





Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

REACTION (FP7 248590)

ID2-8-4 Change request and re-engineering report 3

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1 Abbreviations and acronyms

BT	BlueTooth
CGM	Continuous Glucose Monitoring
CGMA	Continuous Glucose Monitoring Algorithm
DAO	Data Access Object
DCCT	Diabetes Control and Complications Trial
DCK	Device Connectivity Kit
DSS	Decision Support System
EPR	Electronic Patient Record
FTP	File Transfer Protocol
GSM	Global System for Mobile communication
HMPG	Home Mains Plug Gateway
IPR	Intellectual Property Rights
IR	Infra Red
ISF	Interstitial Fluid
LED	Light-Emitting Diode
LL	Lesson Learned
MDD	Medical Device Directive
MPV	Multi-Protocol Version (gateway)
NHS	National Health Service (UK)
NMS	Network Monitoring System
OAD	Oral Antidiabetic Drug
PBCT	Paper-based Clinical Trial
PMS	Profile Management System
PoC	Point of Contact
RBAC	Role-Based Access Control
RTD	Research and Technical Development
SIM	Subscriber Identity Module
SMD	Surface Mount Device
SMS	Short Message Service (for text messages)
SpO_2	Oxygen Saturation
SQL	Structured Query Language
URL	Uniform Resource Locator
Wi-Fi	Wireless Internet
WS	Web Service
XML	Extensible Markup Language

2 Introduction

This internal document describes the work performed in the third development cycle as part of the iterative requirements engineering process adopted for the REACTION project.

2.1 Purpose, context and scope of this deliverable

The document reports the Lessons Learned and the resulting change requests and re-engineering, as well as summaries of validation results and an assessment of the impact for the solution architecture.

The deliverable provides input for the analysis to be documented in *D2-9 Updated requirements* report.

2.2 Content of the deliverable

Section 3 provides a brief summary of the research and development methodology defined for the REACTION project. A more detailed description can be found in *D2-8 The Requirement engineering process*.

Section 4 contains the results of the steps in the re-engineering process. The first step is the collection and documentation of Lessons Learned. The LLs are listed for each work package followed by an analysis and discussion of the changes in or new requirements derived from them.

Sections 5 and 6 include summaries of verification and validation results and summaries of results from usability testing and outcomes of field trials for the In-hospital prototype and Primary care prototype, respectively.

Finally, Section 7 presents an assessment of the impact of the changes made on the system architecture.

Appendices A through D contain details of test results from Sections.5 and 6.

3 Research and development methodology

The REACTION project seeks to use the great potential that new technologies offer to address the major societal challenges of coping with the massive increase in number of citizens suffering from diabetes mellitus.

The REACTION solutions will be validated for use in both primary care (general practice) and secondary care (hospital general wards).

A description of the software engineering process and an overview of the iterative approach as they pertain to the REACTION project can be found in the internal deliverable *ID2-8-2 Change request and reengineering report 1*. A detailed account of the process is available in the deliverable *D2-8 The requirement engineering process*.

3.1 Re-engineering of requirements

After the successful completion of a prototype cycle, each work package analyses and reports their development results, RTD experiences, Lessons Learned in the development and integration work and other relevant knowledge gained during the development cycle. Knowledge gained from formal testing and system integration is also collected together with latest developments in technology, regulatory affairs and markets, which influence the REACTION solutions and their exploitability.

3.2 The REACTION approach to Lessons Learned

Lessons Learned help support project goals in the RTD work by promoting recurrence of successful outcomes and precluding the recurrence of unsuccessful outcomes.

The REACTION Lesson Learned process has six steps:

- Collection
- Verification
- Storage
- Dissemination
- Reuse
- Identification of improvement opportunity

The RTD work provides a large amount of Lessons Learned, by virtue of the many researchers participating in this. The Technical Management and the WP leaders have identified the Lessons Learned and verified them for correctness, significance, validity, and applicability.

All Lessons Learned have been entered into the Lesson Learned repository of the REACTION TWiki.

Again, further details can be found in internal deliverable *ID2-8-2 Change request and reengineering report 1* and deliverable *D2-8 The requirement engineering process*.

4 Lessons Learned and requirements engineering

This section contains all Lessons Learned collected and validated in cycle 3 and the subsequent requirements analysis. To facilitate referring to individual Lessons Learned they have been named LL followed by the relevant work package number and Lesson number (as they appear in the TWiki repository), e.g., LL WP4-1. The process results in the identification of a series of improvement opportunities and the need for new, changed and rejected requirements. The changes in requirements are commented and the impact on the present REACTION architecture is assessed.

The change requests are grouped per work package. The changes and updates to the requirements arising from the Lessons Learned are listed and discussed for each work package. The final reengineering of the requirements will be analysed and discussed in detail in deliverable *D2-9 Updated requirements report*, which will also contain the complete list of updated requirements.

A total of 58 Lessons Learned has been reported in the third iteration cycle, resulting in 13 new requirements, 4 updated requirements and 27 deleted requirements.

4.1 Lessons Learned in WP1

The work undertaken in WP1 involves the managing of the REACTION project. ATOS is the WP leader and 1 Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
FORTH-ICS 1	The development of a tool/platform/software may involve several institutions that are assigned a particular task. There should be an agreement ahead of time how the Intellectual Property Rights (IPR) will be handled giving each partner their due based on the work that they have performed.	The IPR for each partner should be accurately defined in a reasonable and fair way based on the contribution of each partner	

Table 1: Lessons Learned in WP1

4.2 Change request and re-engineering originating from WP1

4.2.1 Analysis of Lessons Learned

WP1 reported one Lesson Learned from the work performed in the third cycle.

LL WP1-1 concerns IPR rights, the handling of which is defined in the REACTION Consortium Agreement. The handling of knowledge follows the APCA conventions, i.e.: "Background IPR" or "Pre-existing Know-how" already exist and are necessary for the work in the project. The participants owning relevant background IPRs make them available for the project work free of charge. This requires a clear identification of such background IPR from the beginning. The "Foreground IPR" or "Knowledge" is resulting from the project work. A detailed description of IPR handling is part of the REACTION Consortium Agreement.

At month 9, deliverable *D1.3 Plan for managing knowledge and intellectual property* was released. This deliverable deals with the initial plan for managing the Pre-existing know-how and the Knowledge developed within the project. When this deliverable was written there was a significant degree of uncertainty about the future situation concerning IPR usage. In this report we also highlighted the potential complexity entailed in joint ownership. Joint research efforts may lead to the joint ownership of the results, either because the entities are collaborating on a research project or because legislative provisions establish a joint ownership regime in certain circumstances. Therefore, flexibility in the use of IPR protection may be essential in forming a wide range of collaborations, as well as for commercially exploiting the results.

Although the REACTION CA formalised IPR issues and deliverable D1.3 provided the initial plan for IPR management, it has been discussed and agreed that there is a lack of clear definition of the individual or joint partners' foreground IPR as results of the progression of the project. This is an important matter that impacts on the early exploitation of results. Exploitation is covered in task T12.3 led by IN-JET, and IPR handling is covered in Subtask 1.4.2 led by UBRUN.

ATOS will set up and lead an IPR team that will take care of IPR issues as they pertain to the Consortium Agreement and to the plan established in D1.3, in order to define lines for specific partners' exploitation agreements.

On completion of the REACTION project, there are no deliverables, other than D1.3 and D12.3 Final plan for dissemination and exploitation of knowledge, which give special attention to IPR and exploitation. Thus, the purpose of this team will be to maximise the value of the project's IP, to enable competitive advantage to be derived from it, and to minimise infringement risks. The team will not handle copyright or trademark registrations but will be related of IPR management for exploitation activities.

In projects like REACTION, different partners with different interests have to work together. To make this happen in the most productive way, setting up proper rules for protecting IP is a must.

A plan for using the knowledge, containing an initial IP list of results (foreground knowledge), will be developed by UBRUN by month 42. This list will be a living IPR document and will be updated with new knowledge (foreground) contributions as needed. These activities will lead to an optimal patent search and filing strategy. This will make exploitation of the results convenient, such as technology transfer, potential spin-off creation and publication strategy.

The team will also cover the issue of protecting and/or sharing background in an appropriate manner if necessary for exploitation activities of the project's results. In this respect, a key role will be played by IN-JET as WP12 Leader.

4.2.2 New/updated/deleted requirements

No requirements have been added, updated or deleted.

4.3 Lessons Learned in WP2

The work undertaken in WP2 relates to managing the process of requirements engineering and validation. IN-JET is the WP leader and two Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
IN-JET 1	The use of the JIRA tool to manage requirements is still not fully exploited	Frequent follow-up is required to monitor project progress	(None)
FORTH-ICS 2	In European projects, partners from different countries have different understandings of the requirements of a project. It is important that early on a spirit of teamwork, common understanding and timely response to responsibilities is encouraged among partners in order to relieve potential conflicts.	Communication among partners, teamwork and common understanding of chosen approaches are key for the timely design and development of health technologies	

Table 2: Lessons Learned in WP2

4.4 Change request and re-engineering originating from WP2

4.4.1 Analysis of Lessons Learned

WP2 reported 2 Lesson Learned from the work performed in the third cycle.

LL WP2-1 continues the discussion initiated in previous versions of this document. To further underpin the use of the JIRA requirements database as a tool for monitoring project progress, the partners agreed to add and fill in two new fields in the Volere template. One field is 'Due date', the other is 'Version'. The latter is not intended for versions in the normal software sense; rather it will be used to assign each individual requirement to the different prototypes being developed, e.g., 'Primary Care Basic Prototype' or 'In-Hospital Extended Prototype'.

Though this Lesson impacts all requirements it does not change their substance.

LL WP2-2 reports another facet of the same issue as LL WP2-1 from the perspective of differences between countries in interpretation of what is required. The Lesson stresses the importance of constant communication of means and goals to ensure a common understanding and strengthening of team efforts between partners.

4.4.2 New/updated/deleted requirements

No requirements have been added, updated or deleted.

4.5 Lessons Learned in WP3

The RTD work undertaken in WP3 involves the development of glucose sensors and monitoring and contextualisation of these. IMM is the WP leader and nine Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
BTS 1	Large recommendations for insulin dose may be declined by nurse/doctor (even though eligible)	Improve trust in algorithm choices by starting with semi- tight control	
BTS 2	In-silico validation not suitable to test for model extrapolations in case of outliers in-vivo	Continuously improve robustness properties of the GCA, train model kernels on new data from the public domain and if possible in new clinical trials	REACTION- 481, REACTION- 482, REACTION- 483,
			REACTION- 484,
			REACTION- 485, REACTION- 501, (REACTION- 78)
MUG 3	Error in the testing procedure resulted in wrong selection of parameters	Improvement in the design of the test strategy	
MUG 4	System should be flexible to be fixed on either on the right or left arm	Design of the system enables fixation on both sites	(REACTION- 186)
MUG 5	Strong drift of the sensor over the period of investigation	Compensation or retrospective fit	(REACTION- 183), (REACTION- 267)
IMM 6	For sensor calibration it would be better if stronger glycaemic changes would be present during the first hours	The calibration is more accurate if the range is larger	(REACTION- 183), (REACTION- 267)

IMM 7	The linear drift present in the sensor system is difficult to be compensated with only a two-point correction, because both, reference data and sensor data might contain an error and sum up to a wrong correction, especially with increasing time	Use more data points for drift calibration compensation	(REACTION- 183, REACTION- 267)
IMM 8	The Microeye PME1000 catheter seems to perform better than the Microdialysis CMA64 catheter (dialysate data is of better quality)	Only use the PME1000	(REACTION- 183), (REACTION- 267)
IMM 9	Bubble events with the need of flushing and chip removal need new calibration afterwards	Avoid bubble formation or recalibrate system after bubble event	(REACTION- 183), (REACTION- 267)

Table 3: Lessons Learned in WP3

4.6 Change request and re-engineering originating from WP3

4.6.1 Analysis of Lessons Learned

WP3 reported nine Lessons Learned from the work performed in the third cycle.

