	Major	Clinician generated feedback to patient	It should be possible for clinician/staff to submit additional information to patients, e.g. for educational or encouragement purposes.	At least to provide a two way communication, e.g. shared white board.
REACTION-26	Functional - REACTION platform	Major	Embedded intelligence	*Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions …*	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.
REACTION-46	Non-functional - Maintainability and portability	Minor	Error messages must be understandable and helpful	*When an application fails this must happen gracefully while providing sufficient and easy to understand messages to the user. In this way …*	*For each application, developers must ensure that error messages should be brief, easy to read, understood even by non-specialists and should also …*
REACTION-67	Non-functional - Maintainability and portability	Major	Component Repository	A repository for the binary components has to be set-up in order to ease the integration and the internal test	A server for the containment of the components will be set-up
REACTION-69	Functional - REACTION platform	Critical	System Configuration	The components and applications should be made in a way that makes easy the configuration	Theoretically without any recompilation, the application should be easily configurable for the different environments

REACTION-71	Non-functional - Maintainability and portability	Critical	Simulators for the internal tests	The internal test is performed without real users (clinicians & patients) and therefore some devices have to be simulated	Simulated components performing the same operations with exactly the same interface have to be available
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	*Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	*In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an …*	Front-end for therapy-scheme quality presentation
REACTION-96	**Functional - Inpatient pilot application**	**Major**	**Visualization individual patient data to support glucose control (decision support)**	**Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")**	**Inpatient REACTION pilot offers dynamic visualization module for decision support**
REACTION-132	Non-functional - Usability	Major	The platform shall help the user to avoid making mistakes	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows	End-users will be guided through the workflows they have to perform.
REACTION-138	Non-functional - Performance	Major	The platform shall be expected to operate within reasonable maintenance effort for all the duration of the field trials	Problems at the field trials should be minimized	Problems signalled at the field trials should be under a fixed threshold
REACTION-139	Non-functional - Operational	Major	The platform shall be able to be installed and configured at the field trial sites by the local technical partner without too much effort	The local technical partners shall take care of the installation and configuration of the field trials	Adequate installation and configuration manuals have to be provided to the local technical partners.
REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	*A centrally managed data repository enables easy updating of information and access to the latest version of information from different access …*	Clinicians can input relevant information via tablet PC from every place within the hospital ward.

REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters.** **Main parameters for documentation (once, at the enrolment)** **1. type of diabetes (insulin requirement)** **2. newly diagnosed diabetes** **3. weight** **4. classification of the patient regarding insulin sensitive/normal/resistant** **Parameters required regularly (for decision support)** **1. glucose level (time, trend, last measurement)** **2. injected insulin** **3. food intake / nutrition** **4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	*An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	*After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-179	Functional - Outpatient pilot application	Major	Daily data review by clinicians or telehealth support team	*When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the …*	*The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or …*

REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	*At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also …*	*Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the …*
REACTION-189	Functional - Outpatient pilot application	Major	Other managements for type I diabetic patients	*Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, …*	In the care program, management of diabetes (through insulin) should be accompanied by management of complications
REACTION-190	Constraint - Implementation Environment	Major	In the outpatient environment the medications are usually self-administered by the patient himself or by informal carers (rarely)	Usual practice for diabetic patient outside from secondary or tertiary care is self-administration of medications	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home
REACTION-191	Functional - Outpatient pilot application	Major	Structured programme for the management of diabetic patients	*The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, …*	The applications shall allow the implementation of the structured programme.
REACTION-194	Functional - Outpatient pilot application	Major	Regular visits/reviews at the Primary Health Care	*Outcomes of regular visits at the Primary Health care centre shall be registered in the platform through the use of specific forms/user …*	Specific forms and user interfaces for the doctors/nurses have to be present
REACTION-196	Functional - Outpatient pilot application	Major	End of process for the diabetic patient in the outpatient environment	*There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from …*	*Patient discharge from the outpatient environment has to be foreseen only in case of a) death; b) patient removal outside from the practice catchment …*
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	*Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done …*	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-203	Functional - Outpatient pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization
REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	*Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of …*
REACTION-234	Functional - Inpatient pilot application	Major	Determination of health status in Inpatient environment	*At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or …*	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.

