Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

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Author(s)	F. Chiarugi (FORTH), A. Kouroubali (FORTH), V. Lagani (FORTH), H. Udsen (IN-JET), J. Thestrup (IN-JET), Fursse (CHC), M. Clarke (UBRUN), E. Kiss (ALL), S. Spat (MSG), K. Neubauer (MUG), T. Klotzbuecher (IMM), G. Vasilakis (FORTHNET), P. Rosengren (CNET), M. Enzmann (FHG-SIT), S. Schaller (BTS), J. Branebjerg (DELTA), I. Ramos (ATOS)
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Abstract	This document is a separate Appendix to deliverable D2-10 Final validation report of the REACTION platform, containing a complete list of requirements implemented in the final REACTION solutions.
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1 Appendix – List of Requirements

This Appendix contains a complete list of requirements that have been implemented in the final REACTION solutions. The list has been extracted from the JIRA Repository and ordered by Work Package and component.

1.1 Requirements of WP3 – Sensors Monitoring and Contextualisation

1.1.1 Data management

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

1.1.2 Health professional sphere

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

				insulin, Meal, Oral Glucose) **- Measurement data entry (Plasma Glucose)** **- Visualization of:** **- Plasma glucose** **- Plasma insulin** **- Applied rate of insulin** **- Confirm (update) inputs** **- Apply calculated or anter dose Insulin manually**	
REACTION-485	**Functional – REACTION platform**	**Major**	**GCS - Interface for online model optimization**	**2nd part of the third Component of the GCS - Interface for the further individualization of the GIM model based on past glucose measurements, allows:** **- Visualization of:** **- Plasma and interstitial glucose** **- Plasma and interstitial insulin** **- Values of optimized parameters** **- Values of penalty function components (met constraints)** **- Level of manual interaction to be defined**	**Matlab GUI as defined in rationale**

1.1.3 Medical and environmental devices

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

REACTION-180	Functional - REACTION platform	Major	Measurement of glucose should be specific and the glucose sensor should be able to monitor glucose in complex media	If the glucose monitoring is not specific, detection could be disturbed by other components of the ISF or the blood, influencing the accuracy of the sensor. For realisation of a closed-loop-system (glucose measurement + insulin dosage) a highly accurate sensor is required.	Sensor should exhibit a high accuracy even if other media are in contact with the sensor area.
REACTION-183	Functional - REACTION platform	Major	The sensitivity of the glucose sensor should be high, the SNR must be large and changes of glucose concentration in the range 1-15 mM must be detectable	For 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-204	Functional - REACTION platform	Critical	Wireless interfacing of other devices than ePatch	The ePatch is the preferred device and technology used to attached and connect sensors to the body. However, it should be possible that data from commercially available sensors not connected to the ePatch can be read by the REACTION platform.	Hardware fabricated.
REACTION-205	Functional - REACTION platform	Minor	Docking station for the ePatch	Charging of the reusable sensor in the ePatch	Hardware fabricated.
REACTION-206	Functional	Major	ePatch reusable sensor	The ePatch reusable sensor contains the optical and electrical sensor components, electronics, radio, antenna, and battery. Eventually the ePatch might be consisting of two components, one reusable, containing the optics and	Hardware fabricated.

				electronics, and one disposable, containing the optical cell and waste for the dialysis.	
REACTION-207	Functional	Major	ePatch communication	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.	The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the "black box").
REACTION-208	Functional	Major	ePatch adhesive base	The adhesive base forms the contact between the ePatch sensor and the skin surface of a human. Sensors measuring physiological data should be specified. First sensor is a bioelectronic sensor for ECG. Second sensor is an optical sensor for oxygen saturation and NIR spectroscopy.	ePatch can stick to the skin and sensor can measure physiologic data.
REACTION-209	Functional	Major	ePatch adhesive base has unique physical properties	The ePatch adhesive base contains 3 gel electrodes with impedance matched to the skin. The gel or part of the gel is optical transparent in the visible and NIR range of the electromagnetic spectrum.	ePatch can stick to the skin and optical or NIR sensor (if required) can measure physiologic data.
REACTION-210	Functional	Major	ePatch adhesive base has unique adhesive properties	The ePatch adhesive base contains at least two type of adhesive materials: 1) One with good skin adhesive properties 2) An adhesive gel or similar with electrical and optical properties matched to electrical and optical sensors.	Adhesive can stick to skin and sensors can measure.
REACTION-214	Functional - REACTION platform	Major	Activity parameters must be measured (e.g. pulse frequency, body temperature) by sensors	For input to the AGC algorithm to make prediction of glucose levels activity parameters are required. Which ones are	Activity parameter sensors must be integrated into the REACTION e-patch.

				still tbd but heart rate and body temperature should be included.	
REACTION-265	Functional - In-hospital pilot application	Major	Annotation of blood glucose values, especially in In-hospital environment	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.
REACTION-266	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-267	Functional - REACTION platform	Major	Type of sensor/signal should be specified	Type of sensor/signal, whether chemical, electrical, optical, etc. is important for integration in e-patch and sensor platform and for the possibility to build an online sensor.	Type of sensor specified by the sensor manufacturers.
REACTION-268	Functional - REACTION platform	Major	Accuracy/precision of sensors should be specified	For all types of sensors the accuracy/precision has to be known. In some sensors a high accuracy can be required, as, for example, for online monitoring of	The accuracy/precision should be specified by the sensor manufacturers.

				glucose where a high precision is required, especially in the hypoglycaemic regime.	
REACTION-269	Functional - REACTION platform	Major	Response time and drift of the sensors should be specified	Response time of the sensor is important for online monitoring and it may not be too long, drift could influence the accuracy and could require regular calibrations.	Response time and drift should be specified by the sensor manufacturers.
REACTION-270	Functional - REACTION platform	Major	Working range of sensors should be specified (linearity and detection limit)	The working range of the sensors should cover the required ranges as defined by the clinicians and ideally should be linear, the detection limit should be well below the minimal relevant measured variable.	Working range of the different sensors should be specified by the sensor manufacturers.
REACTION-271	Functional - REACTION platform	Major	Operating temperature of sensors should be specified and kept on equal level for the IR GM sensor reference and measuring channel	The temperature might influence the result of the measurement and its accuracy.	Either sensor manufacturers should specify the operating temperature of the sensors or the device should be able to adjust the measurement based on the temperature value (in this case a temperature sensor has to be integrated in the device)
REACTION-272	Functional - REACTION platform	Major	The calibration of the sensors should be specified (strategy, intervals, reference, algorithms)	The sensor must be calibrated before usage and might be re-calibrated after a certain time, also might the calibration required to be individual for a single patient.	Calibration routines of the sensors should be specified by the sensor manufacturers.
REACTION-273	Functional - REACTION platform	Major	The body interface of the sensors should be specified	The body interface of the sensors determines whether it is invasive or non-invasive, it probably influences the accuracy and operating time of the sensors.	The body interface should be specified by the sensor manufacturers.

REACTION-274	Functional - REACTION platform	Major	The sensor safety should follow the device directive 93/42/EEC and subsequent amending directives like the directive 2007/47/EC	The safety directive is essential for sensors being operated on patients. The off-the-shelf sensors/devices and the consortium-designed sensors/devices must comply with the device directives in force. In addition document history files among other quality assurance documents must be available to be submitted to the local authorities when conducting clinical trials.	Sensors should be designed in a way that the directive 93/42/EEC is fulfilled.
REACTION-280	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-472	Non-functional - Legal	Major	Device manual for clinical trials	For clinical trials a sensor device manual must be available.	Manual available for clinical trials.
REACTION-478	Functional - REACTION platform	Major	A portable sensor patch should have as reduced visibility as is technically feasible	The lower the visibility of such equipment the less the chance that an individual's condition might become apparent to others in situations where the patient does not wish this to happen. This is important in connection with issues of stigmatization - see task 9.2	Equipment should have as low a level of visibility as is technically possible.

1.1.4 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion

REACTION-49	Non-functional - Usability	Major	The touch/tablet/phone device must allow the execution of processes in the background	The applications developed for the portable devices should start and stop only when the user wants. If the portable device is a mobile phone when the user receives a phone call or SMS then the application should continue in the background without closing (preventing data loss). Therefore the portable devices should allow applications running in the background.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-126	Functional - REACTION platform	Major	Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake)	The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. The possibility to collect this information using the same portable device used for the BAN/PAN integration reduces the overall cost of the acquisition system improving the sustainability of the overall solution. The portable device could eventually be a part of the "black box".	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device
REACTION-128	Functional - REACTION platform	Major	Home gateway	The portable device should be able to act as home and mobile gateway. When connection to the public wireless network is not available at home, the portable device should be able to use a home gateway (PC) in order to send the acquired information. The home gateway should work only as gateway and not as a data collection device. The mobile gateway function has to be performed by the portable	Specific tests have to be performed when public wireless network is not available at home.

				device and not by a further hand-held device.	
REACTION-347	Functional - REACTION platform	Major	Storage of events for context of measurements	Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context for the acquired measurements. A suitable user interface has to be provided in order to facilitate patients performing this task (any data entry can be felt as too intrusive for patients). The possibility of integrating existing commercial log-devices used by the patients has to be considered.	There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint display of the acquired measurements and the relevant associated events (giving a context for the measurements)

1.1.5 Third party system interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-236	Functional - In-hospital pilot application	Major	Blood glucose measurements in In-hospital environment	PoC devices are currently used and will be used in In-hospital environment. The procedure is reliable and has been used since several years. Substitution of the used PoC devices with other devices (consortium sensors) in the daily practice can be done only after passing through a very severe procedure. This might not be foreseen (for the daily practice) in this project.	There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose sensors using a procedure which should be quite simple and user friendly.

1.2 Requirements of WP4 – Data Management and Service Orchestration

1.2.1 Application development kit (ADK)

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-42	Non-functional - Maintainability and portability	Major	The technical interfaces to the platform must be documented and in such a way that the stakeholders can 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-232	Functional - REACTION platform	Major	Continua Manager emulation	The integration of Continua devices requires a Continua Manager component as part of the architecture. In the absence of such a manager, the system should provide an emulation of the corresponding functionality.	A Continua Manager stub exists allowing simulated access to a Continua device.