Five of them (LLs WP3-5, WP3-6, WP3-7, WP3-8 and WP3-9) affect the accuracy of the sensor (REACTION-183 \rightarrow accuracy should be high, REACTION-267 \rightarrow accuracy should be specified). LL WP3-5 and WP3-7 are both concerned with the drift of the IMM IR CGM sensor. The drift of the sensor voltage signal is most likely connected with the chip based measuring technique, to be used in combination with microdialysis. To compensate for this drift a simple two-point calibration bears the risk that temporal drift is not corrected adequately, since both the sensor data itself as well as the measured reference data is superimposed with an error (even the lab gold standard shows an error of about 5-10%), therefore eventually (in case that errors do not compensate) causing a dramatic increase of the overall error with increasing time. To solve this problem either the complete data set must be analysed retrospectively (only practicable for the study) or a more advanced calibration technique has to be applied (e.g., more reference data points during a run-in period, eligible for the real sensor).

During the clinical trials it came up that the micro-eye PME011 seems to be better suited, since the dialysate control data showed a better behaviour. For the second half of the clinical trials therefore only the PME011 was used instead of the microdialysis CMA64 catheter. Also an artefact that is mainly caused by usage of microdialysis is the formation of bubbles within one of the optical measuring cells that sometimes occur. In case that these bubbles stick in the optical cell, strong signal disturbances are arising that requires a kind of flushing routine (temporal increase of dialysis pump flow rate). After such a flushing procedure sensor data often shows an offset, although drift often remains the same. This means that in this case a new offset calibration has to be performed. It is expected that the later sensor version, where the optical cell is integrated into the catheter, will not face these problems (bubbles and drift), since no transport of the dialysate liquid to the outside of the body is required but measurement is undertaken directly in the ISF or vein, being diffusion controlled.

LL WP3-4 refers to REACTION-186 which states that the sensor should be simple to wear and operate. Since the newest version of the IMM IR CGM sensor will be connected wirelessly the uncomfortable connection via cable will not be an issue anymore in the future. LL WP3-1 and WP3-2 refer to the algorithm of BTS. During the clinical trials clinicians sometimes did not trust the suggestions of the algorithm and overruled it manually, to avoid complications. This can be improved after complete analysis of data, improving the trust in the algorithm. LL WP3-2 states that in-silico validation is not suitable to test for model extrapolations in case of outliers in-vivo. To overcome this problem, the CGMA must be improved continuously in robustness and model kernels must be trained on new data from the public domain and if possible in new clinical trials. Also sometimes errors in the testing procedure resulted in wrong selection of parameters for the Algorithm. This can only be

overcome by improvement in the design of the test strategy. Six new requirements pertaining to the Glucose Control Suite were created for this purpose.

At this stage, the Lessons Learned have not led updates of existing requirements. More knowledge has been gained on how to fulfil them, and it is expected that the Lessons may lead to changes to the requirements shown in brackets in Table 3 above in the fourth iteration cycle.

4.6.2 New requirements

As a result of the work undertaken and the findings and issues encountered in connection with the development of the glucose sensors six new requirements have been added.

Кеу	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION- 481	Functional - REACTION platform	Major	Glucose Control Suite (GCS) - Matlab GUI	Implementation of a Matlab based GUI for the clinical validation of the closed loop glucose control algorithm	Operable Interface on a laptop within a patients room in the clinic
REACTION- 482	Functional - REACTION platform	Major	GCS - Interface to create individual model file	Interface to create Individual specifying: Race, Gender, Age, Weight and Height	A new individual model file is created. The model initialization is initiated.
REACTION- 483	Functional - REACTION platform	Major	GCS - Interface for Model Initialization	Second Component of the GCS - Interface for the Initialization (Individualization) of the PBPK/PD model during Observation Phase, allows: - Input scheduling (IV Glucose, IV Insulin) - Measurement Data Entry (Plasma Glucose) - Visualization of Best Model Fits	Matlab GUI fitting rationale described above
REACTION- 484	Functional - REACTION platform	Major	GCS - Interface for semi- automatic online glucose control	Third Component of the GCS - Interface for the calculation of insulin infusion rates based on glucose measurements, allows: - Input scheduling (SC Insulin infusion rate, IV insulin, Meal, Oral Glucose) - Measurement data entry (Plasma Glucose) - Visualization of: - Plasma glucose - Plasma insulin - Applied rate of insulin - Confirm (update) inputs - Apply calculated or alter dose Insulin manually	Matlab GUI as described in rationale
REACTION- 485	Functional - REACTION platform	Major	GCS - Interface for online model optimization	2nd part of the third Component of the GCS - Interface for the further individualization of the GIM model based on past glucose measurements, allows: - Visualization of: - Plasma and interstitial glucose - Plasma and interstitial insulin	Matlab GUI as defined in rationale

				 Values of optimized parameters Values of penalty function components (met constraints) Level of manual interaction to be defined 	
REACTION- 501	Functional - REACTION platform	Major	Glucose Control Suite (GCS) - 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 validation of the closed loop glucose control algorithm	Operable Interface on a laptop within a patients room in the clinic

Table 4: New requirements – WP3

4.6.3 Updated requirements

No requirements have been updated.

4.6.4 Deleted requirements

No requirements have been deleted.

4.7 Lessons Learned in WP4

The RTD work undertaken in WP4 relates to data management and service orchestration. CNET is the WP4 leader and six Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
CNET 1	In the lessons learned cycle 2 it was pointed out that REACTION should analyse new markets in more detail regarding adoption of standards and approaches. A variable to look for is in particular the number of new adopters on the market for Continua.	The general adoption of Continua is a slow process. Continua do their best to ease certification and compliance tests. However, technology enabling the possibility to adopt the guidelines is still under- developed making it hard for adopters to integrate the concept.	
CNET 2	Experiments with different user interfaces for entering of context information (i.e. nutrition) has been carried out or investigated. A survey on the existing market apps for Android, iPhone and Windows Phone has been done with the aim to spot missing gaps of service, functionality and user interaction. Three main experiences are that 1) it is for the user difficult to assess the accuracy of contextual input such as number of calories eaten etc. 2) it is difficult to motivate the use of the app for a longer period, 3) the more sensor	The main lessons are to 1) provide different methods for manual estimating the nutritional input e.g. volume to weight conversion, 2) provide different automated input modalities e.g. QR code, image processing, spoken language that makes it unobtrusive to input data, 3) provide support for intelligent understanding of user repetitive behaviour e.g. adding favourite meals for breakfast.	

CNET 3	inputs you have the more precise the nutritional calculation will end up to be. Service interoperability has been studied in more detail regarding the paradigm "Device as a service" e.g. Withings scale, Pill dispenser. The issue was raised as data more often is being directly sent to services on the Internet moving the integration point from the device to a service on the net, and creates new interoperability at problems at the ser level.	This clearly affects the Medical Device class and the REACTION DCK. Considerations are being taken on how to ease the integration of measurements from services in the cloud.	
CNET 4	End customers in the healthcare sector, e.g. municipalities, often already have devices or have preferences which devices to buy. This means that a software platform distributor cannot dictate which device communication protocol to support.	Any gateway solution designed to run in the home of the patient must provide multiprotocol support in terms of data interoperability (IEEE 11073, ANT+ or proprietary formats) and communication interoperability (e.g. ZigBee, Bluetooth, USB) in order to be attractive on the market for exploitation.	
CNET 5	The lack of a service layer on top of the application specific Reaction database used for the primary care prototype has slowed down the joint component development in the project.	Need to develop service- oriented layer for accessing domain information in order to facilitate exploitation and use of the platform beyond project time and the project trials.	
CNET 6	There is no current market where emergency centres consume and manage responses on remote monitoring data.	An opportunity for exploitation of the REACTION platform can be initiated after project end time.	

Table 5: Lessons Learned in WP4

4.8 Change request and re-engineering originating from WP4

4.8.1 Analysis of Lessons Learned

WP4 reported six Lessons Learned from the work performed in the third cycle.

The analysis shows that the REACTION platform will be able to act as a pioneer on the market adopting Continua Guidelines. But it will still support widely commercially available medical devices and cloud services. More Continua adopters will follow as soon as the technology behind device communication becomes more available and easier to integrate with. It can also be seen as the REACTION platform pushes development forward as it already today offers an easier way to integrate devices and a basic understanding to the Continua guidelines build-up enabling faster compliance efforts.

To further pave the way for future exploitation and sustainability of the REACTION platform beyond project lifetime and trial applications we need to develop a service layer to make component independent of underlying database structure and we need to improve on methods for context input such as nutrition.

No new or updated requirements emerged from the Lessons Learned. Seven requirements have been removed from the updated set of requirements as being Duplicates or Out of Scope.

4.8.2 New requirements

No requirements were added in the third cycle.

4.8.3 Updated requirements

No requirements were updated.

4.8.4 Deleted requirements

Requirements REACTION-195 and REACTION-211 have been resolved as being Duplicates. REACTION-369, REACTION-393, REACTION-396, REACTION-433 and REACTION-458 have been resolved as being Out of Scope.