REACTION-235	**Functional - Inpatient pilot application**	**Major**	**Therapy scheme in Inpatient environment registered immediately after the patient enrolment**	**The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status, nutrition, insulin resistance. Eventual additional data might be added during the course of the project.**	**The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.**
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	*Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be …*	*Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for …*

6.8.3 Backend Middleware

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-65	Functional - REACTION platform	Major	System availability	*The system should be continually monitoring and gathering data about the patients status with no excessive down time. Availability here means ….*	The end user applications and the devices in the vicinity of the patient should always operable
REACTION-71	Non-functional - Maintainability and portability	Critical	Simulators for the internal tests	The internal test is performed without real users (clinicians & patients) and therefore some devices have to be simulated	Simulated components performing the same operations with exactly the same interface have to be available
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	*Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients

REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	*A centrally managed data repository enables easy updating of information and access to the latest version of information from different access …*	Clinicians can input relevant information via tablet PC from every place within the hospital ward.
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	*An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	*After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	*Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done …*	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	*Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of …*
REACTION-226	Functional - Inpatient pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	*Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, …*	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	*Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be …*	*Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for …*

6.8.4 Communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-23	Functional	Major	Clinician generated feedback to patient	It should be possible for clinician/staff to submit additional information to patients, e.g. for educational or encouragement purposes.	At least to provide a two way communication, e.g. shared white board.
REACTION-57	Non-functional - Performance	Critical	Performance and Scalability	*Responsive enough to integrate with the clinician workflow. The response to the users action should be acceptable, depending on how …*	Criteria are different depending on the user action. For time-critical actions the response should be almost instant.
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	*Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	*A centrally managed data repository enables easy updating of information and access to the latest version of information from different access …*	Clinicians can input relevant information via tablet PC from every place within the hospital ward.
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-189	Functional - Outpatient pilot application	Major	Other managements for type I diabetic patients	*Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, …*	In the care program, management of diabetes (through insulin) should be accompanied by management of complications
REACTION-190	Constraint - Implementation Environment	Major	In the outpatient environment the medications are usually self-administered by the patient himself or by informal carers (rarely)	Usual practice for diabetic patient outside from secondary or tertiary care is self-administration of medications	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home
REACTION-191	Functional - Outpatient pilot application	Major	Structured programme for the management of diabetic patients	*The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, …*	The applications shall allow the implementation of the structured programme.

REACTION-225	Functional - Inpatient pilot application	Major	PoC device for blood glucose measurement will be used in the first-year prototype	*The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the consortium sensors …*	*The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. The …*
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	*Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be …*	*Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for …*

6.8.5 Context Management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-8	**Functional - Outpatient 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 patients.**	**User interface exists.**
REACTION-15	Constraint	Major	System must keep track of work flow stages	To identify in which stage within the diabetes management the patient is: newly diagnosed, medication titration, and ongoing management.	Individual patient can always be mapped into a work flow stage.
REACTION-23	Functional	Major	Clinician generated feedback to patient	It should be possible for clinician/staff to submit additional information to patients, e.g. for educational or encouragement purposes.	At least to provide a two way communication, e.g. shared white board.
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	*Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	*In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an …*	Front-end for therapy-scheme quality presentation

REACTION-96	**Functional - Inpatient pilot application**	**Major**	**Visualization individual patient data to support glucose control (decision support)**	**Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")**	**Inpatient REACTION pilot offers dynamic visualization module for decision support**
REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters. Main parameters for documentation (once, at the enrolment) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight 4. classification of the patient regarding insulin sensitive/normal/resistant Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform
REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	*At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also …*	*Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the …*

REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	*Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to …*	*There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint …*
REACTION-240	**Functional - Inpatient pilot application**	**Trivial**	**Intravenous insulin**	**In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.**	**The insulin administration shall allow also the IV way in the user interface**
REACTION-245	**Functional - Inpatient 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 checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.**	**Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.**

6.8.6 Data Management

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

REACTION-96	**Functional - Inpatient pilot application**	**Major**	**Visualization individual patient data to support glucose control (decision support)**	**Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")**	**Inpatient REACTION pilot offers dynamic visualization module for decision support**
REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	*When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from …*	*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 …*
REACTION-153	**Functional - Outpatient pilot application**	**Major**	**Symptoms of diabetes or hyperglycaemia**	**At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).**	**Specific design in the user interfaces, ontologies and data management**
REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	*A centrally managed data repository enables easy updating of information and access to the latest version of information from different access …*	Clinicians can input relevant information via tablet PC from every place within the hospital ward.

REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters.** **Main parameters for documentation (once, at the enrolment)** **1. type of diabetes (insulin requirement)** **2. newly diagnosed diabetes** **3. weight** **4. classification of the patient regarding insulin sensitive/normal/resistant** **Parameters required regularly (for decision support)** **1. glucose level (time, trend, last measurement)** **2. injected insulin** **3. food intake / nutrition** **4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	*An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	*After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-179	Functional - Outpatient pilot application	Major	Daily data review by clinicians or telehealth support team	*When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the …*	*The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or …*

REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	*At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also …*	*Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the …*
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	*Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done …*	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-203	Functional - Outpatient pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization
REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	*Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of …*
REACTION-224	Functional - Inpatient pilot application	Major	Basic workflow is repeated 4 times a day in inpatient environment	*The first workflow is in the morning a little before breakfast time (administration of bolus insulin), the second is at midday before lunch …*	These 4 loops should be easily identified in the Inpatient application
REACTION-226	Functional - Inpatient pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	*Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, …*	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.
REACTION-230	Functional - Inpatient pilot application	Major	Overall evaluation in Inpatient environment	*Supervision of glycaemia and according treatment is performed once a day. Adaptation of therapy or changes of medications have to be …*	Every day an evaluation report has to be stored and available in the Inpatient application
REACTION-234	Functional - Inpatient pilot application	Major	Determination of health status in Inpatient environment	*At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or …*	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.

REACTION-235	**Functional - Inpatient pilot application**	**Major**	**Therapy scheme in Inpatient environment registered immediately after the patient enrolment**	**The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status, nutrition, insulin resistance. Eventual additional data might be added during the course of the project.**	**The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.**
REACTION-240	**Functional - Inpatient pilot application**	**Trivial**	**Intravenous insulin**	**In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.**	**The insulin administration shall allow also the IV way in the user interface**
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	*The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose …*	*A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant …*
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	*In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered …*	*A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the …*
REACTION-245	**Functional - Inpatient 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 checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.**	**Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.**
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	*Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be …*	*Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for …*

REACTION-250	Functional - Inpatient pilot application	Major	Different contextualization of the patient clinical information	*Different modes of visualisation with different relevant parameters for decision support shall be foresee. The relevant data have to be displayed …*	The possibility of configure the display of the patient clinical data (mainly the fever chart) has to be present.

6.8.7 Glucose Control Algorithm

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-223	Functional - Inpatient pilot application	Major	Basic workflow for insulin treatment in Inpatient environment	*The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on …*	The basic workflow should be easily accessible in the REACTION Inpatient application
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	*The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose …*	*A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant …*
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	*In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered …*	*A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the …*
REACTION-245	**Functional - Inpatient 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 checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.**	**Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.**

6.8.8 Interfaces with HIS/ERP

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-41	Non-functional - Maintainability and portability	Major	*The tools developed by the consortium must be properly documented in such a way that the end user can understand them and …*	*Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The …*	*Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely …*
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	*Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients

REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	*When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from …*	*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 …*
REACTION-153	**Functional - Outpatient pilot application**	**Major**	**Symptoms of diabetes or hyperglycaemia**	**At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).**	**Specific design in the user interfaces, ontologies and data management**
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	*Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done …*	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-225	Functional - Inpatient pilot application	Major	PoC device for blood glucose measurement will be used in the first-year prototype	*The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the consortium sensors …*	*The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. The …*
REACTION-258	Functional - Inpatient pilot application	Major	Automated transfer of patient related data from the hospital information system	*At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred …*	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.

6.8.9 Networking

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-26	Functional - REACTION platform	Major	Embedded intelligence	*Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions …*	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.
REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	*Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-96	**Functional - Inpatient pilot application**	**Major**	**Visualization individual patient data to support glucose control (decision support)**	**Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")**	**Inpatient REACTION pilot offers dynamic visualization module for decision support**
REACTION-169	Functional - Inpatient pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	*A centrally managed data repository enables easy updating of information and access to the latest version of information from different access …*	Clinicians can input relevant information via tablet PC from every place within the hospital ward.

REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters.** **Main parameters for documentation (once, at the enrolment)** **1. type of diabetes (insulin requirement)** **2. newly diagnosed diabetes** **3. weight** **4. classification of the patient regarding insulin sensitive/normal/resistant** **Parameters required regularly (for decision support)** **1. glucose level (time, trend, last measurement)** **2. injected insulin** **3. food intake / nutrition** **4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform
REACTION-174	Functional - Inpatient pilot application	Blocker	Inpatient: Interfaces to HIS, data management, data structures for inpatient scenario	The platform should offer interface to HIS; moreover the system needs data structures and data management functionality for the inpatient scenario	Data structures and data management functionality
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	*Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be …*	*Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for …*

6.8.10 Ontology/Terminology

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	*Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients

REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	*In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an …*	Front-end for therapy-scheme quality presentation
REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters.** **Main parameters for documentation (once, at the enrolment)** **1. type of diabetes (insulin requirement)** **2. newly diagnosed diabetes** **3. weight** **4. classification of the patient regarding insulin sensitive/normal/resistant** **Parameters required regularly (for decision support)** **1. glucose level (time, trend, last measurement)** **2. injected insulin** **3. food intake / nutrition** **4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	*An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	*After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-179	Functional - Outpatient pilot application	Major	Daily data review by clinicians or telehealth support team	*When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the …*	*The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or …*
REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	*At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also …*	*Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the …*

REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	*Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to …*	*There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint …*
REACTION-191	Functional - Outpatient pilot application	Major	Structured programme for the management of diabetic patients	*The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, …*	The applications shall allow the implementation of the structured programme.
REACTION-194	Functional - Outpatient pilot application	Major	Regular visits/reviews at the Primary Health Care	*Outcomes of regular visits at the Primary Health care centre shall be registered in the platform through the use of specific forms/user …*	Specific forms and user interfaces for the doctors/nurses have to be present
REACTION-196	Functional - Outpatient pilot application	Major	End of process for the diabetic patient in the outpatient environment	*There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from …*	*Patient discharge from the outpatient environment has to be foreseen only in case of a) death; b) patient removal outside from the practice …*
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	*Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done …*	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.
REACTION-203	Functional - Outpatient pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization
REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	*Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of …*
REACTION-223	Functional - Inpatient pilot application	Major	Basic workflow for insulin treatment in Inpatient environment	*The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on …*	The basic workflow should be easily accessible in the REACTION Inpatient application
REACTION-226	Functional - Inpatient pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	*Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, …*	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.
REACTION-234	Functional - Inpatient pilot application	Major	Determination of health status in Inpatient environment	*At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or …*	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.