1.2.2 Data management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-3	Functional - REACTION platform	Major	Support for IEEE 11073 medical device standards	To support a wide variety of medical devices, the selected subsets of the IEEE 11073 medical device standards should be supported. An architecture supporting standards will enable flexibility in adding new sensors (plug and play interoperable).	Show that REACTION device proxies can be developed for at least 2 different devices from different manufacturers.
REACTION-6	Functional - REACTION platform	Major	Any REACTION device should have an associated semantic model (description)	To facilitate device discovery and application development, a device ontology should be part of the architecture.	New devices can be matched against descriptions in the device ontology.
REACTION-11	Functional - Primary care pilot application	Major	Life style baseline data	The system needs to store a set of baseline data regarding life style for each patient.	Life style data can be retrieved and updated per patient

REACTION-14	Functional - REACTION platform	Major	Persistent local/global data storage	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).	At least global storage is supported.
REACTION-68	Functional - REACTION platform	Major	Component Versioning	In order to facilitate the software development cycle (especially the testing phase) all components and mainly the applications should contain the version number (e.g. in the about menu). In this way we should be able to reduce misunderstandings in setting up varios testing configurations at different partners' premises and minimize signalling of "false bugs".	The test facility will take into account also the version of components including in the feedback to the developers (test reports) also the version number of the various applications/components.
REACTION-75	Functional - REACTION platform	Major	Maintain and continuously update a patient health status profile	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)	Up-to-date data are available in the REACTION platform as a basis for higher level functionality
REACTION-76	Non-functional - Usability	Major	Portability	All components should have the capability of running at least under two of the most common operating systems (e.g. Linux and Windows 7 or XP)	Specific test has to be done on each component
REACTION-156	Functional - In-hospital pilot application	Major	The system should provide a regular backup of data	Inpatient pilot application offers data backup mechanism	Regular backup of data

REACTION-165	Functional - In-hospital pilot application	Major	Error Messages	Error messages for every component within the application have to be foreseen so that they are helpful for the end user.	Services and feedback to user.
REACTION-228	Functional - In-hospital pilot application	Major	Blood glucose measurements have to be contextualized (e.g. before/after meal)	The availability of the blood glucose measurements shall be accompanied also by the context of the measurements	Measurements before any usage have to be contextualized
REACTION-231	Functional - In-hospital pilot application	Major	End of process for the diabetic patient in the In-hospital environment	The workflows in the In-hospital glycaemic control management ends with the patient discharge from the department. However, there should be a transition of care (from secondary to primary or tertiary care) which should be considered in the discharge management.	At the patient discharge from the department, the workflow related to the patient has to be terminated
REACTION-284	Functional - In-hospital pilot application	Major	Clinical data to be stored in the In-hospital environment	The data management shall be design in order to allow the storage of the clinical data to be registered at the patient enrolment and other clinical parameters which have to be acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, comorbidities, therapy scheme. Other parameters have to be acquired more frequently: glucose level,	The data management shall allow the insertion and the update of all the listed clinical parameters.

				injected insulin, food intake/nutrition, estimation of insulin sensitivity and resistance. The possibility of adding further parameters should be foreseen in the design.	
REACTION-340	Functional - REACTION platform	Major	Storage of insulin administration	Insulin administrated to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable).
REACTION-348	Functional - REACTION platform	Major	High-level data fusion	Besides low-level data fusion on the client side a high-level data fusion should be available for the REACTION platform. The high-level data-fusion should provide the integration of external gathered information to the REACTION platform data structure and the fusion of REACTION-internal processed data.	High-level data fusion functionality will be available for the REACTION hosting server.
REACTION-351	Functional - Primary care pilot application	Major	Telemonitoring data should be visualized to patients and professionals in a flexible and performant way	GPs and nurses as well as patients and their carers use the telemonitoring data to get an impression of the patient status. So telemonitoring data needs to be visualized in a flexible way (aggregation level, combination of parameters ...) Data has to be handled in a way that this visualization can be generated on-demand with good performance.	Data can be visualized flexibly and with good performance to professionals
REACTION-371	Functional - REACTION platform	Critical	Use of activity patterns for context annotations	Context has to be expressed synthetically in some way. A possible and common option is through activity patterns (to be	Collect measurements about physical activity, environmental data, additional information and evaluate the activity

				specified for the two environments).	patterns verifying their correctness.
REACTION-372	Functional - REACTION platform	Major	Context of observations	The middleware of the REACTION platform should support context management for observed values.	The REACTION platform supports context management on the client side.
REACTION-374	Functional - Primary care pilot application	Major	Annual clinical checks	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies and data management.
REACTION-381	Functional - REACTION platform	Minor	Definition of a common ontology to refer to data, metadata, interfaces and models	A common ontology facilitates components integration and maintain a common language among the technical people and stakeholders.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
REACTION-396	Functional - Primary care pilot application	Major	Consider patient's preferences, wishes and decisions	The data set should allow documentation of patient's preferences, wishes and decisions. This information should also be considered in the evaluation of rules etc., so that no recommendations against the will of the patient are made.	Patient's preferences, wishes and decisions can be documented and rules consider this data.

REACTION-423	Non-functional - Operational	Major	Sensor quality parameters	The REACTION data management model should consider data storage for sensor quality parameters from devices reports like for example mis-calibration, or low battery. The parameters should be used for QoS.	Data fields for sensor quality parameters are available in the data management model.
REACTION-442	Functional - Primary care pilot application	Major	Management of complications	Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems).	Data management should include the necessary structures for assuring the storage of all necessary information for the management of complications.
REACTION-444	Functional - Primary care pilot application	Major	6-month clinical checks	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in ontologies and data management.
REACTION-455	Functional - REACTION platform	Major	REACTION data storage	The REACTION platform should provide a storage module (database). Data gathered within REACTION should be stored here, as well as relevant data from external sources. The REACTION data storage should also use security mechanisms to include/exclude patient data access.	The REACTION platform provides a persistence layer for data storage with emphasis on data security and data access.
REACTION-456	Functional - In-hospital pilot application	Major	Nutrition information has to be stored in the data management	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation (the use of glycaemic index and load	The data management shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of

				tables for various types of food might be taken into account). Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	insulin shall vary with the variation of the nutrition.
REACTION-459	Functional - In-hospital pilot application	Major	Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.
REACTION-460	Functional - REACTION platform	Major	Measurements of HbA1c	The risk of developing diabetic complications is strongly affected by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy in outpatient environment and at the patient enrolment in the inpatient environment (updates are decided by clinicians).	Specific fields have to be foreseen in data management.
REACTION-463	Functional - In-hospital pilot application	Major	Context management for clinical (lab) values.	Contextualization of measured values (e.g. blood glucose values) is important in order to support REACTION applications like decision support. For example pre- or post-meal glucose values have very different meanings for treatment. Therefore the data	The data management model support context management functionality for the inpatient prototype application.

				management model has to provide context management.	
REACTION-467	Functional - REACTION platform	Major	Semantics based data management	The monitoring and other data need to be properly annotated with ontological descriptions.	Relevant entries in the REACTION's databases are annotated with semantic concepts.

1.2.3 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
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-155	Functional - In-hospital pilot application	Major	The System should keep an electronic paperless data record of the data relevant for Glucose Management	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)	The inpatient pilot application stores data records/charts
REACTION-161	Functional - In-hospital pilot application	Major	The system should remind caregivers to perform measurements.	Measurements are required to allow the algorithm to function accurately and safely. A decision was taken not being too intrusive and providing only passive reminders (for the moment)	Reminder to perform measurements is available within the inpatient platform.
REACTION-219	Functional - In-hospital pilot application	Major	Safe Glycaemic Control (SGC)	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each

				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.	patient based on his medical history and actual state.
REACTION-227	Functional - In-hospital pilot application	Major	Initialization of the fever/sugar chart	Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be registered in the fever/sugar chart	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient
REACTION-229	Functional - In-hospital pilot application	Major	Decision on therapy in In-hospital environment	Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history and associated parameters. It might imply changes in the therapy scheme.	Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the administration of carbohydrates is necessary (hypoglycaemic episode).
REACTION-238	Functional - In-hospital pilot application	Major	Update and entering of drug administration (OAD and/or insulin) data	Drug administration (time, type, dosage and other relevant information) has to be immediately annotated by the administering nurse.	The nurse through an appropriate user interface can check the last drug administration and insert the relevant data related to the drug administration she has just performed.
REACTION-246	Functional - In-hospital pilot application	Major	Multi-user availability and display of the fever chart	The fever/sugar chart shall be considered as a central document and collects all the information about the 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-251	Functional - In-hospital pilot application	Major	Creation of electronic decision support rules shall be supported	An electronic decision support system with standardised instructions	Suggestions on treatments shall be available in order to facilitate the clinical decision.