4.9 Lessons Learned in WP5

The RTD work undertaken in WP5 is related to network management and service execution. FORTHNET is the WP leader and six Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
FORTHNET	The NMS was originally planned to be part of the first version of the Primary Care Prototype, however, it was later decided that the first version of the prototype would only address basic services and needs for the primary care and so the NMS would be part of the second version of the prototype. As a result some of the effort spent to finalize the NMS could have been used to realize other more pressing needs and better utilize time and resources.	Careful planning is paramount in the design and implementation of a system. Changes in requirements should be identified as early as possible to reduce their impact in the implementation tasks.	
FORTHNET 2	The original prototype for the SMS service provided an XML based interface which was platform independent but did not follow a WS design. Even though there was no explicit requirement for a WS implementation this was necessary at the end. Furthermore, a secure connection to the SMS service was also necessary to ensure that the communicated information was encrypted.	Great care should be paid, especially with regards to the integration of components implemented by different partners, so that any necessary technological requirements are not neglected.	
FORTHNET 3	The first version of the SMS service showed there were some reliability issues with message deliveries. The cause of this unreliability was initially attributed solely to the REACTION SMS service implementation. However, the implementation of several features (e.g. load balancing) to address this improved the problem but did not resolve it. A large part of the problem was found in the end to be the unreliable service of some SMS providers used to forward	Requirements cannot be static since there are cases where a requirement that has been set is proven to be not realistic in practice. In such a case there must be enough flexibility to modify specific goals and provide feasible solutions.	

	and a second second second second		[]
	messages to international		
	destinations. Since there was no way		
	to improve the reliability of the		
	providers used the solution adopted		
	was to implement priority queues		
	with different performance and		
	reliability features and perform quality		
	checks to assign each provider to		
	some queue. Some providers with		
	very poor reliability were also		
	substituted with more reliable ones.		
FORTHNET	SMS delivery (especially to	A commercial REACTION SMS	
4	international destinations) has proven	service must support "message	
4	more unreliable than was originally	delivery notifications", to	
	assumed it would be, due to the	compensate for the unreliability	
	restrictions and SMS delivery	of message delivery, since the	
	failures, imposed by various SMS	latter can be improved but	
	operators.	cannot be avoided altogether.	
CNET	An event driven architecture provides	Component developers need to	
F	an extensible and flexible way for	agree on common event types	
5	loosely coupled components	that all components should	
	interaction. However, to be efficient a	understand.	
	common set of events have to be		
	agreed at system level.		
CNET	The REACTION DCK has been	The REACTION DCK provides a	
6	tested in several applications and	stable and flexible way of	
U	environments.	integrating medical devices in	
		several different scenarios and it	
		can be easily extended to meet	
		new domain requirements.	

Table 6: Lessons Learned in WP5

4.10 Change request and re-engineering originating from WP5

This Section provides an analysis of the six Lessons Learned in WP5 in the third cycle.

4.10.1 Analysis of Lessons Learned

WP5 reported six Lessons Learned from the work performed in the third cycle.

LL WP5-1 is related to the Network Management System and more specifically with its intended implementation deadline.

Lessons LL WP-2 through LL WP5-4 are related to the SMS service which is used in the REACTION back end for the delivery of notification messages to patients and clinicians.

LL WP5-2 involves changes to the programming interface that is used to access the SMS service and the associated security measures that need to be established for the communication. The changes involved were carried out as integration activities in order to make the SMS service accessible from the Primary Care Prototype residing at the UBRUN premises and did not cause any significant delays to the WP schedule.

LL WP5-3 is related with the reliability of the SMS service and the feasibility of the associated requirements.

LL WP5-4 identifies the need for any commercialization actions regarding the SMS service (which could take place after the end of the project) to focus on providing support for delivery notifications.

The last two Lessons Learned refer to the REACTION architecture and the Device Connectivity Kit (DCK).

LL WP5-5 refers to the necessity of a shared event framework by the components of the architecture.

Finally WP5-6 refers to the flexibility of the REACTION DCK in the integration of medical devices in different application scenarios.

No changes to the requirements resulted from the WP5 Lessons Learned in the third cycle.

4.10.2 New/updated/deleted requirements

No requirements were added, updated or deleted.

4.11 Lessons Learned in WP6

The RTD work undertaken in WP6 involves risk assessment and feedback. MSG is the WP leader and four Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
BTS 1	Upgrade to new model Platform and revalidation took longer than expected due to an increase in model complexity.	More time for re-evaluation of model adaptations/upgrades will be scheduled for future model upgrades	
FORTH-ICS 2	The clinical parameters considered in the DCCT study and the clinical parameters usually measured in nowadays European (British) clinical settings may vary considerably.	Clinical and medical data prevenient from diverse sources should be carefully compared in order to verify whether an eventual harmonization is feasible / easy to perform	
FORTH-ICS 3	The Long Term Risk Assessment models are going to be validated on past data extracted from CHC repositories. This type of study is generally called "retrospective validation". There are several ways to design a retrospective validation, and there are several issues to cope with; one over all, the need of collecting a sample that ensures a sufficient statistical power. Moreover, our study is further complicated by the presence of censored data.	A close collaboration among statistical experts and clinicians is needed in order to optimally design a sound retrospective validation.	
MSG 4	Bug fixing and change requests within the influence of the MDD is very work intensive due to needed documentation and needed signatures.	Clear analysis and planning of changes; more effort for testing before start of clinical trial.	

Table 7: Lessons Learned in WP6

4.12 Change request and re-engineering originating from WP6

4.12.1 Analysis of Lessons Learned

WP6 reported four Lessons Learned from the work performed in the third cycle.

BTS will consider more time in the planning of model adaptations in the future. FORTH-ICS will validate their long-term risk models against current population in the database of CHC (with support of clinicians) to ensure that the models work with a known accuracy. MSG will consider elevated effort in the further development of the GlucoTab due to MDD in their planning of new releases.

No new or updated requirements emerged from the Lessons Learned. Three requirements have been removed from the updated set of requirements as being Out of Scope.

4.12.2 New requirements

No requirements were added in the third cycle.

4.12.3 Updated requirements

No requirements were updated.

4.12.4 Deleted requirements

REACTION-192, REACTION-200 and REACTION-243 have been resolved as being Out of Scope.

4.13 Lessons Learned in WP7

The RTD work undertaken in WP7 revolves around security, safety and privacy issues. FHG-SIT is the WP leader and two Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
FHG-SIT 1	Access control rules stated in terms of standard RBAC (Role-Based Access Control) do not allow expressing dynamic constraints, e.g., a nurse may only access data of patients during her own shift. Such constraints require context information, e.g., time and shift plans, in order to be taken into account for access control.	In order to deal with such constraints REACTION's current RBAC language constructs need to be extended and modules for dynamic constraints need to be developed. This is reflected by the introduction of a new requirement "Access control mechanisms should be able to process context information".	
FHG-SIT 2	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, instead of running scripts directly on the database tables.	Administrators of the Profile Management System cannot be assumed to have the same skills as developers. Therefore, administrators must be given 'productivity tools' allowing them to effectively manage the users' data and respond to their requests.	REACTION- 497

Table 8: Lessons Learned in WP7

4.14 Change request and re-engineering originating from WP7

4.14.1 Analysis of Lessons Learned

WP7 reported two Lessons Learned from the work performed in the third cycle.

LL WP7-1 describes the need to sometimes include dynamic information, i.e., data being different for each user, into access control decisions. This is in contrast to simple access control rules where user data is largely fixed once the users is added to the system. Requirement REACTION-480 was created to address this.

In LL WP7-2 it is realised that administrators will not – and should not need to – have in-depth knowledge of the internals of the Profile Management System. Therefore they will need tools providing a reasonable abstraction of the data managed by the PMS in order to allow them to effectively operate and maintain the system. This aspect is addressed in Requirement REACTION-497.

4.14.2 New requirements

The Lessons Learned in the third cycle resulted in the creation of two new requirements.

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

Table 9: New requirements - WP7

4.14.3 Updated requirements

No requirements have been updated.

4.14.4 Deleted requirements

No requirements have been deleted.

4.15 Lessons Learned in WP8

The RTD work undertaken in WP8 relates to clinical practice and associated field trials. MUG is the WP leader and eight Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
MUG 1	The patient recruitment for the first clinical trial took longer than expected.		
MUG	The four blood glucose measurements per day during the	The continuous glucose monitoring with the MiniMed	

2	first clinical trial delivered limited information about the efficacy of the paper-based REACTION algorithm.	Medtronic sensor could give more information about the REACTION algorithm. Study endpoints were defined and into the statistical analysis plan of the first clinical trial included.	
MUG 3	Functionality and calculation problems of the GlucoTab system were seen.	To reduce these problems, the patient data of the first clinical trial were used to test the GlucoTab system before the second clinical trial is performed.	
MUG 4	The questionnaire about the satisfaction with paper-based REACTION algorithm has shown that 7 of 12 nurses think that the work effort is constant or increased with the paper-based REACTION algorithm compared with standard glycaemic care.	An electronic decision and workflow support system should reduce the glycaemic management work effort for medical personnel.	
CHC 5	Device connectivity has proven to be problematic of both the CNet and Brunel acute technology.	Rigorous testing is in place and outcomes logged in order to identify and track issues.	
CHC 6	The user manuals needed to be updated to provide better information for users	User manuals should be developed in conjunction with users and prior to deployment of devices	
BTS 7	Composition of an investigators brochure including system documentation and risk analysis took longer than expected	Preparations for a possible second clinical trial will be initiated earlier	REACTION- 502
BTS 8	The clinical trial layout as described in the clinical protocol was not ideal for the identification of the relevant parameters of the model kernel of the glucose control algorithm	The clamp phase of the clinical trial will be adapted/optimized for model identification for a possible second clinical trial	REACTION- 502

Table 10: Lessons Learned in WP8

4.16 Change request and re-engineering originating from WP8

4.16.1 Analysis of Lessons Learned

WP8 reported eight Lessons Learned from the work performed in the third cycle.

Analysis of Lessons Learned reported by MUG

As a result of LL WP8-1 the inclusion criteria were changed for the pilot trial to speed up the recruitment process. The GlucoTab system was applied to more types of patients.

The results of the continuous glucose monitoring of the first clinical trial gave more information about the REACTION algorithm. The lunch glucose peaks were frequently outside the target range, most likely caused by an elevated morning glucose excursion which was not sufficiently controlled by the administered morning insulin dose. Therefore the bolus insulin dose of the REACTION algorithm was changed in the next clinical trial in 15 patients. The bolus insulin was changed from three equal doses (33% at breakfast, 33% at lunch, 33% at dinner) to 45% at breakfast, 25% at lunch and 30% at dinner. This results from LL WP8-2.

Patient data of the first clinical trial were used to test the GlucoTab system before the second clinical trial to reduce functionality and calculation problems of GlucoTab system as reported in LL WP8-3. Preliminary results show that no calculation problems occurred by using the GlucoTab system during the trial. Functionality problems were documented systematically including description and identification of the problem, risk identification and implemented measures.

The expected result of LL WP8-4 is that the increased workload for the medical personnel with the paper-based REACTION algorithm in the first clinical trial will be reduced by using the GlucoTab system in the pilot trial. A questionnaire at the end of the clinical trial will be performed to assess nurses' experiences about the workload by using the GlucoTab system.

Analysis of Lessons Learned reported by CHC

During pre-pilot testing, reliable physiological device connectivity to the gateways was found to be an issue. As reported in LL WP8-5 this resulted in data not being transmitted in a reliable or timely manner. While these issues were being resolved, data was recorded manually on paper and/or on the patient portal in order to cross-match data and test for accuracy. Discrepancies were logged and fed back to the technical partners.

LL WP8-6 addresses the importance of involving the end users, also regarding user manuals, etc.

Analysis of Lessons Learned reported by BTS

The investigator brochure was successfully finalised and the clinical trial could be started in time. As addressed in LL WP8-7, the investigators brochure and the experiences of the first clinical trial will be implemented in the next investigator brochure. The expected workload will be less than the first time.