REACTION-240	**Functional - Inpatient pilot application**	**Trivial**	**Intravenous insulin**	**In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.**	**The insulin administration shall allow also the IV way in the user interface**
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	*The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose …*	*A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant …*
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	*In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered …*	*A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the …*
REACTION-245	**Functional - Inpatient 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 checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.**	**Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.**
REACTION-258	Functional - Inpatient pilot application	Major	Automated transfer of patient related data from the hospital information system	*At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred …*	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.

6.8.11 PAN/BAN

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-26	Functional - REACTION platform	Major	Embedded intelligence	*Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions …*	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.

REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform

6.8.12 Portable Devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-13	Functional	Major	To update EPRs with collected data	Provide an interface for updating EPRs.	Support at least IHE-PCD01.
REACTION-15	Constraint	Major	System must keep track of work flow stages	To identify in which stage within the diabetes management the patient is: newly diagnosed, medication titration, and ongoing management.	Individual patient can always be mapped into a work flow stage.
REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-96	**Functional - Inpatient pilot application**	**Major**	**Visualization individual patient data to support glucose control (decision support)**	**Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")**	**Inpatient REACTION pilot offers dynamic visualization module for decision support**
REACTION-170	Functional - Inpatient pilot application	Major	Selection of a mobile device for inpatient glucose control based on given requirements	*The devices should be: - Lightweight/portable - Easy to hold / handle and ergonomic design …*	Devices with desired functionality are available within the project

REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters.** **Main parameters for documentation (once, at the enrolment)** **1. type of diabetes (insulin requirement)** **2. newly diagnosed diabetes** **3. weight** **4. classification of the patient regarding insulin sensitive/normal/resistant** **Parameters required regularly (for decision support)** **1. glucose level (time, trend, last measurement)** **2. injected insulin** **3. food intake / nutrition** **4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform
REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	*Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to …*	*There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint …*

6.8.13 Portable User Interface

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-41	Non-functional - Maintainability and portability	Major	*The tools developed by the consortium must be properly documented in such a way that the end user can understand them and …*	*Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The …*	*Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely …*
REACTION-44	Non-functional - Security	Critical	Protection against unintended user actions	*Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not …*	The functional test should include specific tests in order to verify such circumstances

REACTION-48	Non-functional - Usability	Major	Support for multilingual user interface	Users from different countries should have access to services.	*Any type of text in any graphical user interfaces that will be developed (labels, text fields, labels, etc.) must be able to easily configured and …*
REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	*In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an …*	Front-end for therapy-scheme quality presentation
REACTION-96	**Functional - Inpatient pilot application**	**Major**	**Visualization individual patient data to support glucose control (decision support)**	**Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")**	**Inpatient REACTION pilot offers dynamic visualization module for decision support**
REACTION-117	Non-functional - Usability	Major	Cross-platform usability: user experience should be the same on all platforms	Users should only see familiar interfaces in order to adapt to a new platform more easily.	Different platforms do not have significantly different user interfaces, i.e., REACTION should be 'platform agnostic'.
REACTION-130	Non-functional - Look and feel	Major	The platform shall be easily used by elderly people with no specific technological knowledge	*Being the diabetes quite common in elderly people, several patients will have no specific knowledge in technology, but they should be able …*	User learning curve (especially with elderly people) should be very quick
REACTION-132	Non-functional - Usability	Major	The platform shall help the user to avoid making mistakes	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows	End-users will be guided through the workflows they have to perform.

REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters.** **Main parameters for documentation (once, at the enrolment)** **1. type of diabetes (insulin requirement)** **2. newly diagnosed diabetes** **3. weight** **4. classification of the patient regarding insulin sensitive/normal/resistant** **Parameters required regularly (for decision support)** **1. glucose level (time, trend, last measurement)** **2. injected insulin** **3. food intake / nutrition** **4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**
REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform

6.8.14 Risk Assessment

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

REACTION-96	**Functional - Inpatient pilot application**	**Major**	**Visualization individual patient data to support glucose control (decision support)**	**Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")**	**Inpatient REACTION pilot offers dynamic visualization module for decision support**
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	*An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	*After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	*The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose …*	*A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant …*
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	*In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered …*	*A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the …*
REACTION-245	**Functional - Inpatient 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 checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.**	**Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.**

6.8.15 Security

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-44	Non-functional - Security	Critical	Protection against unintended user actions	*Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not …*	The functional test should include specific tests in order to verify such circumstances
REACTION-84	Functional - REACTION platform	Major	Interface to patients health history information from EPR/HIS	*Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform …*	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients
REACTION-140	Non-functional - Security	Major	The platform shall prevent incorrect data from being introduced	Incorrect data might hamper a correct clinical decision	Check that the user interface and specific procedures protect the end-user from the introduction of incorrect data as much as possible
REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	*When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from …*	*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 …*
REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters.** **Main parameters for documentation (once, at the enrolment)** **1. type of diabetes (insulin requirement)** **2. newly diagnosed diabetes** **3. weight** **4. classification of the patient regarding insulin sensitive/normal/resistant** **Parameters required regularly (for decision support)** **1. glucose level (time, trend, last measurement)** **2. injected insulin** **3. food intake / nutrition** **4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**

REACTION-172	Functional - Inpatient pilot application	Blocker	Automatic transmission of glucose values from POCT system to REACTION platform (time-critical!)	*The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the …*	POCT data is transmitted within short time to the platform

6.8.16 Sensors

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-36	Functional - REACTION platform	Major	Fail-safe design (a design that will enable the system to continue operation, even if at a reduced level, if possible)	Failure to a component may result in a severe breakdown.	A possible reduction in throughput or even an increase in response time in the event, without a too high loss in performances
REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-71	Non-functional - Maintainability and portability	Critical	Simulators for the internal tests	The internal test is performed without real users (clinicians & patients) and therefore some devices have to be simulated	Simulated components performing the same operations with exactly the same interface have to be available
REACTION-225	Functional - Inpatient pilot application	Major	PoC device for blood glucose measurement will be used in the first-year prototype	*The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the consortium sensors …*	*The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. The …*

6.8.17 Web User Interface

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-41	Non-functional - Maintainability and portability	Major	*The tools developed by the consortium must be properly documented in such a way that the end user can understand them and …*	*Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The …*	*Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely …*
REACTION-44	Non-functional - Security	Critical	Protection against unintended user actions	*Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not cause the system to close down, …*	The functional test should include specific tests in order to verify such circumstances
REACTION-47	Non-functional - Look and feel	Minor	Web pages must be suited for screen readers, scaling to visually-impaired users, and utilizing the full screen size on small as well as large screens.	Will allow the easy interaction with the platform. Will also provide, as much as possible, to people with disabilities the ability to use the platform.	*Use of large fonts, use of colours with strong contrast, possible use of audio messages and implementation of other commonly used accessibility …*

REACTION-48	Non-functional - Usability	Major	Support for multilingual user interface	Users from different countries should have access to services.	*Any type of text in any graphical user interfaces that will be developed (labels, text fields, labels, etc.) must be able to easily configured and …*
REACTION-64	Non-functional - Usability	Major	Friendly applications	*The use of end-user applications and the devices both in the in-patient but also (and most importantly perhaps) in the outpatient cases should be …*	No complex user interfaces, the user should be familiar with the applications in short time (training is foreseen)
REACTION-77	Non-functional - Usability	Major	Browser Compatibility	The web based interface should be perform properly in the last 2 editions of the 5 most common browsers	Specific tests have to be performed
REACTION-85	Functional - Outpatient pilot application	Major	Present effectiveness of medication therapies to patients and carers	*In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an …*	Front-end for therapy-scheme quality presentation
REACTION-96	**Functional - Inpatient pilot application**	**Major**	**Visualization individual patient data to support glucose control (decision support)**	**Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")**	**Inpatient REACTION pilot offers dynamic visualization module for decision support**
REACTION-117	Non-functional - Usability	Major	Cross-platform usability: user experience should be the same on all platforms	Users should only see familiar interfaces in order to adapt to a new platform more easily.	Different platforms do not have significantly different user interfaces, i.e., REACTION should be 'platform agnostic'.
REACTION-130	Non-functional - Look and feel	Major	The platform shall be easily used by elderly people with no specific technological knowledge	*Being the diabetes quite common in elderly people, several patients will have no specific knowledge in technology, but they should be able …*	User learning curve (especially with elderly people) should be very quick
REACTION-132	Non-functional - Usability	Major	The platform shall help the user to avoid making mistakes	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows	End-users will be guided through the workflows they have to perform.