				and decisions (e.g. evidence based medicine, support identification of "patients at risk") shall be present. There have to be "guidelines" on how to titrate insulin. An active alarm system would remind the staff to perform measurements/injections.	An available protocol from literature (e.g. RABBIT II trial) should be implemented and improved. Alerts for next insulin administration should be provided together with a support for calculation of insulin amount depending on known (acquired or estimated/evaluated) parameters.
REACTION-328	Functional - Primary care pilot application	Major	Ability to manage alerts to the user as clinician	The clinician should be able to set/edit and remove alert parameters around the patients physiological data, for instance if the physiological value is above limits or data is missing or if there are any technical /communication problems. The system shall have an acceptance bandwidth; the data which is not within this defined bandwidth shall be recognized and the clinician shall be notified of them.	The functionality shall be evaluated with test plan.
REACTION-355	Functional - REACTION platform	Major	Computer interpretable guidelines	Evidence based guidelines as important constituents of the knowledge base must be encoded in a computer-interpretable way for decision support.	Guidelines are encoded.
REACTION-367	Functional - Primary care pilot application	Major	Insertion of baseline physiological measurements at the first visit	At the first visit, baseline physiological measurements (the exact set has to be clearly defined) have to be inserted in the platform.	The data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrollment).
REACTION-375	Functional - In-hospital pilot application	Major	Therapy scheme in In-hospital environment	Decision on therapy has to be performed immediately after performing any measurements based also on patient history and associated parameters. It might imply changes in the therapy scheme.	The pharmaceutical and non-pharmaceutical treatment (or therapy scheme) has to be stored in the data management and can be modified during any clinical evaluation of the patient. It has to be initialized immediately after the patient

					enrolment.
REACTION-386	**Functional - REACTION platform**	**Minor**	**Medical knowledge base**	**Contains the relevant medical knowledge or is able to connect to external sources, e.g. evidences, diabetes guidelines etc.**	**A medical knowledge base is built.**
REACTION-388	**Functional - In-hospital pilot application**	**Major**	**Insulin sensitivity and insulin resistance**	**Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be directly measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.). Glucose control algorithm and physiology models should use these two parameters.**	**The data management has to allow for the insertion and subsequent modifications of these values by clinicians.**
REACTION-391	**Constraint**	**Major**	**Data fields for the In-hospital glucose control prototype (eDSS).**	**Following data fields should be provided: - administrative data (patient name, address, PID, ward, hospital bed, physician(s) in charge, nurse(s) in charge)** **- demographic data** **(age, sex, date of birth)** **- medical history** **(type of diabetes, medication, comorbitities, former complications, pre-existing conditions)** **- anamnesis data** **(fever, infections, diarrhea,**	**Required data fields will be provided by data structure.**

				vomiting, hypo-hyperglycemia) - lab data	
REACTION-399	Functional - Primary care pilot application	Major	Ongoing management	Ongoing management follows investigative stage. This stage is used to: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, support changes in patient lifestyle, identify better diabetes management for patients.	Specific fields have to be present in ontologies and data management
REACTION-402	Functional - In-hospital pilot application	Major	Measurements of blood glucose and insulin injections in In-hospital environment	In In-hospital environment, the blood glucose level measurements are, in most cases, performed by nurses with treatment performed by clinicians and/or nurses.	Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.
REACTION-408	Functional - REACTION platform	Major	Non-pharmacological and/or pharmacological treatment	Non-pharmacological (diet, lifestyle, education) and pharmacological (OAD, insulin and interfering drugs) treatments have to be assigned to each patient and can be modifed at each check.	In the ontologies and data management there should be the possibility of registering the different types of treatment for each patient and of modifying them at each check.
REACTION-426	Functional - REACTION platform	Major	Comorbidities have to be registered	Co-morbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient.	In the design of data management and ontologies the possibility of registering the co-morbidities with a basic set of attributes has to be guaranteed. Co--morbidities with their attributes have to be registered at the patient enrolment and at each subsequent visit or evaluation when new co-morbidities take place.
REACTION-428	Functional - In-hospital pilot application	Major	Drug administration data (OAD and/or insulin)	Drug administration (time, insulin type, administration type -IV or SC-, dosage and	Data on drugs administered have to be stored in the data management where they can

				other relevant information) has to be immediately registered in the data management by the administering nurse.	be also retrieved as part of the fever/sugar chart.
REACTION-432	Functional - In-hospital pilot application	Major	Special examinations/treatments to be registered in fever chart	For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Iin such cases treatment must therefore be adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). However a problem may arise if the patient has to wait longer than expected due to unforseen delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). The dose of insulin and/or OADs will therefore need to be adapted, the patient receives some food in the event of hypoglycaemia and receives insulin by injection in the event of hyperglycaemia.	These events (special examination/treatments) have to be registered in the data management where they can be retrieved for the composition of the fever/sugar chart.
REACTION-433	Functional - REACTION platform	Major	Results of screening, symptoms and types of diabetes or hyperglycaemia	At the diabetic patient enrolment his/her symptoms or results of screening confirming presence of diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the	Possible classifcations should be present in the knowledge base & ontology and in the database fields for multiple selections from the classifications. Does the data need to be stored at each subsequent visit or evaluation?

				HIS/EPR).	
REACTION-435	Functional - Primary care pilot application	Major	Outcomes of regular visits at primary healthcare centres	Outcomes of monitoring should be recorded in the Clinical Portal.	Outcomes of the monitoring will be stored in a notes section on the clinical portal. This notes section should be able to be exported in order to attach to the EPR via a hyperlink. The outcomes of each visit have to be stored as much as possible in a structured way.
REACTION-449	Functional - Primary care pilot application	Major	Personalized care plan	A copy of the patients diabetes care plan will be entered onto the clinical portal (manually). This can be viewed by the patient on the patient portal. The care plan is based on a validated care plan used within primary care to aid the management of patients with Diabetes and is part of the current workflow to be incorporated into Reaction as per the clinical requirments.	The care plan can be updated by the clinician within the clinical portal.
REACTION-462	Functional - In-hospital pilot application	Major	Interface for user inputs from portable computer in order to store data in In-hospital data storage	For the In-hospital prototype user input should be possible. The user data should be stored in the data storage.	User input can be stored in the In-hospital prototype storage for further processing.
REACTION-465	Functional - In-hospital pilot application	Major	Clinical evaluation report	Supervision of glycaemia and associated treatment is performed once a day. The clinical evaluation report has to be produced daily. Adaptation of therapy or changes of medications has to be evaluated including by consultation with the duty-physician.	A daily clinical evaluation report has to be stored and available in the Inpatient application.
REACTION-466	Functional - In-hospital pilot application	Major	(Web) Service to present decision support for glucose control to clinicians	After processing of data by the glucose prediction algorithm, the results should	A service will be available to support physician with glucose control of patients.

				be presented by the system to the physician. The physician can use the result for decision support. The service uses data stored in the data storage and user additional user input as input for processing.	
REACTION-468	Functional - REACTION platform	Major	Provide regular update of data model for Health Care profil	Most application depends on current clinical data (e.g. blood glucose). A mechanism for regular data updates should be provided.	The Data Model for REACTION should provide a regular update mechanism for personal health care profiles.

1.2.4 Internal communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-24	Non-functional - Maintainability and portability	Critical	Logging of events from components	All software components shall keep a detailed activity log, which will support the tracing and debugging of possible functioning errors, security holes, mis-configurations and other implementation issues.	A log file will be available for each component, containing data which will be defined by the design process.
REACTION-32	Functional - REACTION platform	Major	The architecture should support the Continua WAN interface (WAN-IF)	Need to support Continua	The REACTION system implements at minimum the IHE PCD01 format
REACTION-66	Functional - REACTION platform	Major	Component Interface	Interoperability among components should be guaranteed by the use of standard interfaces.	The test facility will be based on the implemented standard
REACTION-345	Functional - REACTION platform	Major	Two-way communication between REACTION server and client	There is a need for two-way communication between server and client e.g.for remote configuration of the end-user application running in the AHD. The data fusion engine also needs to be configured based on which values the clinician wants to observe. There is also a need for 2-way communication from the point of view of error handling. If the observed	Two way communication between Client and Server will be available for the REACTION platform in order to perform: e.g. data fusion configuration, error-handling, data security (consent management).

				values suddenly appear out-of-range it might be necessary to check with the client if this is an error state. Other devices/sensors, e.g.the Continua-devices, might also require different types of communication. **It might be necessary to reverse a patient's consent that had to be given 'remotely', e.g. at the doctor's surgery, because the hosting client at the patient's home is simply a 'box' with no display or input capabilities. In this restricted 'boxed case', it would be hard to change the patient's privacy settings, once they are initially configured, if we were unable to push data back to the box.**	
REACTION-365	**Functional - Primary care pilot application**	**Critical**	**Data should be stored in proper way in order to be easily transmitted over mobile networks in case that broadband network is not available.**	**In the event that the hosting client is not connected through a broadband connection, the patient will be able to upload data using GPRS / 3G data networks. In this case we need to examine possible limitations.**	**Functional test uploading data over slow mobile networks.**
REACTION-448	**Functional - REACTION platform**	**Major**	**Alert / notification messages should be short enough in order to be delivered as SMS messages if necessary**	**User's terminal mobile device will likely be used as a GSM mobile phone. Considering the advantages of Short Message Service (fast delivery, provides an alternative data path when an Internet connection is not available etc) the time critical messages for the patients should be able to be forwarded as SMS**	**functional tests when user is away from broadband connection.**

				messages.	
REACTION-451	Functional - REACTION platform	Major	In-hospital prototype communication with REACTION platform	The current design of the In-hospital prototype and the Primary care prototype does not consider the communication between these two prototypes (e.g. SOA). An internal deliverable will be presented discussing alternatives of communication between the two systems.	A internal deliverable with communication and data transfer concepts between In-hospital and Primary care prototypes will be available.
REACTION-453	Functional - REACTION platform	Major	Communication interface between REACTION Client and REACTION Server	A communication standard between REACTION client and server should be established (e.g. IHE-PCD01) in order to transport data from client to server side (and vice versa).	Communication interface between REACTION Client and REACTION Server will be available.
REACTION-454	Functional - REACTION platform	Major	Content formatter	A formatter for converting the acquired data to useful information for the patient shall be available.	Use a standard format or a verification mechanism.

1.2.5 Medical and environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-237	Functional - In-hospital pilot application	Major	Annotation of blood glucose values, especially in In-hospital environment	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.

				available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.	
REACTION-334	Functional - Primary care pilot application	Major	Devices should be able to operate anywhere in the home	To make a system that is ubiquitous and fits patient lifestyle	Device specification
REACTION-401	Non-functional - Operational	Critical	Device specialization - A list of devices to be provided	Based on the necessary information to be monitored from the patient, a complete list of IEEE 11073 device specialization has to be completed. Measurements which cannot be collected using IEEE 11073 device specialization are also to be mentioned in this list. The complexity of the IEEE 20601 manager also depends on the number of device specializations to be managed.	For each device the supported standard has to be specified (or the company documentation).