The identification of the relevant parameters of the model kernel was difficult in the current investigation due to lack of dynamics of the glucose signal before start of the control using the algorithm. Therefore parameter identification was repeated after glycaemic load and the improved parameters were changed during the trial which improved the results considerably. For the next clinical investigation the protocol will be changed to guarantee dynamic glycaemic changes before the start of the experiment. This was based on the findings in LL WP8-8.

4.16.2 New requirements

No new requirements have been defined.

4.16.3 Updated requirements

Requirement REACTION-502 has been updated. This requirement is a Sub-task of REACTION-501, see under WP3 (Section 4.6.2).

4.16.4 Deleted requirements

No requirements have been deleted.

4.17 Lessons Learned in WP9

The work undertaken in WP9 relates to the socioeconomic framework of the REACTION project. VUB is the WP leader and four Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
FORTH-ICS 1	Involving end users through focus groups provides important knowledge and insight for how the application will be useful but also for how the application can be commercially exploited at a national level.	Discussion with end users provides significant insights for the development and exploitation of new technologies.	
VUB	Liability regimes for product liability and medical liability differ	Knowledge of Member State legislation with regard to liability	

2	considerably in EU Member States. EU legislation provides only a basic framework for product liability but does not bring complete harmonisation of Member State legislation.		
VUB 3	REACTION is supposed to be used in different cultural and social settings. Expectations and needs of users therefore differ.	The possibility to configure REACTION applications is essential. Different language settings, icons and the possibility to individualise privacy settings could be a response.	REACTION- 494, REACTION- 495
VUB 4	Mistakes of users (care providers, patients) and data processors when entering and processing health data are to be expected.	It must be possible to rectify data. Additionally, patients have the right to erase and block their (health) data.	REACTION- 493

Table 11: Lessons Learned in WP9

4.18 Change request and re-engineering originating from WP9

4.18.1 Analysis of Lessons Learned

WP9 reported four Lessons Learned from the work performed in the third cycle.

LL WP9-1 reports that FORTH-ICS used focus groups for one of the deliverables in WP9. This has been found a useful tool in order to gain insights regarding the development of new technologies and their subsequent exploitation.

LL WP9-2 notes the limited harmonisation of legislation in the area of product liability. With regard to medical liability there is no EU legislation. Member State legislation in the area of liability differs considerably. If REACTION services are used in different Member States knowledge of the respective national law is inevitable. Particularly, in a cross-border context the different jurisdictions can lead to problems and an exact analysis of the legal situation is necessary. For details, refer to *D9-3 Product liability issues in REACTION applications*.

LL WP9-3 acknowledges differences in culture and in social background throughout Europe and also within countries. To be responsive to such differences and the expectations and needs different groups of users might have it is necessary to be able to configure REACTION applications individually. Next to different languages in which REACTION services need to be available, it should be considered if different icons and symbols need to be used and how the applications can be responsive to different educational backgrounds of users. The technical illiteracy of certain groups can limit the application of REACTION. Furthermore, the possibility to individualise privacy settings should be considered. Requirements REACTION-494 and REACTION-495 were created to address adjustability for the clinical portal and the patient portal, respectively.

LL WP9-4 describes that making mistakes during entering data and in data processing is possible. These mistakes can have great impact in the area of health. Patients therefore have the right to correct, rectify or block their personal (health) data. Ex-post control of personal data by patients is addressed in REACTION-493.

4.18.2 New requirements

Three requirements have been added in the third cycle.

Кеу	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION- 493	Non- functional - Legal	Major	The user must be able to correct, rectify, block or	People make mistakes and novel information may	Levels of ex-post user control that can be

	1				
			erase personal data that has		distinguished are:
			erase personal data that has been disclosed.	render earlier decisions unfortunate. This goes for users and service providers alike. User control mandates that users can correct mistakes they, or the service providers, make with respect to their data. A step further is that users also have the possibility to reset choices they made. If users are not content with the way their data is used, they should be able to recall or change the access rights to their data. In legal terms, this requirement derives from article 12 of the Data Protection Directive which provides a right to the user to access personal data provided. Access to the data is a prerequisite to rectify, or even block or erase, the personal data that is stored.	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?
				provided. Access to the data is a prerequisite to rectify, or even block or erase, the personal data that is stored. This is strengthened in the new proposal on a data protection	
REACTION- 494	Non- functional - Cultural and political	Major	It should be possible to configure the application to different socio- cultural settings - Patient Portal	framework of the EC. 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?

Table 12: New requirements – WP9

4.18.3 Updated requirements

No requirements have been updated.

4.18.4 Deleted requirements

Requirements REACTION-142, REACTION-143 and REACTION-147 have been resolved as being Duplicates. REACTION-148, REACTION-149 and REACTION-150 have been resolved as being Out

of Scope. REACTION-474, REACTION-476 and REACTION-477 have been resolved with resolution 'Cannot be implemented'.

4.19 Lessons Learned in WP10

The work undertaken in WP10 involves platform integration and implementation. FORTH-ICS is the WP leader and 15 Lessons Learned have been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
CHC 1	Existing browsers within patients homes were not supported by REACTION Patient Portal which meant that certain functions were not able to be used by the patient.	Better understanding required of technology used by target users of the patient portal.	
CHC 2	Updating of portals has had affects on end users ability to use the clinical and patient portal.	Fully test updates before they are released to end users. Communicate updated to end users before undertaking the update.	
CHC 3	Existing user manuals were not sufficient to support the drop ship of patient gateway.	Develop manuals with the target user group to understand requirements.	
FORTH-ICS 4	Diabetes management is scientifically managed in a similar manner throughout Europe. However, the national health system practices & culture have a significant effect on how people with diabetes experience their disease.	The practices and culture of national health systems should be taken into consideration for the exploitation future of a remote management system.	
FORTH-ICS 5	It may happen that agreed procedures may not be understood or put into practice in a common way by the involved partners, causing delays in the development process.	Even if agreements on specific procedures have been obtained among involved partners, procedures have to be written on papers and continuously checked in order to minimize occurrences of misunderstanding which may hamper and delay the design, development and integration process.	
FORTH-ICS 6	It can happen that the deployed system in different (test or pilot) sites has different versions of the components and presents a different behaviour.	In order to facilitate the verification and validation phases, each component should have the capability of displaying its version number (e.g. in the "About" menu).	REACTION- 68
FORTH-ICS 7	Users in in-hospital pilot site are well- trained and fully satisfied with the use of the PoC device.	PoC device use is consolidated in in-hospital pilot site. This device will be used in the clinical trials.	REACTION- 225
FORTH-ICS 8	Fever chart management is not a main requirement for the glucose management system in in-hospital environment.	It is not necessary to implement an electronic fever chart in the glucose management system for the in-hospital environment.	REACTION- 238 & REACTION- 250

UBRUN 9	Components should reflect national requirements, policies, guidelines or provisions.	Components should be flexible to match these national requirements.	REACTION- 492
MSG 10	More detailed description of user interfaces for the primary care environment might be necessary.	All user interfaces in all front- end applications must be accurately described.	REACTION- 496
CNET 11	Installation of multiprotocol home gateway ("Black Box") went smooth although some technical factors in the home could not be foreseen. Installation time was around 30 minutes.	Need to develop a check point questionnaire that reflects the technical infrastructure of patient's home, i.e. ask the right questions and get the right answers. Following this questionnaire might lower unanticipated installation time or the installation could be done by the patients themselves.	
MSG 12	In general wards, insulin is generally administered subcutaneously. In intensive care and intermediate care, insulin is often administered intravenously, but not injected but administered as insulin infusion.	Insulin infusion is not an aim of REACTION, we always aimed at the general ward. A system for insulin infusion was developed in the EU project CLINICIP.	REACTION- 240
CNET 13	The REACTION platform can flag when a value is out of range.	However, the use of a video- conference (e.g. Skype telco) is up to the clinicians and patients.	REACTION- 212
IN-JET 14	Clinicians are responsible for prescriptions.	It is Out of Scope for the REACTION platform to ensure that OADs are not prescribed for Type 1 diabetic patients on insulin.	REACTION- 185
UBRUN 15	Since it is error-prone and undesired by end users (time-consuming) double input of data should be avoided.	Some data are regularly stored in the EPR (e.g. regular visits/reviews) and this information should not be duplicated in the REACTION database.	REACTION- 194

Table 13: Lessons Learned in WP10)
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4.20 Change request and re-engineering originating from WP10

WP10 reported 15 Lessons Learned from the work performed in the third cycle. The work resulted in two requirements being added and four updated. 7 requirements were deleted (i.e., resolved as Out Of Scope or Duplicate).

4.20.1 Analysis of Lessons Learned

The main outcomes of Lessons Learned are:

LL WP10-1 refers to the browser compatibility at patients' homes. This LL is covered by requirement REACTION-76 (specifying the most common operating systems) and REACTION-77 (specifying 2 last versions of the 5 most common browsers). Actually the REACTION patient portal in its last version has an even more high level of compatibility since it works fine with Internet Explorer 8+, Mozilla Firefox12+, Google Chrome 15+, Opera 10+, Safari 5+ and Dolphin HD+ (which are by all means the most common browsers worldwide), and with the three major desktop operating systems (Windows XP+, Mac OS X 10.7+, Ubuntu Linux 10.04+) as well as with the three major mobile operating systems (iOS5, Android 3+, WP7+). No need for any change in the existing requirement is thus foreseen.

LL WP10-2 refers to some problems faced during the initial tests with a small subset of real patients. Those problems were due to changes in the database schema which produced a side effect in the patient portal. Since any change in common modules of the back end can have a serious impact in other existing components, better communication has to be guaranteed in the development group and guidelines in such direction have been agreed among the consortium and issued by the coordinator.

LL WP10-3 refers to the need of having more accurate manuals for the user and the technical people, but this issue is already covered by requirements REACTION-41 and REACTION-139. Of course manuals have to be updated till the last version of components will be released.

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

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

LL WP10-6 points out some problems emerged during the verification and the initial validation phase, when different versions of components were used in different sites. Since this is a situation that can happen again, it would be useful to have the version of the main components easily identifiable at runtime. This LL had an impact in REACTION-68 which was modified accordingly.

LL WP10-7 and FORTH-ICS-8 refer to the first results of the in-hospital clinical trials and identified that end users like to work with the PoC device (and do not want to change) and do not use the electronic fever chart. These LLs had impact in REACTION-225, REACTION-238 and REACTION-250 which were modified accordingly.

LL WP10-9 is in a certain way related to LL WP10-4 and addresses the same concerns but at the component level. A new specific requirement (REACTION-492) was added reflecting this LL.

LL WP10-10 is in a certain way related to LL WP10-3 and addresses the same concerns but at the end user level in all environments and specifically for the user interfaces. A new specific requirement (REACTION-496) was added reflecting this LL.

LL WP10-11 describes the complexity of the installation phase in different patient homes and addresses the need to reduce the installation time or, even better, the capability to make the end-user capable of performing the installation by himself. It is possible that new requirement(s) may be added during the next iteration period.

LL WP10-12 addresses the glucose management in general ward (as foreseen by the REACTION project) excluding the glucose management in intensive or intermediate care (not foreseen by the REACTION project) and consequently the intravenous administration of insulin. For this reason, REACTION-240 was deemed out of scope.