REACTION-152	Functional - REACTION platform	Major	Patient recruitment (or enrolment)	*When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from …*	*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 …*
REACTION-153	**Functional - Outpatient pilot application**	**Major**	**Symptoms of diabetes or hyperglycaemia**	**At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).**	**Specific design in the user interfaces, ontologies and data management**
REACTION-171	**Functional - Inpatient pilot application**	**Major**	**Data input application for inpatient glucose control**	**The system should ask for data entry of relevant parameters.** **Main parameters for documentation (once, at the enrolment)** **1. type of diabetes (insulin requirement)** **2. newly diagnosed diabetes** **3. weight** **4. classification of the patient regarding insulin sensitive/normal/resistant** **Parameters required regularly (for decision support)** **1. glucose level (time, trend, last measurement)** **2. injected insulin** **3. food intake / nutrition** **4. hypoglycaemic and hyperglycaemic episodes**	**Data entry system will be available for inpatient decision support system with devices (tablet PC)**
REACTION-177	Functional - Outpatient pilot application	Major	Investigative stage	*An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has …*	Specific fields have to be present in data management, ontologies and web user interfaces.

REACTION-178	Functional - Outpatient pilot application	Major	Ongoing management	*After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in …*	Specific fields have to be present in data management, ontologies and web user interfaces.
REACTION-179	Functional - Outpatient pilot application	Major	Daily data review by clinicians or telehealth support team	*When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the …*	*The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or …*
REACTION-181	Functional - Outpatient pilot application	Major	Decision on therapy in Outpatient environment	*At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also …*	*Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the …*
REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	*Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to …*	*There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint …*
REACTION-189	Functional - Outpatient pilot application	Major	Other managements for type I diabetic patients	*Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, …*	In the care program, management of diabetes (through insulin) should be accompanied by management of complications
REACTION-190	Constraint - Implementation Environment	Major	In the outpatient environment the medications are usually self-administered by the patient himself or by informal carers (rarely)	Usual practice for diabetic patient outside from secondary or tertiary care is self-administration of medications	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home
REACTION-191	Functional - Outpatient pilot application	Major	Structured programme for the management of diabetic patients	*The structured programme includes: blood glucose control (regular measurements), self-monitoring of additional parameters/events, …*	The applications shall allow the implementation of the structured programme.
REACTION-194	Functional - Outpatient pilot application	Major	Regular visits/reviews at the Primary Health Care	*Outcomes of regular visits at the Primary Health care centre shall be registered in the platform through the use of specific forms/user …*	Specific forms and user interfaces for the doctors/nurses have to be present
REACTION-196	Functional - Outpatient pilot application	Major	End of process for the diabetic patient in the outpatient environment	*There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from …*	*Patient discharge from the outpatient environment has to be foreseen only in case of a) death; b) patient removal outside from the practice …*
REACTION-199	Functional - Outpatient pilot application	Major	Baseline and clinical history should be handled by the data management system	*Immediately after the patient recruitment, medical baseline and clinical history has to be entered in the platform. This can be done …*	A specific user interface has to be designed and developed in order to allow the insertion and check of the baseline and clinical history.