1.2.6 Network management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-18	Functional	Major	Monitoring devices must be discoverable by existing network infrastructure	Device must be discovered in order to be able to communicate with other devices and platforms.	At least to automatically discover devices using protocols supported in the Hydra middleware such as BT, ZigBee etc.
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-134	Non-functional - Performance	Major	Any interface between an end-user and the platform shall have a reasonable maximum response time in condition of public network optimally working	Response time should be quick enough except for reasons independent from the technical design of the platform	The platform when the public network is perfectly working at the max speed shall respond in less than 5 sec in 90% of functions activated by the user

					interface. No response shall take longer than 10 sec.
REACTION-358	Functional - REACTION platform	Major	Network manager for hosting client	TODO (Peter Rosengren) incl. security mechanism ("the Network Manager would be configured to encrypt the data") "The LinkSmart Network Manager has two roles, it takes care of the P2P between different nodes. It also keeps a list of LinkSmart Identifiers for different devices/services and there local endpoints. In this way it "virtualizes" devices, services, and applications behind identifiers."	TODO (Peter Rosengren)
REACTION-439	Functional - REACTION platform	Major	Information should be cashed in local storage to prevent loss in case of a node or communication failure.	In case of network error the client application should be able to store temporary data. This will a) allow user to continue the process later and b) prevent corrupted / incomplete data to be uploaded to the main server.	The functional test should include specific tests in order to ensure that there is no data loss in case of network failure.

1.2.7 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-12	Functional	Major	Automatic update on lifestyle data	Automatic update of lifestyle data based on sensors such as pedometers but also retrieval from health and lifestyle services and databases.	At least one external service is supported.
REACTION-338	Non-functional - Security	Critical	All data entered must be checked for format, consistency and validity	Unintended user actions should not harm data integrity and the overall functioning of the platform.	The functional test should include specific tests in order to verify such circumstances.

				In case of doubt, the user must be warned and asked how to proceed. The user must be able to correct mistakes easily.	
REACTION-342	Functional - REACTION platform	Major	Low-level data fusion	The REACTION platform should support low-level data fusion in order to interpret measurements occurring in PAN. The Data Fusion needs to take place close to the patient/user.	Low-level data fusion will be available for the REACTION platform (middleware).
REACTION-344	Non-functional - Look and feel	Major	Display of acquired measurements (values, time, context (if available))	Provide immediate and consistent (if possible also contextualized) information to the patient.	The user interface on the mobile device shall have this functionality.
REACTION-349	Non-functional - Usability	Major	Patient questionnaires (lifestyle, physio-psychological conditiond, checking medication compliance, adherence to clinical pathways, education, self management)	Questionnaire for patients in order to collect qualitative (or quantitative but not directly measurable) information related to the parameters to be monitored has to be available. They are part of the monitoring (using a frequency set) administered by the responsible clinician.	The mobile device shall have user interfaces allowing completion of these questionnaires.

1.2.8 Security and safety

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-93	Non-functional - Security	Major	Confidentiality: Sensitive information must not be readable by unauthorised persons	Various stakeholders exchange information over the REACTION platform which, without any safeguards, would allow third parties to learn sensitive information of patients	Availability of a mechanism for ensuring data confidentiality
REACTION-376	Non-functional - Security	Critical	Integrity check for the stored data	To guarantee the integrity of the stored data in the case of an unwanted happening.	Use of adequate methods like e.g. Hash keys or redundancy codes for the data stored.

REACTION-387	Functional - REACTION platform	Critical	Information related to informed consent stored in the platform	An ethical approved declaration of informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION platform.	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the signed paper This procedure shall be completed before any other operation can be performed.

1.2.9 Service orchestration

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-9	Functional	Major	Formalized feedback model	A model describing which parameters to be collected, the frequency of collection, and target users of the data	System is able to provide feedback in satisfactory time
REACTION-17	Functional	Major	Configurable data transfer frequency	Possibility to configure the periodical transfer of the collected sensor data to external services such as WAN devices.	Lowest periodical transfer is once per day.
REACTION-70	Functional - REACTION platform	Blocker	Processing of multi-parametric clinical and non-clinical data from different sources	The individualized health status profile is the initial point to support management of the disease and predict the risk 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	Platform flexibly supports processing of data from multiple sources

				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.**	
REACTION-136	**Non-functional - Performance**	**Major**	**The platform shall cater for 20 simultaneous users in the field trials. In the end product this number is expected to grow to 100.**	**A maximum number of simultaneous users has to be fixed. These numbers are very reasonable considering the number of potential end-users at the field trial sites and also considering the initial expectations as product on the market.**	**The platform will be tested with the max number of simultaneous users verifying that the response time for the most common operations are satisfactory**
REACTION-202	**Functional - Primary care pilot application**	**Major**	**Set up remote patient monitoring scheme**	**At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)**	**An enrolled patient can be assigned to a configurable RPM scheme**
REACTION-213	**Functional - Primary care pilot application**	**Major**	**Outcomes of the clinical case conference shall be social intervention (changes in non-pharmacological treatment and education) and therapeutic intervention (changes in therapy)**	**The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed**	**The system shall allow at the end of any clinical case conference the insertion of changes in the non-pharmacological and pharmacological treatment**
REACTION-217	**Functional - Primary care pilot application**	**Major**	**Acquired values in the alarm range**	**When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be**	**Check the overall procedure in case of acquired measurements in the alarm range.**

				sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed	
REACTION-380	Functional - REACTION platform	Major	Set of alerts and reminders	A set of possible alerts and reminders. These can be thought as "prototypes". Action rules can define when and how they must be sent with which parameters.	Alerts and reminders can be defined and stored.
REACTION-404	Functional - REACTION platform	Major	Service Orchestration Manager	It should be possible to express execution of a set of services in combinations and sequences	Sercice orchestrations can be defined and stored
REACTION-419	Functional - REACTION platform	Major	Set of event rules	Event rules define the criterions of different events. Events are detected based on these rules. Personalization is possible through the use of individual thresholds and other parameters.	Event rules can be defined and stored.
REACTION-425	Functional - REACTION platform	Major	Set of action rules	Action rules define what should be done if an event occurs, e.g. who should be notified and how.	Action rules can be defined and stored.
REACTION-441	Functional - In-hospital pilot application	Major	Basic workflow in In-hospital environment	The basic workflow is based on measurement of blood glucose and evaluation of the necessary insulin (bolus or basal), based also on additional parameters and insulin administration.	There should be the possibility of acquiring, storing and retrieving all the information generated during any basic workflow performed during any time of the day/night.

1.2.10 Third party system interface

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-336	Functional - REACTION platform	Major	HIS interfaces for patient demographic data - Patient enrolment (or recruitment)	When an interoperable HIS or EPR is present in the managing organization, the patient data at the patient enrolment should be	When an interoperable HIS/EPR is present, a new diabetic patient cannot be created in the REACTION platform if not present in

				obtained from the HIS or EPR through interoperable user interfaces.	the HIS/EPR. When a diabetic patient is created, his/her data have to be taken from the HIS/EPR.
REACTION-352	Non-functional - Maintainability and portability	Major	Scalable / easy to use solution for REACTION software in GP surgery	The REACTION software which is executed in the GP surgery has to be usable for practices in different setting with different EPR systems. It should provide a user interface for disease management as well as Web Services which can be implemented by EPR manufacturers to easily integrate REACTION features into their products.	REACTION software is easy to run beside an EHR application or EHR manufacturer is satisfied with ease of integration of REACTION
REACTION-361	Functional - REACTION platform	Major	Baseline and clinical history handled in the data management	Immediately after patient recruitment, his/her baseline and clinical history has to be entered in the platform. This can be done by extracting this information from the HIS/EPR (if available and interoperable) and completing manually (through a proper UI) the missing information.	The data management should allow the storage of baseline and clinical history and these data can be extracted from the HIS/EPR (if available and interoperable).
REACTION-362	Functional - In-hospital pilot application	Major	Interface to patient demographic register	In order to import demographic data from the patient demographic register has to be imported from the HIS. A standardized interface e.g. HL7 has to be used for data interchange. Required data fields are: - unique PID - name	Standardized interface (HL7) to patient demographic register is available for the In-hospital pilot application

				- age (data of birth) - sex - address	
REACTION-363	Functional - In-hospital pilot application	Major	Interface to Hospital Information System for clinical data import/export	In order to exchange clinical data between In-hospital pilot application and Hospital information System (HIS) an interface based on HL7 has to be provided.	Standardized Interface (HL7) to HIS / EPR to exchange clinical data.
REACTION-395	Constraint - End-User Workplace Environment	Major	A REACTION application needs to be executed in the patient surgery independent from the EPR	As it is not possible to influence/ modify many EPR systems, REACTION features inside the GP surgery have to be provided by a dedicated and independent application. This application communicates with - the REACTION platform over the Internet. - other systems in the surgery (EPR, lab, etc.) This application can be server-based and always on, for a prototype also an application client could be used.	An easy to run possibility to run and access REACTION features inside the GP surgery is available.
REACTION-413	Functional - REACTION platform	Major	Connection with external services like MS HealthVault	External interfaces to services of MS HealthVault should be taken into account in the REACTION platform.	Interfaces to MS HealthVault will be available.