LL WP10-13 separates the capability of the REACTION platform of flagging out of range values by the use of video conference that can instead be activated by clinicians or patients every time a specific need arises. For this reason, REACTION-212 was deemed out of scope.

LL WP10-14 deals with the fact that responsibility for prescriptions is of clinicians and thus it is not out of scope for the REACTION platform to ensure that OADs are not prescribed for Type 1 diabetic patients on insulin. Consequently, REACTION-185 was deemed out of scope.

LL WP10-15 deals with the issue of avoiding double inputs which are error prone and time consuming. An immediate consequence is to avoid inserting the results of regular visits and reviews also in REACTION since these data are already collected in the EPR. Consequently, REACTION-194 was deemed out of scope.

4.20.2 New requirements

Two new requirements have been added as a consequence of LL WP10-9 and WP10-10. Details are shown in the table below.

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

Table 14: New requirements – WP10

4.20.3 Updated requirements

Four requirements were reviewed and updated as a consequence of LL WP10-6, WP10-7 and WP10-8.

Details of the modified requirement are shown below.

Кеу	Requirement Type	Priority	Summary	Rationale	Fit Criterion
REACTION- 68	Functional - REACTION platform	Major	Component Versioning	menu). In this way we should be able to reduce misunderstandings in setting up varios testing	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/com ponents.
REACTION- 225	Functional – In-hospital pilot application	Major	PoC device for blood glucose measureme nt will be	The first-year prototype has to be ready quite early and at that time no sufficient development will be made for the	a) The blood glucose measurement in the first-year prototype will be

Кеу	Requirement Type	Priority	Summary	Rationale	Fit Criterion
			used by the in-hospital glucose managemen t system	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.	performed in the same way in which it is currently performed. b) The acquired measurements will be manually inserted using the front-end in the tablet PC and stored in the REACTION data management.
REACTION- 238	Functional – In-hospital pilot application	Major	Update and entering of drug administrati on (OAD and/or insulin) data	Drug administration (time, type, dosage and other relevant information) has to be immediately annotated by the administering nurse.	The nurse through an appropriate user interface can check the last drug administration and insert the relevant data related to the drug administration she has just performed.
REACTION- 250	Functional – In-hospital pilot application	Major	Different contextualiz ation of the patient clinical information	Different modes of visualisation with different relevant parameters for decision support shall be foresee. The relevant data have to be displayed contextualized. The relevant values have to be highlighted.	The possibility of configure the display of the patient clinical data (mainly the sugar chart) has to be present.

Table 15: Updated requirements – WP10

4.20.4 Deleted requirements

REACTION-15, REACTION-185, REACTION-194, REACTION-196, REACTION-212, REACTION-216 and REACTION-240 have been resolved as being Out of Scope. REACTION-191 has been resolved as being Duplicate.

4.21 Lessons Learned in WP12

WP12 is responsible for dissemination and exploitation activities in the REACTION project. IN-JET is the WP leader and one Lesson Learned has been collected and validated from this WP.

Org.	Experience and knowledge gained	Lesson Learned	Requirement
No.			affected
FORTH-ICS 1	Any dissemination activity should give credit to all partners involved in the building process of the components, subsystems or systems which it is disseminating	Dissemination activities should be performed in the full respect of the IP of the involved partners	

Table 16: Lessons Learned in WP12

4.22 Change request and re-engineering originating from WP12

WP12 reported one Lesson Learned in the third iteration cycle. Due to the nature of WP12, this has not resulted in changes to the requirements.

4.22.1 Analysis of Lessons Learned

LL WP12-1 concerns dissemination activities at other than consortium level and stresses the obligation of each individual partner to ensure that all contributing partners are given proper credit for their contribution to components or other building blocks forming part of this dissemination. This is already stipulated in the Consortium agreement and should be strictly adhered to.

4.22.2 New/updated/deleted requirements

No requirements have been added, updated or deleted.

4.23 Other Work Packages

No Lessons Learned have been reported for WP11 or WP13 in the third iteration cycle.

5 Validation results – In-hospital prototype

5.1 Summary of verification results

These verification results refer to the third year prototype development process. Specifically this verification phase has been performed using the source code release-1.4.1 (in the FTP repository) of the REACTION components (i.e., back end and front end). The development process has been conducted meeting the procedures listed in *ID2-6-2 Prototype Application Specification 2*. The Inhospital prototype has been structured into two main layers. The back end layer contains the implementation of several services (GlucoManSys) and the front end layer contains the user interface (UI) implementation (GlucoManSysFrontEndAndroid). Table 17 presents a mapping of the implemented services (in the left column) of the back end mapped in the system main functionalities (in the right column) required for the third year prototype.

Back end (server) functionalities	REACTION system functionalities for In-hospital prototype
UserService	User Management
EnrolmentService FacilityService PatientDataManagementService PrintService	Ward Management
TherapyService MeasurementService PatientService DrugService ProposedMedication Service MedicationService RecentActivitiesService NutritionService	Data Management (i.e., Glucose and Drug Management)
TaskManagementService	Open Task Management
BasalBolusTherapyRegimentHandlerService	Decision Support System

Table 17: Mapping between implemented services and main functionalities

The complete list of the implemented services (left column) in the back end can also be mapped into the use cases shown in Figure 1, presenting in more details the required functionalities to be accomplished by the in-hospital prototype. Each specific implemented service consists of sub-functions (methods) which are able to address and satisfy the sub-cases shown in the figure.

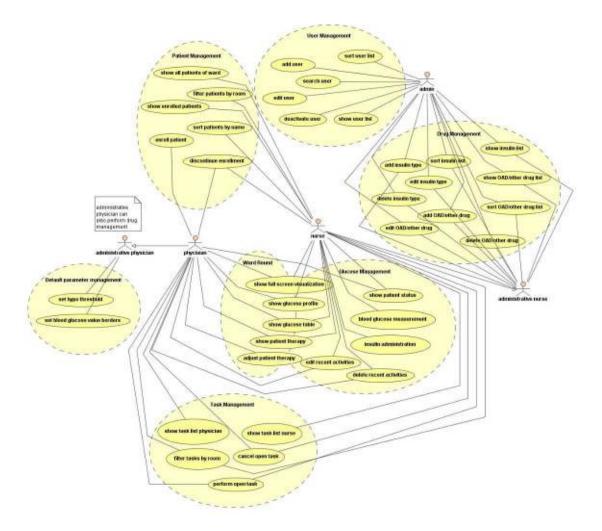


Figure 1: Use cases from ID 2-6-2

5.1.1 Back end unit tests

The unit tests that evaluate the back end development can be divided in two major categories, Domain tests and Service tests.

Domain tests are the unit tests that evaluate data persistence functionality (DAO tests). These, more into details, have to do with Entity functions that implement data persistence transactions (i.e., Create, Read, Update and Delete) and the required transformation procedures regarding the value objects (i.e., the objects that are being exposed as input/output of the business logic). These entity functions have to be tested in specific test cases in order to verify their proper operation and transformation, providing the expected results. This stage is essential in order to proceed with the next development level which is the service implementation.

The domain test report has been summaeised in Appendix A.

Service tests are the next level of the development phase and represent the functions that would be exposed and used from the front end application due to various use cases. Moreover the service tests provide an assessment mechanism for the proper execution of the business logic of the back end.

The service test has been divided in the following categories:

- DSS tests
- Medication tests
- Nutrition tests
- Patient tests
- Recent Activities tests

- Task manager tests
- Therapy tests
- User tests
- Enrolment tests
- Measurement tests

Each of these categories contains test cases for the methods which have to succeed for a successful verification of their operation.

The results of the test cases for each of the above categories are shown in Appendix B.

5.1.2 Unit and integration tests back end

Figure 2 provides a summary of all backend unit and integration tests performed for GlucoTab R1.4 and R1.4.1. All tests have been successful, two tests have been skipped.

ID	Name	Number PASSED	Number SKIPPED	Number FAILED
SC_B01	PatientWebService	17	0	0
SC_802	PatientDataManagementWebService	56	0	0
SC_803	UserWebService	12	0	0
SC_B04	DrugWebService	6	0	0
SC_B05	EnrolmentWebService	22	0	0
SC_BO6	TherapyWebService	47	0	0
SC_807	MeasurementWebService	34	0	0
SC_BO8	MedicationWebService	37	0	0
SC_809	NutritionWebService	30	0	0
SC_B10	BasalBolusTherapyRegimenHandlerWebService	75	0	0
SC_B11	TaskManagementWebService	31	0	0
SC_B12	RecentActivitiesWebService	5	0	0
SC_B13	ConfigurationWebService	7	2	0
SC_B14	SharedCommon	70	0	0
SC_B16	FrameworkUtility	7	0	0
SC_B17	PrintWebService	49	0	0
SC_101	HL7v2Interface	84	0	0

Components

Figure 2: Summary of back end unit and integration tests

5.1.3 Front end unit tests

Figure 3 presents all unit test cases for the front end of the GlucoTab R1.4/R1.4.1. All tests have been successful (as indicated by the green colour).

	Unit Tests		
Test Case ID	Test Case Name		
TC_PatientManagementTests_0	testCheckActivityActionBar		
TC_PatientManagementTests_1	testCheckPatientListDefaultPresentation		
TC_PatientManagementTests_2	testCheckPatientListWithoutPatients		
TC_PatientManagementTests_3	testPatientListOnClickListener		
TC_PatientManagementTests_4	testSortAndFilterIngPatientLists		
TC_PatientEnrolmentTests_0	testCheckPatientEnroimentActivityActionBar		
TC_PatientEnrolmentTests_1	testCheckPatientEnroImentActivityInUpdateMode		
TC_PatientEnroimentTests_2	testCheckPatientEnroimentActivityWithAireadyEnrolledPatient		
TC_PatientEnrolmentTests_3	testCheckPatientEnroimentActivityWithNeverEnrolledPatient		
TC_TaskManagementTests_0	tsstCheckCorrectPresentationOFTasks		
TC_TaskManagementTests_1	testCheckTaskListWithoutPatients		
TC_TaskManagementTests_2	testCheckTaskListWithoutTasks		
TC_TaskManagementTests_3	tsatCheckTaskManagementActivityActionBar		
TC_TaskManagementTests_4	testTaskListOnCilckListener		
TC_StartScreenTests_0	festCheckStartScreenActivityActionBar		
TC_GMMainScreenTests_0	testCheckGMMainScreentActivityActionBar		
TC_GMMainScreenTests_1	testCheckPatientDetallsInBasalBolusRegimen		
TC_GMMainScreenTests_2	testCheckPatientDetailsinNonSupportedRegimen		
TC_GMMainScreenTests_3	festCheckPermissionsinBasalBolusRegimen		
TC_GMMainScreenTests_4	testCheckPermissionsinNonSupportedRegimen		
TC_GlucoseTableTests_0	testCheckGlucoseTable		
TC_GlucoseProfileTests_0	testCheckGlucoseProfile		
TC_FullScreenTests_0	testCheckPatientDetailsinFullScreen		
TC_FullScreenTests_1	testCheckTherapyProfileContainsAllExpectedPoints		
TC_FullScreenTests_2	testCheckTherapyProfileScaling		
TC_BGMeasurementTests_0	testCheckBGMeasurement		
TC_BasalBolusinsulinAdministrationTests_0	testCheckinsulinAdministrationinBasalBolus		