REACTION-203	Functional - Outpatient pilot application	Major	Care plan (defined for each patient) has to be personalized	The care plan which includes disease management, risk management and lifestyle management has to be personalized for each patient.	The user interfaces shall allow the introduction and the display of the care plan and allow its personalization
REACTION-216	Functional - Outpatient pilot application	Major	Conference report has to be stored for any issued case conference	A conference report has to be stored for any issued case conference	*Check in the user interface the possibility of storing and displaying the conference report. After filling in the conference report, the outcomes of …*
REACTION-223	Functional - Inpatient pilot application	Major	Basic workflow for insulin treatment in Inpatient environment	*The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on …*	The basic workflow should be easily accessible in the REACTION Inpatient application
REACTION-224	Functional - Inpatient pilot application	Major	Basic workflow is repeated 4 times a day in inpatient environment	*The first workflow is in the morning a little before breakfast time (administration of bolus insulin), the second is at midday before lunch …*	These 4 loops should be easily identified in the Inpatient application
REACTION-226	Functional - Inpatient pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	*Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, …*	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.
REACTION-230	Functional - Inpatient pilot application	Major	Overall evaluation in Inpatient environment	*Supervision of glycaemia and according treatment is performed once a day. Adaptation of therapy or changes of medications have to be …*	Every day an evaluation report has to be stored and available in the Inpatient application
REACTION-234	Functional - Inpatient pilot application	Major	Determination of health status in Inpatient environment	*At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or …*	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.
REACTION-235	**Functional - Inpatient pilot application**	**Major**	**Therapy scheme in Inpatient environment registered immediately after the patient enrolment**	**The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status, nutrition, insulin resistance. Eventual additional data might be added during the course of the project.**	**The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.**

REACTION-240	**Functional - Inpatient pilot application**	**Trivial**	**Intravenous insulin**	**In rare cases, insulin can be delivered intravenously (common and mostly used way is subcutaneously). In this case the insulin reacts much faster and this way of delivery has to be registered in the fever chart.**	**The insulin administration shall allow also the IV way in the user interface**
REACTION-241	Functional - Inpatient pilot application	Major	Management of hypoglycaemic episodes in Inpatient environment	*The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose …*	*A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant …*
REACTION-242	Functional - Inpatient pilot application	Major	Management of hyperglycaemic episodes in Inpatient environment	*In case the blood glucose level is over a certain threshold a hyperglycaemic episode has occurred. The reasons for such episode have to be registered …*	*A specific procedure has to be present for the management of hyperglycaemic episodes. This procedure shall allow also the …*
REACTION-245	**Functional - Inpatient 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 checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.**	**Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.**
REACTION-247	Functional - Inpatient pilot application	Major	Mobile access point in wards of Inpatient environment	*Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be …*	*Web user interfaces have to be targeted on standard PC but also on mobile devices like tablet PCs. One specific type of mobile device for …*
REACTION-250	Functional - Inpatient pilot application	Major	Different contextualization of the patient clinical information	*Different modes of visualisation with different relevant parameters for decision support shall be foresee. The relevant data have to be displayed …*	The possibility of configure the display of the patient clinical data (mainly the fever chart) has to be present.
REACTION-258	Functional - Inpatient pilot application	Major	Automated transfer of patient related data from the hospital information system	*At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred …*	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.

REACTION-285	Functional - Inpatient pilot application	Major	User interface for the clinical data stored in the inpatient environment	The user interface shall allow the insertion, modification and visualization of the clinical data registered at the patient enrolment and of the clinical data acquired more frequently. The main data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight, therapy scheme, estimation of insulin resistance. Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, hypoglycaemia and hyperglycaemia. The possibility of adding further parameters at the enrolment or during daily acquisitions should be foreseen in the design.	There shall be a user interface which allows the insertion and the update of all the listed parameters.

6.9 Requirements of WP13 – Training

6.9.1 Architecture

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