1.3 Requirements of WP5 – Network Management and Service Execution

1.3.1 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion

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

1.3.2 Internal communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-1	Functional - Primary care pilot application	Major	Internet communication between patient home and primary/secondary healthcare structures based on public wired or wireless network	A basic communication infrastructure has to be assumed	Tests will be based on this assumption
REACTION-83	Functional - REACTION platform	Major	Interface to clinical data from "near" real-time observations for decision support	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in primary care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)	Data will be available shortly after measurement in the REACTION database
REACTION-88	Functional - Primary care pilot application	Major	Define the provided input for SMS communication	Define the attributes of the provided input for the instant communication method (on SMS).	None

1.3.3 Medical and environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-79	Constraint - Off-the-Shelf Sensors & Devices	Major	Off-the-Shelf Devices	Non standard communication protocols imply a significant development effort. Such development effort can be	The commercial devices not developed by the consortium have to be compliant with relevant communication standard

				very huge and very often also not feasible if non standard protocol is non disclosed.	or, only in special cases, have a full-disclosed protocol
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	Home gateway should be easily extendable in order to receive data from environmental sensors	The home gateway should be able to receive and transmit data from environmental sensors, provided as an update of the REACTION platform	BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium devices/sensors and by off-the-shelf devices used in the platform

1.3.4 Network management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-25	Functional - REACTION platform	Critical	Fault tolerance to network malfunctioning	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.
REACTION-54	Functional	Major	Network & system monitoring	Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements using SNMP and Netflow Records for network monitoring, in	none

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

1.3.5 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-34	Functional - Primary care pilot application	Major	Define "black box" to be used in primary care environment	Define the hardware to be used in primary care environment for acquiring and transmitting sensor data to the REACTION	None

				middleware (use a mobile device or a "home-pc").	
REACTION-53	Non-functional - Usability	Major	*The portable touch device must have at least the following connectivity options: WiFi (802.11g or 802.11n), Bluetooth, USB; *Also it must have built in at least the following sensors: GPS, accelerometer; *If mobile phone it must support 3G networks.	The device must support the latest and most widespread communication protocols. The presence of specialized sensors like the accelerometer, and the GPS will improve the usability of the device, and will allow the collection of additionally useful information.	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
REACTION-127	Functional - REACTION platform	Major	Home gateway	The portable device should be able to act as home and mobile gateway. When connection to the public wireless network is not available at home, the portable device should be able to use a home gateway (PC) in order to send the acquired information. The home gateway should work only as gateway and not as a data collection device. The mobile gateway function has to be performed by the portable device and not by a further hand-held device.	Specific tests have to be performed when public wireless network is not available at home.
REACTION-168	Functional - Primary care pilot application	Major	Remote Patient Monitoring (RPM)	RPM has to be used in the Primary care Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.	RPM module has to be present in the Primary care field trials

1.3.6 Security and safety

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion

REACTION-94	Non-functional - Security	Major	Availability: Patient data and other resources must be available to ensure proper treatment	Non-availability of patient data will hamper further treatment and might even impair the patient's health	REACTION platform should remain operational in case of failures

1.4 Requirements of WP6 – Integrative Risk Assessment and Feedback

1.4.1 Data management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-73	Functional - Primary care pilot application	Major	Short-term risk management (primary care)	Identification of short-term risks would help to optimize the patient's management and to prevent the development or deterioration of complications.	A module is available for the identification of short-term risks (based on pattern management).
REACTION-255	Functional - In-hospital pilot application	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-337	Functional - In-hospital pilot application	Minor	Management of missing data	Mandatory fields have to be filled otherwise the user cannot go on the workflow of the inpatient prototype.	A health status model is present.
REACTION-392	Functional - Primary care pilot application	Major	Personal Health Status Profiles	Personal Health Status Profile for each patient must be generated, stored and regularly updated. It serves as an input for risk assessment and disease management.	Personal Health Status Profiles can be generated.

1.4.2 Health professional sphere

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

				should provide an electronic decision support system (eDSS) to suggest insulin dosing	
REACTION-81	Functional - Primary care pilot application	Major	Long-term risk calculation and health professional-oriented presentation	Calculate long-term risk based on patient health profile and visualize in a health professional-oriented form. The long-term risk calculator mainly will be used in the outpatient/primary care area as input for decision support	The REACTION platform offers a service to calculate diabetes dependent long-term risks
REACTION-86	Functional - In-hospital pilot application	Major	Visualization individual patient data to support glucose control (decision support)	For the REACTION project data mining methods and heuristic algorithms should be used in order to identify: - risk profiles for short- and medium-term risk based on stratification of population health data in large populations - successful therapy strategies for different patient groups to be used as input for decision support	Health risk profiles (short- and medium-term) are available for risk profiling, and knowledge discovery within the data sets can be conducted. Based on a score for "therapy success" more successful therapies can be identified for different patient groups.
REACTION-98	Functional - Primary care pilot application	Minor	Support identification of "patients at risk" for developing diabetes in primary care	Support identification of "patients at risk" for developing diabetes. The risk management component shall be able to evaluate this kind of risk.	The platform provides a component to calculate the risk of diabetes.
REACTION-184	Functional - Primary care pilot application	Major	Risk values for HbA1c	Maintaining glycated haemoglobin (HbA1c) below 7.5% is likely to minimize risk of developing diabetic complications. If there is evidence of increased arterial disease risk (raised albumin excretion rate, features of metabolic syndrome or other arterial risk factors),	Thresholds have to be foreseen in the risk assessment module and advices have to be sent to patients.

				HbA1c should be maintained under 6.5% or even less.	
REACTION-193	Functional - Primary care pilot application	Major	Alarm & alert generation	The alerts and alarms should not be generated too often in such a way the system will be considered too intrusive for the patient himself. However serious and especially life-threatening situations have to be promptly signalled. ROC analysis might be used in order to tune the alarm and alert system.	Some serious or life-threatening situations can be simulated in the integration environment and the production of adequate alarms can be verified.
REACTION-409	Functional - Primary care pilot application	Major	Risk assessment models and rules	Models and rules must be defined to determine personal risks.	Models and rules for risk assessment are present.
REACTION-421	Functional - REACTION platform	Major	Models and rules for insulin dose prediction (In-hospital)	Calculation rules and/or algorithm must be stored for insulin dosing support based on clinical protocols.	Necessary models and rules are defined and stored.

1.4.3 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-78	Functional - REACTION platform	Major	Mechanistic physiology-based models of insulin and glucose kinetics	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment 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)

1.4.4 Third party system interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion

REACTION-346	Functional - REACTION platform	Major	Knowledge Discovery from unstructured clinical text information	In order to use unstructured text information for decision support or diabetes management the information has be pre-processed. NLP-technologies to find relevant information for REACTION applications from these textual bases can be a useful tool.	REACTION provides a knowledge discovery module to process unstructured information and store this information in the data storage for further processing.

1.5 Requirements of WP7 – Security, Privacy and Safety

1.5.1 Data management

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

1.5.2 Security and safety

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-45	Non-functional - Security	Critical	Protection against threats	Medical data are sensible data and protection against threats and and unauthorized access should be provided. The system must protect against: *Unauthorized persons obtaining manager rights through the internet (hacking). *Unauthorized persons getting access to personal data. *The system must conform to Law on Handling of Personal Data.	The functional test should include specific tests in order to verify such circumstances

REACTION-63	Functional - REACTION platform	Major	Security and privacy related to patient data	Privacy concerns are of utmost importance. The patient data should be transfer and maintained in a secure way while any access to them should be monitored and logged (getting advantage of a login mechanism available in the applications).	Verify that any access to patient data is logged and is performed in a secure way
REACTION-90	Non-functional - Security	Major	Identifiability: Recipients and senders of information must be identifiable, though not necessarily personally identifiable	Reports/measurements must be assignable to the 'right' patient file/device	Recipients and senders must have unique identifiers
REACTION-91	Non-functional - Security	Major	Authenticity: Processors of information should be able to determine whether the data being processed is authentic	Medical personnel should know if information relating to their patient originates from a known/trusted source, e.g., the patient's blood glucose sensor or medical personnel, in order to assess the data's quality	Availability of a mechanism that allows to verify the authenticity of some information
REACTION-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 made the decision, what kind of decision was made, and when was it made	Availability of a procedure or mechanism allowing to review relevant actions of stakeholders
REACTION-99	Non-functional - Security	Major	Authorisation: Stakeholders must be authorised before they are allowed to perform relevant actions	Certain actions are not permitted for everybody but may only be carried out by authorised personnel	Availability of a procedure or mechanism allowing to authorise relevant actions

REACTION-100	Non-functional - Security	Major	Access control: Access to sensitive information should only by given to authorised personnel	Sharing patient data is necessary in health care to treat patients but access should only be given to persons involved in the treatment	Availability of a mechanism allowing to control access to sensitive data
REACTION-104	Non-functional - Security	Major	Need-to-know Basis: Stakeholders processing information should only learn what is necessary to carry out their specific task	In an information processing chain, several stakeholders might be involved but it might not be necessary for every stakeholder to know which exact data another stakeholder has processed	Process design takes into account the need-to-know principle
REACTION-109	Non-functional - Performance	Major	Scalability: the security must not materially impact the performance of the system	the security resources have to scale well with the overall architecture	Security does not significantly impact overall latency of the system
REACTION-114	Non-functional - Maintainability and portability	Major	Modularity: the system has to be divided into components	It is easier to implement, exchange, and integrate the modules.	REACTION platform should be modular
REACTION-115	Non-functional - Usability	Major	Transparency: Security configuration should be hidden from the user as far as possible	Users usually do not have the expertise to choose the 'right' security options.	No, or as few as possible, additional user interactions for security.
REACTION-116	Non-functional - Maintainability and portability	Major	Availability of security mechanisms to manage sensitive data	In REACTION, we are dealing with sensitive data, thus security must be available on all platforms.	Security mechanisms are available for all target platforms of REACTION.
REACTION-118	Non-functional - Legal	Major	Assurance: the architecture and its implementation must provide assurance that it delivers the security and compliance properties it promises	If allegedly secure functions do not live up to their expected functionality, the whole platform could be compromised.	Successful review of expected security functionality.
REACTION-197	Functional - Primary care pilot application	Major	Care spaces in the primary care environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be	Each member of the care space will have specific roles and tasks in the patient's care.

				provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).	
REACTION-323	Functional - Primary care pilot application	Major	Providing a complete audit trail for each user's data and action taken on the system	There must be a complete audit trail of all actions taken in the system by any user. No user shall have the permission to permanently delete data from the system. This refers to the system logging and all actions taken by different users. The system shall also provide traceability of each action to the user taken those actions.	The system shall foresee the possibility of traceability for each action which has been taken in the system by the user.
REACTION-339	Non-functional - Security	Major	Communication between the Reaction Device Hosting Server and the patient's/GP's web browser MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the Reaction Device Hosting Server to the patient's/GP's web browser and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
REACTION-341	Non-functional - Security	Major	Roles MUST be defined for stakeholders of the Reaction platform, e.g., doctor, nurse, patient, informal carer, administrative personnel etc.	Each person in the Reaction platform has the right to perform a certain set of actions. In order to simplify the administration of these rights, each person is assigned to a role and roles are assigned to permissible actions. The	Roles are defined for every actor from the Reaction use cases.