TC_NonSupportedInsulInAdmInistrationTests_0	testCheckInsulinAdministrationInNonSupported
TC_TherapyAdjustmentTests_0	testCheckDallyDoseAdjustment
TC_TherapyAdjustmentTests_1	testDallyDoseAdjustmentAireadyPerformed
TC_BasalBolusTherapySettingsTests_0	testCheckBasalBolusTherapySettings
TC_NonSupportedRegImenTherapySettingsTests_0	testCheckNonSupportedTherapySettings
TC_TaskUpdaterServiceTests_0	testisTaskUpdaterServicelsStartable
TC_TaskUpdaterServiceTests_1	testServiceTestCaseSetUpProperty
TC_TaskUpdaterServiceTests_2	testAndroidTestCaseSetupProperly
TC_BroadcastServiceTests_0	testsBroadcastServicelsStartable
TC_BroadcastServiceTests_1	tastServiceTestCaseSetUpProperty
TC_BroadcastServiceTests_2	testAndroidTestCaseSetupProperty
TC_AndroidindependentUtilsTests_0	testCalculateTherapyPlanWithReactionAlgo
TC_AndroidIndependentUtilsTests_1	testDateFormatUtilMethods
TC_AndroidIndependentUtilsTests_2	festFilterActivitiesByLastVersion
TC_AndroidIndependentUtilsTests_3	testGetInformationAboutLastBGMeasurement
TC_AndroidIndependentUtilsTests_4	testGetLastTherapyDate
TC_AndroidIndependentUtilsTests_5	testGetMillisecondsForHours
TC_AndroidIndependentUtilsTests_6	testGetProductCodeOfOrderedinsulin
TC_AndroidIndependentUtilsTests_7	testisActualBGAvailable
TC_AndroidIndependentUtilsTests_8	testParseDateUtilMethods
TC_YesNoDialogTests_0	testYesNoDialogFunctionality
TC_AddTaskDialogTests_0	testCheckAddTaskDlalogFunctionality
TC_CaicDailyInsulinDoseDlalogTests_0	testCalcDallyInsulInDoseDialogFunctionality
TC_ChartPointinfoDialogTests_0	testChartPointinfoDialogFunctionalityWithBG
TC_ChartPointinfoDialogTests_1	feetChartPointInfoDialogFunctionalityWithBGInHistoryMode
TC_ChartPointinfoDialogTests_2	testChartPointInfoDlaiogFunctionalityWithBolusinsulin
TC_ChartPointinfoDlalogTests_3	testChartPointinfoDialogFunctionalityWithNutrition
TC_DailyinsulinDoseDialogTests_0	testDallyInsulInDoseDlalogFunctionality
TC_DateTimeDialogTests_0	testDateTimeDialogFunctionality
TC_ListOperatorDialogTests_0	testListOperatorDialogFunctionality
TC_ListSelectorDialogTests_0	testListOperatorDialogFunctionality
TC_LowerUpperBorderDlalogTests_D	testLowerUpperBorderDlaiogFunctionality
TC_MessageDialogTests_0	testMessageDialogFunctionality
TC_RangeDialogTests_0	testRangeDialogFunctionality
TC_RootDialogTests_0	testRootDialogWithFunctionality

TC_SelectBasalBolusInsuInDIalogTests_0	testSelectBasalBolusInsulInDIalogFunctionality
TC_SelectFreeInsulInDIalogTests_0	testSelectFreeInsulInDIalogFunctionality
TC_SelectTabletsDialogTests_0	testSelectTabletsDialogFunctionality
TC_TaskDetailsDlalogTests_0	testTaskDetailsDialogFunctionalityWithBG
TC_TaskDetailsDlalogTests_1	testTaskDetailsDialogFunctionalityWithMedication
TC_TaskDetailsDlalogTests_2	testTaskDetailsDialogFunctionalityWithTA
TC_TextinputDialogTests_0	testTextInputDialogFunctionality
TC_WheelPickerDialogTests_0	testWheelPickerDialogFunctionality
TC_DateDialogTests_0	testDateDialogFunctionality
L	

Figure 3: Summary of front end unit tests

5.1.4 Integration test front end

Figure 4 presents the performed integration test for the front end. All tests have been successful (green colour).

Component Tests				
Test Case ID	Test Case Name			
TC_IntegrationTests_0	test1UserManagement			
TC_IntegrationTests_1	test2ConfigurationManagement			
TC_IntegrationTests_2	test3HistoryManagement			
TC_IntegrationTests_3	test4GlucoseManagement			
TC_IntegrationTests_4	test5PatientManagement			
TC_IntegrationTests_5	test6TaskManagement			
TC_IntegrationTests_6	test7TherapySettings			
TC_IntegrationTests_7	test8TherapyVIsualization			

Figure 4: Summary of front end integration tests

5.1.5 Web service tests

In the following sections web service tests for the GlucoTab R1.4 and R1.4.1 are presented. All tests have been successful.

5.1.5.1 Result overview

Component	tests	errors	faults	skipped	Success rate	time
WebServiceTests	79	0	0	0	100%	36,663

Figure 5: Result overview

5.1.5.2 WebServiceTests package

		Component	tests	errors	faults	skipped	Success rate	time
--	--	-----------	-------	--------	--------	---------	-----------------	------

	TaskManagementServiceSoapBindin g TestSuite	6	0	0	0	100%	1,274
<u> </u>	Utility TestSuite	1	0	0	0	100%	0,128
<u></u>	UserServiceSoapBinding TestSuite	3	0	0	0	100%	0,277
<u> </u>	DrugServiceSoapBinding TestSuite	3	0	0	0	100%	0,55
	PatientDataManagementServiceSoa pBinding TestSuite	10	0	0	0	100%	2,814
	EnrolmentServiceSoapBinding TestSuite	5	0	0	0	100%	1,129
	PrintServiceSoapBinding TestSuite	8	0	0	0	100%	13,775
<u></u>	TherapyServiceSoapBinding TestSuite	8	0	0	0	100%	3,55
<u> </u>	BasalBolusTherapyRegimenHandler ServiceSoapBinding TestSuite	6	0	0	0	100%	6,247
<u> </u>	RecentActivitiesServiceSoapBinding TestSuite	3	0	0	0	100%	0,58
	PatientServiceSoapBinding TestSuite	4	0	0	0	100%	0,481
	NutritionServiceSoapBinding TestSuite	6	0	0	0	100%	1,347
	MeasurementServiceSoapBinding TestSuite	7	0	0	0	100%	1,502
	MedicationServiceSoapBinding TestSuite	6	0	0	0	100%	2,251

Figure 6: Results from Web Service Tests package

5.1.5.3 Test case results

5.1.5.3.1 TaskManagementServiceSoapBinding TestSuite

	DB Clean	0,06
2	DB Init	0,127
2	createTask TestCase	0,062
2	findTasks TestCase	0,646
2	resolveTask TestCase	0,247
	cancelTask TestCase	0,132

Figure 7: Results from Task Management tests

5.1.5.3.2 Utility TestSuite

		1
🗻	DB Clean	0,128

Figure 8: Results from Utility test

5.1.5.3.3 UserServiceSoapBinding TestSuite

	DB Clean	0,076
<u>a</u>	DB Init	0,112
2	findUsers TestCase	0,089

Figure 9: Results from User Service tests

5.1.5.3.4 DrugServiceSoapBinding TestSuite

	DB Clean	0,107
	DB Init	0,171
2	DrugServiceSoapBinding TestSuite	0,272

Figure 10: Results from Drug Service tests

5.1.5.3.5 PatientDataManagementServiceSoapBinding TestSuite

	DB Clean	0,081
	admitPatient TestCase	0,829
	cancelAdmission TestCase	0,265
	cancelAdmission patient enrolled TestCase	0,243
	dischargePatient TestCase	0,284
	dischargePatient patient enrolled TestCase	0,422
	cancelDischarge TestCase	0,335
	mergePatientInformation Surviving Patient Not exists TestCase	0,122
2	transferPatient TestCase	0,116
	updatePatientInformation TestCase	0,117

Figure 11: Results from Patient Data Management tests

5.1.5.3.6 EnrolmentServiceSoapBinding TestSuite

2	DB Clean	0,071
<u>a</u>	DB Init	0,184
2	startEnrolment TestCase	0,576
<u>a</u>	updateEnrolment TestCase	0,124
2	stopEnrolment TestCase	0,174

Figure 12: Results from Enrolment Service tests

5.1.5.3.7 PrintServiceSoapBinding TestSuite

2	DB Clean	0,041
<u>a</u>	DB Init	0,36

2	printDailyDoseAdjustment TestCase	3,584
2	printGlucoseSummary TestCase	5,698
2	printInsulinAdministration TestCase	1,344
	printMedicationAdministration TestCase	0,852
<u>a</u>	printPatientSummary TestCase	0,947
	printTherapyInitialization TestCase	0,949

Figure 13: Results from Print Service tests

5.1.5.3.8 TherapyServiceSoapBinding TestSuite

	DB Clean	0,034
	DB Init	0,376
2	findTherapySettings TestCase	0,412
2	getCurrentTherapySettings TestCase	0,217
	getLatestInsulinDoseAdjustment TestCase	0,216
	addNewInsulinDoseAdjustment TestCase	0,772
	addNewTherapySettings TestCase	1,286
	updateCurrentTherapySettings TestCase	0,237

Figure 14: Results from Therapy Service tests

5.1.5.3.9 BasalBolusTherapyRegimenHandlerServiceSoapBinding TestSuite

2	DB Clean	0,23
	DB Init	0,763
	getCurrentDailyInsulinDose TestCase	3,77
<u>.</u>	getInitialDailyInsulinDose TestCase	0,558
2	getNewDailyInsulinDose TestCase	0,511
	getPartialInsulinDoseRecommendation TestCase	0,415

Figure 15: Results from Insulin Handling Service tests

5.1.5.3.10 RecentActivitiesServiceSoapBinding TestSuite

2	DB Clean	0,033
2	DB Init	0,183
	IoadRecentActivities TestCase	0,364

Figure 16: Results from Activities Service tests

5.1.5.3.11 PatientServiceSoapBinding TestSuite

	DB Clean	0,039
2	DB Init	0,13
2	findPatients TestCase	0,198

loadPatientEnrolment TestCase 0,114

Figure 17: Results from Patient Service tests

5.1.5.3.12 NutritionServiceSoapBinding TestSuite

	DB Clean	0,079
2	DB Init	0,223
2	addNutrition TestCase	0,482
2	findNutritions TestCase	0,163
2	updateNutrition TestCase	0,204
2	deactivateNutrition TestCase	0,196

Figure 18: Results from Nutrition Service tests

5.1.5.3.13 MeasurementServiceSoapBinding TestSuite

🙇	DB Clean	0,035
🙇	DB Init	0,153
2	addMeasurement TestCase	0,463
	deactivateMeasurement TestCase	0,456
	findMeasurements TestCase	0,201
🙇	loadMeasurementTypes TestCase	0,031
2	updateMeasurementRecord TestCase	0,163

Figure 19: Results from Measurement Service tests

5.1.5.3.14 MedicationServiceSoapBinding TestSuite

	DB Clean	0,04
	DB Init	0,353
2	addMedicationRecords TestCase	0,508
	findMedications TestCase	0,682
2	updateMedicationRecord TestCase	0,21
	deactivateMedicationRecord TestCase	0,458

Figure 20: Results from Medication Service tests

5.1.6 In-vitro tests

The REACTION insulin titration protocol was investigated in a paper-based clinical trial (PBCT). In order to validate the GlucoTab system, data from this trial was used for simulation and system tests. In total, 1190 decision support action points were identified and simulated. Four data points (0.3%) resulted in a GlucoTab system error caused by a defective implementation. In 144 data points (12.1%), calculation errors of physicians and nurses in the PBCT were detected. The test framework was able to verify manual calculation of insulin doses and detect relatively many user errors and workflow anomalies in the PBCT data.