				advantage of this approach is that it is easier to manage the rights of a role than managing individual rights for each person.	
REACTION-343	Non-functional - Security	Major	Every person represented in the Reaction platform MUST be assigned to one or more roles.	In order to interact with the Reaction platform, persons need certain rights. As rights are associated with roles, persons MUST have at least one role to interact with the Reaction platform.	Each person is assigned to at least one role.
REACTION-354	Non-functional - Security	Major	Data/messages exchanged between the Reaction Host Client and the Reaction Device Hosting Server MUST be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the Reaction Host Client and the Reaction Device Hosting Server must be ensured even _after_ the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
REACTION-382	Non-functional - Security	Critical	Privacy enhancing technology	Protect the privacy of users personally identifiable information (PII) and further more personal data.	It must not be possible for any third party to determine the relation between a measurement and the measured patient's real world identity.
REACTION-385	Non-functional - Security	Major	Digital identities for the Reaction platform MUST only be issued or revoked by trusted (third) parties, e.g., a certification authority (CA).	Without a trusted party (TP), anyone could produce its own digital identity and someone relying on such an identity would have to trust that the claimed identity is genuine. By incorporating a TP, relying parties trust that the TP ensures that its issued digital identities are genuine. This makes life easier for relying parties as	Availability of a party which is trusted to orderly issue and revoke digital identities.

				they only have to establish a single trust relationship (with the TP) as opposed to having a multitude of trust relationships with others. The same goes for parties that had been excluded from the Reaction platform, as each relying party would have to determine by itself if another party is still part of the Reaction platform or not. In case of a trusted party, the relying part could simply query the TP if some identity is still valid or had been revoked, e.g., because its owner left the platform.	
REACTION-400	Non-functional - Security	Major	Data/messages exchanged between the Reaction Device Hosting Server and the EPR/EHR System SHOULD be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the Reaction Device Hosting Server and the EPR/EHR System must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
REACTION-403	Non-functional - Security	Major	Each entity in the Reaction platform MUST be representable by a digital identity.	In the Reaction platform, entities must be uniquely identifiable and recognisable in order to allow repeated communication, referrals, accountability of actions, exclusion of ill-behaving entities, etc.	Availability of a digital identity mechanism.
REACTION-412	Non-functional - Legal	Major	It MUST be possible to revoke a consent - data already stored MUST NOT	A patient must have the option to decide whether personal data is processed	Availability of mechanisms and procedures to enable consent revocation.

			be processed any further.	or not at any time. If the patient once gave her consent it must still be possible for the patient to revoke her consent, which means that any further processing of the affected data is forbidden. Also, if a patient revoked her consent the existing data may not necessarily be deleted, however, it MUST be excluded from any further processing.	
REACTION-414	Non-functional - Security	Major	Communication between the Reaction Hosting Client and the Reaction Device Hosting Server MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the Reaction Hosting Client to the Reaction Device Hosting Server and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
REACTION-415	Non-functional - Security	Major	Each person MAY only perform actions permitted by her role.	Before a requested action is performed, a control mechanism has to check whether the requested action is part of the requester's set of permissible actions according to its role.	Availability of a control mechanism which decides whether a requested action may be granted or denied according to the requester's role.
REACTION-431	Non-functional - Security	Major	Data/messages exchanged between the Reaction Device Hosting Server and the GP EPR SHOULD be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the Reaction Device Hosting Server and the GP EPR must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this,	Availability of mechanisms to provide data authenticity, integrity, and confidentiality

				the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	
REACTION-437	Non-functional - Security	Major	Each role MUST be assigned to a set of permissible actions.	Since some actions are reserved for specific roles it has to be decided which actions are permissible for which role.	According to the roles' needs, each role is assigned to a set of appropriate permissions.
REACTION-438	Non-functional - Security	Major	Communication between the Reaction Device Hosting Server and the GP EPR MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the Reaction Device Hosting Server to the GP EPR and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
REACTION-480	Non-functional - Security	Major	Access control mechanisms should be able to process context information	It may not be sufficient to make access control decisions based only on the role(s) owned by a user. In some use cases, access restrictions depend on context information like time, location, and access history, etc. For example, a physician should only be able to treat patients that are assigned to her own ward. Therefore, access control mechanisms applied in REACTION should be able to process access rules that rely on context constraints.	Availability of a control mechanism which decides whether a requested action may be granted or denied based on context information.

1.6 Requirements of WP8 – Clinical Practice and Field Trials

1.6.1 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-35	Non-functional - Usability	Major	Usage Data (Information about elder and juvenile usage of the platform and resources shall be available)	Reports shall be generated in a way that summarizes the use of the platform to meet the expectations of its users.	A survey shall show the percent of the users that regularly use the platform.
REACTION-37	Non-functional - Usability	Major	Applications guidelines (guidelines for formal carers, in-formal carers and patients) have to be clearly defined	To ensure that the applications will run with the best possible way.	To demonstrate the full functionality of the REACTION platform.
REACTION-253	Functional - REACTION platform	Major	Data entry shall be facilitated as much as possible	Data entry in any information system is an additional task for formal carers. This additional workload has not to be burdensome in order to facilitate the adoption of the platform in the clinical sites.	Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work they have to do and how much this additional work (if any) is useful.
REACTION-261	Non-functional - Usability	Major	The platform shall not generate additional workload for the clinical staff	Additional workflow shall be avoided or allowed only when the advantages produced by this workflow overcome the disadvantages	In the filed trials evaluation additional workflow shall be assessed by questionnaire or quantitative measurements and its advantages/disadvantages properly evaluated
REACTION-263	Functional - In-hospital pilot application	Major	Improve documentation quality and streamlined access to information	The registration of all measurements, additional information, decision on treatments, drug administration will improve the quality of documentation. The reduction of the number of missing information and an efficient access to all information related to the patient will improve the quality of care.	The platform shall allow the registration of all relevant information and its contextualized retrieval. In the questionnaires used in the evaluation procedures specific questions should be included in order to verify the user satisfaction about the improvement in the documentation and in the streamlined access to information.
REACTION-279	Non-functional - Legal	Major	Clinical trials investigators brochure	It is important to create an investigators brochure	Investigators brochure present for clinical trials.

				(sensor development) for clinical trials.	
REACTION-283	Non-functional - Legal	Major	Qualification of the investigator for clinical trials	Qualification of investigator must be given for clinical trials.	Qualification of investigator given in advance of clinical trials.
REACTION-325	Functional - Primary care pilot application	Major	The possibility to manage user accounts by user name and password and secure log in and log out	Administrator of the system shall have full ability to reset user name and password of users, Add , Delete and Edit user accounts. The users shall be added to the system by their name and their role (user type) and also the ability to suspend and reactivate the user's account.	The system shall differ between active and suspended user accounts. Active users shall be displayed both with colour indicator and as a list function.
REACTION-327	Functional - Primary care pilot application	Major	Each patient's self-monitoring records shall be displayed to the clinician too	There should be individual records for each patient on the monitoring software that provides an overview of : Demographic detail, Devices assigned to, Disease category, Alert limits and questions sets , educational content , monitoring data, question response data.	Functional - Primary care pilot application
REACTION-481	Functional - REACTION platform	Major	Glucose Control Suite (GCS) - Matlab GUI	Implementation of a Matlab based GUI for the clinical valdiation of the closed loop glucose control algorithm	Operable Interface on a laptop within a patients room in the clinic
REACTION-501	Functional - REACTION platform	Major	Second Prototype of the Glucose Control Algorithm (GCA 2) - Matlab GUI	Second Prototype of the Glucose Control Algorithm (GCA 2, formerly known as Glucose Control Suite, GCS): Implementation of a Matlab based GUI for the clinical valdiation of the closed loop glucose control algorithm	Operable Interface on a laptop within a patients room in the clinic

1.6.2 Medical and environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-281	Non-functional - Legal	Major	Clinical trials CE-certification OR certification that the medical device fulfils the MDD 93/42/EEC and 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.

1.6.3 Network management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-262	Non-functional - Performance	Major	Improve productivity and efficiency, reducing cost	The platform shall improve productivity and efficiency and at the same time shall reduce the cost of the diabetic 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.

1.6.4 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-330	Functional - Primary care pilot application	Major	Patient access to a library of diseases with questionnaires which help the patient to better	An educational library with helpful content about patient's lifestyle shall be created. This library shall	It should be evaluated by focus group and the test plan.

			manage his lifestyle and disease	contain information about diet, activity, medication and advice to the patient in response to patient's lifestyle, etc.	
REACTION-331	Functional - Primary care pilot application	Major	The patient portal's screen shall be easy to read and use	The interface screen used by patients shall be easily customised, e.g., different font sizes, with clear instructions to the patient. It is recommended the use of large fonts, use of colours with strong contrast, possible use of audio messages and implementation of other commonly used accessibility options (utilization of full screen size on small as well as large screens), for the interface used by patients.	The user friendliness and useability of the interface shall be evaluated with a focus group and the test plan.
REACTION-416	Functional - Primary care pilot application	Major	Patient education	Continuous education of the patient adjusted to his/her needs.	Educational material is available.

1.6.5 Security and safety management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-60	Non-functional - Maintainability and portability	Critical	Restore from malfunctioning	System should be able to restore its previous state and the data when an unexpected problem occurred (wrong 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-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-282	**Non-functional - Legal**	**Major**	**Insurance for clinical trials must be made**	**Insurance is required for clinical trials otherwise it can not be performed.**	**Insurance made before clinical trials.**
REACTION-321	**Non-functional - Operational**	**Major**	**Risk analysis**	**Risk Analysis has to be started in the very early stage of the development. The identified risks have to be identified and assessed.**	**All risks must be in an acceptable range according to the assessment criteria.**

1.7 Requirements of WP9 – Socio-Economic Framework

1.7.1 Data management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-141	**Non-functional - Legal**	**Major**	**The user should have choices regarding all data collection activities concerning his personal data**	**"User control implies the option to make choices, even if this means the end of an interaction or transaction. Choice is also mandated by consent, which is an important ground for legitimate collection and use of personal data (see EC Directive 95/46/EC article 7 sub a.: Member States shall provide that personal data may be processed only if: a) the data subject has unambiguously given his consent.).**	**Offering the user opt-in and opt-out choices for particular uses of collected data is an element of choice. When there is a choice to provide the user with an opt-in or opt-out option, the one that limits the user's efforts is to be preferred. Questions to be asked:** **Does the application have mandatory data entry fields only for data necessary for providing a service (also a data minimisation requirement)?** **Does the application provide the users with choices with respect to the use and secondary use of their data, for instance by providing options with respect to:** **- whether or not to provide**

					personal data **- what personal data is to be shared** **- for what purpose data can be used** **- when and how long data may be used**
REACTION-151	**Non-functional - Legal**	**Major**	**The user must be able to correct, rectify, block or erase personal data that has been disclosed - Primary care**	**Choice is interpreted as leaving the user as much room to decide which personal data to disclose as possible. This, for instance, means that mandatory data should be limited. Instead, the user should be left the choice to leave certain fields empty. The user should have choices regarding all data collection activities concerning his personal data"**	**Levels of ex-post user control that can be distinguished are:** **- rectify: the power to change or update personal data that a party possesses.** **- block: the power to cancel or change the rights that parties have to use the personal data** **- erase: the power to delete the personal data that parties possess** **Does the application show the user's rights to access, rectify, block or erase disclosed (personal) data and the procedures to execute these right?**
REACTION-475	**Non-functional - Legal**	**Major**	**Log and log-in system**	**People make mistakes and novel information may render earlier decisions unfortunate. This goes for users and service providers alike. User control mandates that users can correct mistakes they, or the service providers, make with respect to their data. A step further is that users also have the possibility to reset choices they made. If users are not content with the way their data is used, they should be able to recall or change the**	**A log and log-in system has to be implemented, documented and tested.**

				access rights to their data.	
REACTION-493	Non-functional - Legal	Major	The user must be able to correct, rectify, block or erase personal data that has been disclosed - In-Hospital	In legal terms, this requirement derives from article 12 of the Data Protection Directive which provides a right to the user to access personal data provided. Access to the data is a prerequisite to rectify, or even block or erase, the personal data that is stored.	Levels of ex-post user control that can be distinguished are: - rectify: the power to change or update personal data that a party possesses. - block: the power to cancel or change the rights that parties have to use the personal data - erase: the power to delete the personal data that parties possess Does the application show the user's rights to access, rectify, block or erase disclosed (personal) data and the procedures to execute these right?

1.7.2 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-146	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings	To increase the adoption of REACTION technologies within different social groups, it must adapt were possible to social conventions within each group. This is even more important because individuals are part of several social contexts at the same time.	The application should cater for configuring at least: - language settings - different sets of symbols and icons - user help and documentation to the needs and skill levels of different social groups - flexibility to change privacy preferences - ability to predefine sets of privacy preferences for different social contexts. Does the application allow for changing interface

					language, symbol/icon sets, help files and documentation? Does the application allow for managing privacy settings to different social contexts?
REACTION-495	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings - Clinician portal	To increase the adoption of REACTION technologies within different social groups, it must adapt were possible to social conventions within each group. This is even more important because individuals are part of several social contexts at the same time.	The application should cater for configuring at least: - language settings - different sets of symbols and icons - user help and documentation to the needs and skill levels of different social groups - flexibility to change privacy preferences - ability to predefine sets of privacy preferences for different social contexts. Does the application allow for changing interface language, symbol/icon sets, help files and documentation? Does the application allow for managing privacy settings to different social contexts?

1.7.3 Medical & environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-470	Non-functional - Look and feel	Major	The potential stigmatising effect of REACTION due to increased visibility should be decreased to a minimum.	Most diabetic patients experience diabetes as 'discreditable' individuals in terms of stigmatisaiton (See ethical analysis - task 9.1). For such individuals control over personal information is extremely important.	Patients should feel that a REACTION like platform will not result in a overall increase in the visibility of their condition and consequently a reduction in their ability to conceal it, it they should wish to do so.

				Individual patients will not want to unnecessarily increase visibility of their condition as this will mean that they have reduced level of control over their personal information and will therefore have less ability to control who they reveal their condition to. Visibility of components and also electronic visibility of networking components should therefore be kept to a minimum.	

1.7.4 Patient sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-145	**Non-functional - Legal**	**Major**	**The user must consent to the collection of personal data whenever possible**	**The user is taken to be an autonomous individual who, in principle, decides what personal data to disclose and to whom. Of course this is not an absolute right, because legal obligations such as the law, contractual obligations, but also consequences of the performance of a contract, may overrule the right for the individual to withhold consent. Consent contributes to the realisation of a number of fundamental human values founding modern (western) societies, such as individuality, autonomy, dignity and civility.** **The requirement must be updated and better specified in the light of the Proposed Data Protection Regulation COM(2012) 11 final:**	**The fact that consent is instrumental to a number of fundamental values, means that it has to be revocable when it turns out that the effects of the previously given consent are different than the user may have expected given the available information at the time.** **Consent requires the user to be able to:** **• give informed agreement to the collection and processing of personal data** **• give explicit permission to the entity collecting the personal data to perform the servcies contracted for** **• give specific, unambiguous agreement to the collection and processing of sensitive data** **• give special consent when**

				Individual consent does not provide a valid legal ground when the individual has no genuine and free choice and is subsequently not able to refuse or withdraw consent without detriment. In such cases, the valid legal basis for the processing of personal data must be provided by a legitimate interest, such as data processing performed as part of for medical treatment. However, in the case where the individual retains a genuine choice, e.g., when the data processing concerns a specific purpose that is different from the original one (for which consent was obtained or for which a legitimate interest provided the legal basis), consent must be obtained in a distinguishable form. The data subject should be made aware that and to what, he or she gives consent.(see next requirement) The distinguishable form, (explicit written) shall be kept by the controller as proof for the data subject's consent to the processing of their personal data for specified purposes.	data will not be editable • agree to the automatic collection and processing of (personal) data (the main reasons for which this requirement has been inserted) Questions to be asked: Does the application offer the user ways to provide explicit consent to (personal) data disclosure? Does the application offer the user ways to provide explicit permission to use certain data for performing the service contracted for? Does the application offer ways to treat sensitive personal data different from the way it treats other personal data? Does the application provide special warnings when data is not editable after disclosure? Does the application offer ways for the user to explicitly agree to the automatic collection and processing of (personal) data Does the application offer ways to revoke previously given consent?
REACTION-471	Non-functional - Cultural and political	Major	Individuals that suffer stigmatisation (including through conditions such as diabetes) often value the ability to socialise with others having a similar condition or sympathetic	Individual patients often use the opportunity to meet such groups as a coping mechanism for the stigmatising effects there condition can entail. A REACTION platform should	Individuals should not feel that a REACTION platform has eliminated their access to other patients and sympathetic health care professionals which represent an important

			healthcare professionals. REACTION should not eliminate this possibility.	not reduce such possibilities too much. Where such possibilities are drastically reduced alternatives should be offered, for example online social networking possibilities.	coping mechanism for individuals that feel stigmatised.
REACTION-494	Non-functional - Cultural and political	Major	It should be possible to configure the application to different socio-cultural settings - Patient Portal	To increase the adoption of REACTION technologies within different social groups, it must adapt were possible to social conventions within each group. This is even more important because individuals are part of several social contexts at the same time.	The application should cater for configuring at least: - language settings - different sets of symbols and icons - user help and documentation to the needs and skill levels of different social groups - flexibility to change privacy preferences - ability to predefine sets of privacy preferences for different social contexts. Does the application allow for changing interface language, symbol/icon sets, help files and documentation? Does the application allow for managing privacy settings to different social contexts?

1.7.5 Security and safety management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-131	Non-functional - Look and feel	Major	The platform shall appear authoritative	Trust of end-users is paramount	After their first encounter with the product, 2/3 of representative end-users shall agree they feel they can trust the platform and its services

1.8 Requirements of WP10 – Platform Integration and Implementation

1.8.1 Data management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-140	Non-functional - Security	Major	The platform shall prevent incorrect data from being introduced	Incorrect data might hamper a correct clinical decision	Check that the user interface and specific procedures protect the end-user from the introduction of incorrect data as much as possible
REACTION-169	Functional - In-hospital pilot application	Major	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously (mobile access points - e.g. tablet PC at point of care versus fixed access points - e.g. screens at physicians/nurses base)"	Clinicians can input relevant information via tablet PC from every place within the hospital ward.
REACTION-226	Functional - In-hospital pilot application	Major	Electronic fever/sugar chart should be modelled in the data management system	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.
REACTION-250	Functional - In-hospital pilot application	Major	Different contextualization of the patient clinical information	Different modes of visualisation with different relevant parameters for decision support shall be foresee. The relevant data have to be displayed	The possibility of configure the display of the patient clinical data (mainly the sugar chart) has to be present.

				contextualized. The relevant values have to be highlighted.	

1.8.2 Health professional sphere

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-23	Functional - Primary care pilot application	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-85	Functional - Primary care pilot application	Major	Present effectiveness of medication therapies to patients and carers	In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an adequate front-end	Front-end for therapy-scheme quality presentation
REACTION-96	Functional - In-hospital pilot application	Major	Visualization individual patient data to support glucose control (decision support)	Following functions should be fulfilled by the visualization module: - different modes of 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-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	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.

			effort		
REACTION-153	Functional - Primary care pilot application	Major	Symptoms of diabetes or hyperglycaemia	At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening 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-162	Non-functional - Usability	Major	Documentation of user interfaces - in-hospital prototype	Documentation for User Interface of all frontend applications.	User manual for all frontend applications
REACTION-170	Functional - In-hospital pilot application	Major	Selection of a mobile device for In-hospital glucose control based on given requirements	The devices should be: - Lightweight/portable - Easy to hold / handle and ergonomic design - Spill an drip resistant (easy disinfection) - Inputs for stylus and touch operations (incl. touch keyboard) - Wireless communication - Ease of operations	Devices with desired functionality are available within the project
REACTION-171	Functional - In-hospital pilot application	Major	Data input application for In-hospital glucose control	The system should ask for data entry of relevant parameters. Main parameters for	Data entry system will be available for In-hospital decision support system with devices (tablet PC)