5.1.7 Integration testing

Integration testing is the phase in software testing in which individual software modules are combined and tested as a group. It is the next step after unit testing and before system testing. Integration testing takes, as its input, modules that have been unit tested, groups them in larger aggregates, applies tests defined in an integration test plan to those aggregates, and delivers as its output the integrated system ready for system testing.

The integration test has to be performed with the front end and back end components. The integration process has to test all the available back end services that are being activated by the front end application. The procedure regarding the integration testing and the findings is provided below:

Step 1: Deployment of the binary back end component from the FTP (i.e., glucomansys-webservice...war) to Tomcat server.

Status: SUCCESS

Step 2: Installation of the binary front end component to device from the FTP (according to the guidelines).

Status: SUCCESS

Comments: The application has been installed there was an issue with the security component.

Solution: The issue was due to a missing configuration of the xml access files that should putted on the tablet.

Step 3: Initialization of the database and back end integration testing.

Status: SUCCESS

Step 4: Front end integration testing with the back end

Status: SUCCESS

Comments: The front–end component is able to connect with the back end and to access all the services properly.

No modifications were needed by the development team.

The current stable release of the In-hospital prototype is the release-1.4.1 tagged in FTP repository. The integration process has to test all the available back end services that are being activated by the Front end application. Thus there is a need to define which web services in the back end have been:

- Fully integrated
- Partially integrated
- Not integrated

Table 17 represents all back end services and level of integration of the front end for release-1.4.1:

Back end Services	Integration status with the front end
PatientService	Fully integrated
EnrolmentService	Fully integrated
TherapyAdjustmentService	Fully integrated
MedicationService	Fully integrated
MeasurementService	Fully integrated
DrugService	Fully integrated
FacilityService	Fully integrated
ProposedMedicationService	Fully Integrated
UserService	Fully integrated
PatientDataManagementService	Fully Integrated
TaskManagementService	Fully Integrated
BasalBolusTherapyRegimenHandlerService	Fully Integrated
RecentActivitiesService	Fully Integrated
NutritionService	Fully Integrated
PrintService	Fully Integrated

Table 18: Level of integration between the back end services and the front end

Table 18 shows that in the current release, the back end and front end components are fully integrated. The current version of the prototype is currently in clinical trials at the Medical University of Graz.

5.1.8 System tests

System testing is testing conducted on a complete, integrated system to evaluate the system's compliance with its specified requirements. System testing falls within the scope of black box testing, and as such, should require no knowledge of the inner design of the code or logic. All the functional requirements that were determined in *ID2-6-2 Prototype Application Specification 2* were filtered including only the ones impacting on the third year in-hospital prototype. Some requirements that have the status of "duplicates" and "out of scope" have been omitted.

Specific tests have been performed in order to specify which of the functional requirements have been satisfied and the level of the satisfaction. Four levels of satisfaction have been defined and assigned in each of the functional requirements involved:

- Fully satisfied
- Partially satisfied
- Improperly satisfied
- Not satisfied

The distribution is shown in Figure 21.

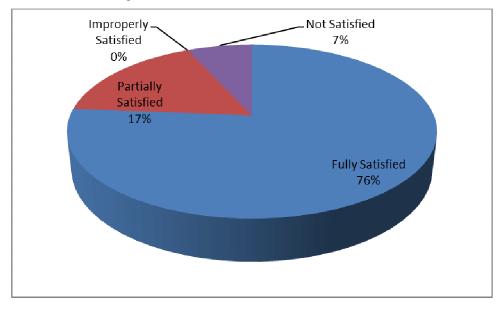


Figure 21: Satisfaction of requirements for third-year in-hospital prototype

In some cases additional tools have been used in order to populate the database and to be able to run specific tests referring to specific requirements.

It must be noted that for several requirements the complete satisfaction of the requirement itself has been gradually scheduled during the entire course of the project, thus the sentence "partially satisfied" has to be seen as "satisfied for the implementation foreseen in the third year (even if implementation has to continue in the next years)".

Details of the satisfaction of requirements are listed in Appendix C.

5.2 Summary of validation results

5.2.1 Summary of results from usability testing

At the beginning of the project nurses filled out a questionnaire about their experience about current glycaemic management. More than 80% of the nurses stated that glycaemia and insulin therapy are

regularly evaluated (Figure 22). Procedures regarding glycaemic management in case of "nothing per mouth" orders were familiar to 57%. Although two-thirds indicated that corrective insulin doses for higher glucose levels are prescribed, less than 50% could specify the target range for these corrective measures. Moreover, both the stated target ranges and the type of target glucose showed high variability (Figure 22).

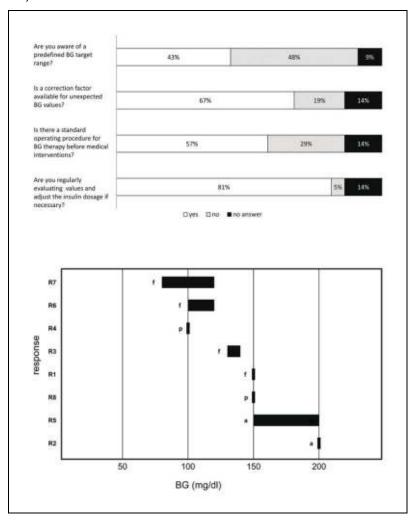
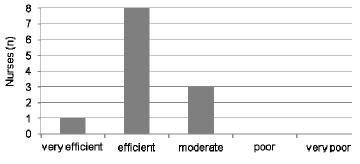


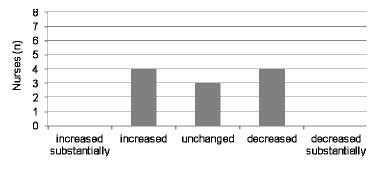
Figure 22: a) Results of an online anonymous questionnaire about current glycaemic management filled in by 21 nurses in both wards. (b) BG ranges stated by 8 nurses in the online questionnaire defining the type of target glucose level either as fasting (f), average (a) or pre-meal (p)

At the end of the first clinical trial, 12 of the 14 nurses in the algorithm group completed a questionnaire (Figure 23). All nurses felt confident using the algorithm. 73% confirmed that the algorithm had improved the quality of glycaemic control including error prevention and 75% reported to have achieved the glycaemic target range. When using the algorithm, four nurses indicated a workload increase, four a workload decrease and another three indicated no change in workload (one did not answer).

A Target glucose control (100-140 mg/dl) as established by the algorithm

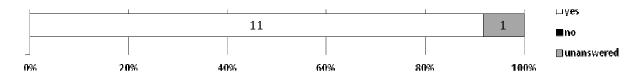


B The workload by the use of the algorithm *



* 1 unanswered

C Glucose control by the use of the algorithm is more efficient as compared to standard routine care?



D Do you think that the algorithm will help to prevent error in the glycaemic management process?

ŀ		1				⊔γes
		8		3	1	∎no
[
					I	■ unanswered
09	6 26	1% 40	F% 60	% 8(166 1	00%

E Did you feel confident using the algorithm based therapy?

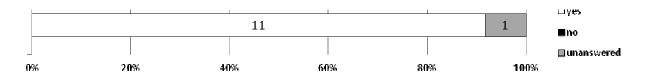


Figure 23: Nurses' questionnaire regarding the efficacy and usability of the algorithm. A Glucose control **B** Workload **C** Algorithm efficacy **D** Error prevention **E** User confidence

Usability tests about the GlucoTab System were performed before the clinical trial. Nurses and Physicians were asked the following questions:

- H1: I always knew where in the system I was and which action was currently in progress
- H2: Texts and symbols were always intuitive

- H3: It was easy to abort and to reverse wrongly performed actions
- H4: The same word, phrase, action, or situation was always clearly visible
- H5: The design of the system prevented user errors
- H6: Objectives, actions and information were always clearly visible
- H7: The system only provided the most important information, less important information was omitted
- H8: Occurred error messages were helpful and easy to understand
- H9: Presented information was adapted to the screen size and legibly
- H10: The system provided a smooth working
- H11: General impression of the system

Results are shown in Figure 24.

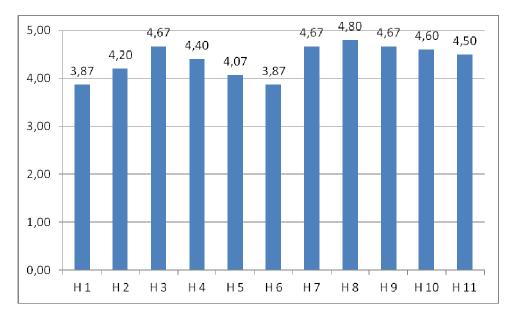


Figure 24: Results of the feedback questionnaire (mean values, 0=disagree/negative, 5=agree/positive)

5.2.2 Summary of outcomes of field trials

As a first step, we assessed the quality of physician-based glycaemic management in two general wards, considering the most recent recommendations for glycaemic control for non-critically ill patients (<140 mg/dl for pre-meal glucose). Glycaemic control was clearly above the recommended target (mean blood glucose levels: endocrinology: $175 \pm 62 \text{ mg/dl}$; cardiology: $186 \pm 68 \text{ mg/dl}$). When comparing the first to the second half of the hospital stay, we found no difference in glycaemic control (endocrinology: $168 \pm 32 \text{ vs.}$ $164 \pm 42 \text{ mg/dl}$, P = 0.67; cardiology: $174 \pm 36 \text{ mg/dl}$ vs. $170 \pm 42 \text{ mg/dl}$ P = 0.51) and in insulin dose (endocrinology: $15 \pm 14 \text{ IU} \text{ vs.}$ $15 \pm 13 \text{ IU}$ per day, P = 0.87; cardiology: $27 \pm 17 \text{ IU} \text{ vs.}$ $27 \pm 18 \text{ IU}$ per day, P = 0.92), despite frequent blood glucose measurements (endocrinology: 2.7 per day; cardiology: 3.2 per day). A lack of clearly defined blood glucose targets was indicated in the questionnaire. In both wards the recommended blood glucose target range was not achieved. Analysis of routine glycaemic management demonstrated considerable glycaemic management effort, but also a lack of translation into adequate insulin therapy. Implementation of corrective measures such as structured treatment protocols is therefore regarded as essential tools to improve this situation.