				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**	
REACTION-179	**Functional - Primary care pilot application**	**Major**	**Daily data review by clinicians or telehealth support team**	**When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the patient progress against individualized targets set up for the patient.**	**The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or pharmacological treatment.**
REACTION-181	**Functional - Primary care pilot application**	**Major**	**Decision on therapy in Primary care environment**	**At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also pharmacological treatment (OAD or insulin) can be reviewed after accurate evaluation of patient kidney functions.**	**Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the relevant information have to be designed.**
REACTION-189	**Functional - Primary care pilot application**	**Major**	**Other implications for type I diabetic patients**	**Type I diabetic patients may have signifcant risk of developing complications (neuropathy, nephropathy,**	**In the care program, management of diabetes (through insulin) should be accompanied by the**

				neurobehavioral complications, retinopathy)	capability of evaluating the risk of long-term complications
REACTION-194	Functional - Primary care pilot application	Major	Regular visits/reviews at the Primary Health Care	Outcomes of regular visits at the Primary Health care centre shall be registered in the platform through the use of specific forms/user interfaces for the doctors/nurses.	Specific forms and user interfaces for the doctors/nurses have to be present
REACTION-230	Functional - In-hospital pilot application	Major	Therapy adjustment in In-hospital environment	Supervision of glycaemia and according treatment is performed once a day. Adaptation of therapy or changes of medications have to be evaluated also consulting the physician on duty.	Every day an evaluation report has to be stored and available in the In-hospital application
REACTION-234	Functional - In-hospital pilot application	Major	Determination of health status in In-hospital environment	At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or adapted to the status of the patient. In the second case a dose-finding procedure for the individual patient will be started associated with education in nutrition and therapy. Type of diabetes has to be registered.	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.
REACTION-235	Functional - In-hospital pilot application	Major	Therapy scheme in In-hospital environment registered immediately after the patient enrolment	The therapy scheme is continued for patients with known diabetes and defined and started for patients 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 therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.

				the project.	
REACTION-285	Functional - In-hospital pilot application	Major	User interface for the clinical data stored in the In-hospital environment	The user interface shall allow the insertion, modification and visualization of the clinical data registered at the patient enrolment and of the clinical data acquired more frequently.	There shall be a user interface which allows the insertion and the update of all the listed parameters.
REACTION-326	Functional - Primary care pilot application	Major	The clinician will be able to register, edit and search for a patient within the clinical portal.	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.	NON
REACTION-492	Functional - REACTION platform	Major	Components should reflect national requirements, policies, guidelines or provisions	National organisations can provide specific requirements, policies and guidelines for health care systems. They may also make national provision for health care services ans IT that are required to be used. Components should be flexible to be substituted to match these national requirements. An example is the SMS messaging service provided by NHS on its secure network.	Components

1.8.3 Internal communication

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion

REACTION-38	Non-functional - Operational	Major	Integration plan (combining the various components)	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.	For each interface/interconnection specify the data content and physical material content.
REACTION-41	Non-functional - Maintainability and portability	Major	The tools developed by the consortium must be properly documented in such a way that the end user can understand them and use them for the intended purpose.	Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The well documented tools will allow the users to make full use of their functions and capabilities and will also provide a complete test of the platform's functionality. Design history file is necessary not only for the end user but also for regulatory approval by the authorities which is mandatory for medical devices.	Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely available and easily accessible via the website.
REACTION-46	Non-functional - Maintainability and portability	Minor	Error messages must be understandable and helpful	When an application fails this must happen gracefully while providing sufficient and easy to understand messages to the user. In this way the user will not get panicked during a failure, while able to understand what happened or whom to contact to report or resolve the problem.	For each application, developers must ensure that error messages should be brief, easy to read, understood even by non-specialists and should also provide some short help (of course they must include the error code and/or description that will allow to understand exactly what is wrong).
REACTION-57	Non-functional - Performance	Critical	Performance and Scalability	Responsive enough to integrate with the clinician workflow. The response to the users action should be acceptable, depending on how time-critical is the action's response. Each component should scale well when increasing the users and the data that is stored and processed.	Criteria are different depending on the user action. For time-critical actions the response should be almost instant.

REACTION-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

1.8.4 Medical and environmental devices

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-225	Functional - In-hospital pilot application	Major	PoC device for blood glucose measurement will be used by the in-hospital glucose management system	The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the consortium sensors. Furthermore, before their regular use in hospital ward consortium sensors have to obtain special approval. Thus, in the Inpatient environment the devices currently used will continue to be used also in the first-year prototype.	a) The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. b) The acquired measurements will be manually inserted using the front-end in the tablet PC and stored in the REACTION data management.

1.8.5 Network management

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-71	Non-functional - Maintainability and portability	Critical	Simulators for the internal tests	The internal test is performed without real users (clinicians & patients) and therefore some interactions have to be simulated	Simulated components performing the same operations with exactly the same interface have to be available
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

1.8.6 Patient sphere

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

				lifestyle behaviour and therapies to clinicians and patients.	
REACTION-48	Non-functional - Usability	Major	Support for multilingual user interface	Users from different countries should have access to services.	Any type of text in any graphical user interfaces that will be developed (labels, text fields, labels, etc.) must be able to easily configured and changed using a easily configurable localization file. A first version of the file will be created in English language, and then it will be distributed to the partners. Once decided which languages will be supported, partners must contribute to the localization of the components, by translating them to its native language (if in the set of supported languages)
REACTION-64	Non-functional - Usability	Major	Friendly applications	The use of end-user applications and the devices both in the in-hospital but also (and most importantly perhaps) in the primary care cases should be intuitive, efficient, and of minor disturbance to the patients, requiring minimal interactions and engagement.	No complex user interfaces, the user should be familiar with the applications in short time (training is foreseen)
REACTION-77	Functional - Primary care pilot application	Major	Browser Compatibility	The web based interface should be perform properly in the last 2 editions of the 5 most common browsers	Specific tests have to be performed
REACTION-117	Non-functional - Usability	Major	Cross-platform usability: user experience should be the same on all platforms	Users should only see familiar interfaces in order to adapt to a new platform more easily.	Different platforms do not have significantly different user interfaces, i.e., REACTION should be 'platform agnostic'.

REACTION-130	Non-functional - Look and feel	Major	The platform shall be easily used by elderly people with no specific technological knowledge	Being the diabetes quite common in elderly people, several patients will have no specific knowledge in technology, but they should be able to easily use the platform.	User learning curve (especially with elderly people) should be very quick
REACTION-188	Functional - REACTION platform	Major	Storage of events for context of measurements	Significant events (e.g. nutritions, drug administrations, advers events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context for the acquired measurements. A suitable user interface has to be provided in order to facilitate patients performing this task (any data entry can be felt as too intrusive for patients). The possibility of integrating existing commercial log-devices used by the patients has to be considered.	There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint display of the acquired measurements and the relevant associated events (giving a context for the measurements)
REACTION-190	Constraint - Implementation Environment	Major	In the Primary care environment the medications are usually self-administered by the patient himself or by informal carers (rarely)	Usual practice for diabetic patient outside of secondary or tertiary care is self-administration of medications	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home
REACTION-247	Functional - In-hospital pilot application	Major	Mobile access point in wards of In-hospital environment	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.	User interfaces have to be targeted on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication,

					ease of operation.
REACTION-496	Non-functional - Usability	Major	Documentation of user interfaces - primary care prototype	Documentation for User Interface of all frontend applications.	User manual for all frontend applications

1.8.7 Security and safety

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-26	Functional - REACTION platform	Major	Embedded intelligence	Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions which are not written or specified in published deliverables or manuals. The applications shall not rely to "default" actions, or fall-back scenarios in exceptional cases, unless these are based on agreed scenarios or models.	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.
REACTION-44	Non-functional - Security	Critical	Protection against unintended user actions	Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not cause the system to close down, neither on the client nor on the server. All data entered must be checked for format, consistency and validity. In case of doubt, the user must be warned and asked what to do. The user must be able to correct mistakes easily. The user must be able to interrupt long functions (e.g. waiting for a remote data transfer).	The functional test should include specific tests in order to verify such circumstances
REACTION-65	Functional - REACTION platform	Major	System availability	The system should be continually monitoring and gathering data about the	The end user applications and the devices in the vicinity of the patient

				patients status with no excessive down time. Support for patients and doctors should be continuous. Availability here means that the vital components of the REACTION platform will be in functioning state in order for the patient safety to be supported.	should always operable
REACTION-132	Non-functional - Usability	Major	The platform shall help the user to avoid making mistakes	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows	End-users will be guided through the workflows they have to perform.

1.8.8 Service orchestration

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-223	Functional - In-hospital pilot application	Major	Basic workflow for insulin treatment in In-hospital environment	The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on additional parameters and insulin administration	The basic workflow should be easily accessible in the REACTION In-hospital application
REACTION-224	Functional - In-hospital pilot application	Major	Basic workflow is repeated 4 times a day in In-hospital environment	The first workflow is in the morning a little before breakfast time (administration of bolus insulin), the second is at midday before lunch time (administration of bolus insulin), the third is in the evening before dinner time (administration of bolus insulin), and finally the fourth is at bedtime (administration of basal insulin and correction of boluses, if necessary).	These 4 loops should be easily identified in the In-hospital application

1.8.9 Third party system interfaces

Key	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION-174	Functional - In-hospital pilot application	Blocker	The system must provide interfaces to HIS and implement data management and data structures for In-hospital scenario	The platform must offer interface to HIS; moreover the system needs data structures and data management functionality for the In-hospital scenario	Data structures and data management functionality
REACTION-258	Functional - In-hospital pilot application	Major	Automated transfer of patient related data from the hospital information system	At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred from the HIS to the platform (when a HIS/EPR is present in the clinical site). This procedure reduces transcription errors and save doctors/nurses time for manual data entry. This procedure must be flexible enough to interface different HIS/EPR HL7-based including the one used at the clinical site.	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.
REACTION-443	Functional - REACTION platform	Major	Data exchange with third party systems	Ideally integrates information from outside the REACTION platform (e.g. Laboratory Information Systems in hospital or primary care with blood glucose and glycated haemoglobine).	Should be able to import and export data in an interoperable way (e.g. HL7) to third-party systems.

1.9 Requirements of WP13 – Training

1.9.1 Patient sphere

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 to be accepted by end users	Should be designed to be as simple to use as possible, especially for elderly