The aim of the second trial was to evaluate glycaemic control and usability of a workflow-integrated algorithm for basal-bolus insulin therapy in a proof-of-concept study to develop a decision support system in hospitalized patients with type 2 diabetes. In this ward-controlled study, 74 type 2 diabetes patients (24 female, age 68±11 years, HbA1c 8.7±2.4%, BMI 30±7) were assigned to either algorithm-

based treatment with a basal-bolus insulin therapy or to standard glycaemic management. Algorithm performance was assessed by continuous glucose monitoring and staff's adherence to algorithm-calculated insulin dose. Average blood glucose levels (mg/dl) in the algorithm group were significantly reduced from 204 ± 65 (baseline) to 148 ± 32 (last 24h) over a period of 7.5 ± 4.6 days (p<0.001). The algorithm group had a significantly higher percentage of glucose levels in the ranges from 100-140 mg/dl (target range) and 70-180 mg/dl compared to the standard group (33% vs. 23\% and 73% vs. 53%, both p<0.001). Physicians' adherence to the algorithm-calculated total daily insulin dose was 95% and nurses' adherence to inject the algorithm-calculated basal and bolus insulin doses was high (98% and 93%). In the algorithm group significantly more glucose values <70 mg/dl were detected in the afternoon relative to other times (p<0.05), a finding mainly related to pronounced morning glucose excursions and requirements for corrective bolus insulin at lunch. The workflow-integrated algorithm for basal-bolus therapy was efficacious in establishing glycaemic control and was well accepted by medical staff. Our findings support the implementation of the algorithm in an electronic decision support system.

The aim of the third trial is to investigate safety, usability and efficacy of the tablet based workflow support system (GlucoTab system) used for glycaemic management of non-critically ill patients with type 2 diabetes at the general ward. The monocentric, open, non-controlled intervention pilot trial will include a total of 30 patients hospitalised with type 2 diabetes.

For a detailed description of the results please refer D8-3 Clinical evaluation of general ward clinical field trial.

6 Validation results – Primary care prototype

6.1 Summary of verification results

6.1.1 Patient home gateways and devices

Two different home gateways will be used in the field trials. Their features and the main outcomes from the verification and validation phases are described below.

6.1.1.1 Home gateway (Multi-protocol version - MPV)

The MPV home gateway is designed to be used by all patients for an initial period of two weeks in order to analyse their needs for future monitoring. Ahead of the roll-out of home gateways from the Chorleywood Health Centre to its patients the MPV unit (a black box PC running the REACTION software developed in the project) was tested in several steps in order to provide as accurate test results as possible and confirm its adequacy for deployment in patient's homes. The test results were obtained during the following phases:

- Development environment
 - **Unit test** continuously tested methods with mock objects and separate calls
 - Integration test combined individual modules, REACTION components together with medical devices that were listed to be used in the pilot trial in order to ensure they are behaving as expected as a group
 - Deployment test/system test in a pre-pilot environment full scale module, software and hardware testing that is done on a complete and integrated end-to-end communicating REACTION platform.
- Home environment
 - Performance test is used to determine how a system performs in terms of responsiveness and stability under a particular home setting and workload. Any deviation was directly reported back to the development team at CNET
 - Ad hoc test being the least formal test method it suited the test scenario well at that point in time as manuals and documents were not yet available, providing a first insight on the behaviour of the MPV home gateway where important defects could be found quickly
 - Implementation test and user acceptance using the NHS Friends and Family \cap Test Implementation Guidance. This type of tests intends to provide a simple, headline metric which, when combined with follow-up guestions, can be used to drive cultural change and continuous improvements in the quality of the care received by patients. CNET made customised questions that would mirror the actual pilot deployment. These had the same questions, question format, and response scale. Furthermore, CNET adopted a minimum response rate on 15% in order to have sufficient data collection on our own Friends and Family tests. Examples of questions asked in the case of malfunctioning or other issues were: "Did you find it easy to make the system work again?" or "How likely is it that this experience has affected you in a negative way?" where the response scales were a six-option scale ranging from 'Extremely positive' to 'Extremely negative' and 'Extremely likely' and 'Extremely unlikely', respectively. The sixth option was for 'Not available'/'Do not know' answers. However, this test had low impact on the MPV home gateway development as prior tests were sufficient to fulfil the tasks.

After the tests were conducted and confirmed by iterative approach in the development and accepted by the pre-pilot test users, i.e. friends and family, the MPV home gateway was ready to be shipped to the Primary care pilot as a first validated prototype.

6.1.1.2 Home gateway (Simple Home Mains Plug Gateway – HMPG)

The primary care pilot has the aim to undertake a brief period of monitoring (2 weeks) of all patients registered with diabetes in a primary care practice in the UK. A survey of patients showed that only 35% of patients had broadband, which would be a constraint for deployment of the MPV home gateway. Furthermore, results from focus groups, advice from the clinicians and experience from other work provided a set of requirements that indicated that platform had to be:

- Self-contained, i.e. provide its own communication
- Could not be tampered with by the use (prevent changing software or applications)
- Extremely simple to use
- Unobtrusive, i.e. could be placed anywhere in the home to avoid stigmatisation
- Inexpensive
- Self-installed
- Full range of devices to support management of co-morbidities and complications

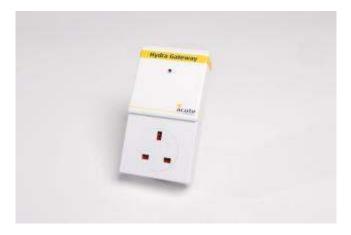


Figure 25: The Home Mains Plug Gateway

Ultimately we needed a platform that we could "drop ship" to a patient with all sensors all aspects of the patient condition and that would be sufficiently simple use without need for a visit to the home for installation and instruction if this is to become a cost effective approach to management of chronic disease and support other acute episodes of care (e.g. gestational diabetes and pre-eclampsia).

We therefore designed and implemented a home gateway that is based on a mains plug as shown in Figure 25. This is entirely self-contained and implements the ZigBee Health Care Profile and IEEE 11073 standard for the devices and uses a GPRS module for the WAN interface. The HMPG provides all the functionality of an AHD of the Continua Alliance reference architecture. The HMPGs are managed through an M2M network provider. The advantage is that the HMPGs are on a private managed network through to the server - the HMPGs are authenticated by the SIM and security is assured. Other advantages include roaming on all UK networks for best signal coverage, website management of the mobile devices, static IP address and a low tariff commensurate with the low data amount transmitted. The company also support roaming over Europe and US to support expansion of the platform.

The HMPG is a single processor design (we re-use the processor for ZigBee) and thus achieves lowest cost. We control the GPRS modem directly, which allows us to program for all events and so ensure highest reliability. The sealed design ensures it cannot be tampered with.

Use of the HMPG for the patient is reduced to plugging in to the mains and ensuring the single light shows green.

The design makes it unobtrusive so it can be placed anywhere that a signal can be received, and might easily be hidden behind furniture. In removing any user interface or need to access the gateway, we free the user to place the gateway and devices for convenience. Use of ZigBee increases range in most situations compared to BlueTooth.

The current HMPG has a limitation of 3 devices being connected concurrently. This is not an issue in early deployment as most patients will receive just blood glucose and blood pressure devices. As complex patients are identified and monitored we anticipate many other devices to be deployed. A revision of the ZigBee board will accommodate 15 devices connected concurrently. This will support the complex patient with motion sensors (e.g. 7), bed/chair sensor (e.g. 3), medication dispenser and the 4 health monitoring devices.

We are developing a revision of the HMPG. This will use SMD for all components and will be a simpler design to reduce manufacturing cost. It has improved antenna design.



Figure 26: The full range of devices to work with HMPG

It was evident that the range of devices that we needed for the project was not available commercially. We have therefore implemented a versatile radio module that implements the standards to be used in commercial devices to put them on the platform, or that we can use as the basis of a device. The devices so far developed for the project are shown in Figure 26. We also incorporated modifications to commercial devices to improve user interface or to simplify use.

- Blood Glucose we could find no blood glucose meter that would integrate directly to the platform. Instead we selected the Lifescan One Touch Ultra 2 as meter as this has a simple serial interface and developed a docking box. This has a lead that plugs directly to the meter. Pressing a single large red button causes latest readings to be sent to the server. The interface was designed to be simple for use by an elderly patient. The LED will show if data has been sent successfully. The docking station implements the IEEE 11073-10418 standard glucose meter.
- Blood Pressure we chose the A&D blood pressure meter and replaced the BT module with our own ZigBee module that is pin compatible and has identical footprint. We have added an LED to show if the device has successfully sent data or out of range.
- Weighing scale we chose the A&D weighing scale and replaced the BT module with our own ZigBee module that is pin compatible and has identical footprint. We have added an LED to show if the device has successfully sent data or out of range.
- Pulse oximeter we chose the cable ended OEM pulse oximeter module from Nonin (IPOD) and built the ZigBee module into a large box. Pressing a single large red button causes a reading to be taken and sent to the server. The LED will show if reading has been taken and sent successfully. We redesigned the pulse oximeter so that it would be large and have a bold interface to suit elderly patients.
- Medication dispenser we chose the Pivotell Carousel and included the ZigBee module within the device. The device can be programmed to present medication in a compartment at set times. The device will send a message if tipped (to remove the medication) or not tipped within a defined interval.
- Motion sensor we wish to monitor behaviour in some patients as it can be used as indicator of deterioration in condition. For example patients with CHF will prefer to sleep in a chair at night in preference to the bed as sleeping upright assists breathing during an exacerbation. CHF is commonly a late stage complication of diabetes. We chose the motion sensor from Optex.
- **Bed/chair sensor** this complements the motion sensor. We chose the bed/chair sensor from Tynetec and replaced the proprietary wireless module with our ZigBee module.

We are currently developing and evaluating simple pictorial instruction sheets to support the drop ship approach we wish to implement in the project.

6.1.2 Clinical portal unit tests

The REACTION clinical portal unit tests have been performed for the main functionalities available in version 2.15.

The results are reported below.

Test ID	testAddNewPatientToClinicalPortal				
Test Result	PASSED				
Description	The user attempts to add a new patient to the REACTION Clinical Web Portal, by providing detailed personal patient information and assigning devices to the patient. Upon success the user is transferred to the 'Today's readings' Home (main) page of the REACTION Clinical Portal.				
Initial Screenshot REACTION Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks None: Add New Patient All Patients Admin Global Settings Personalized Settings Alarms Handlin Patient Details					
	Assign Health professional Assign Devices	Patient Deta	đS		
		Patient deta@s			
		Title	Mr .		
		Sumame:	Jones		
		FiratName:	Russell		
		Contraction of the second	(russel)		
		DOR	21/03/1950		
		Gender	Male .		
		MHS Number:	770766060		
		Address:			
		Home Telephone:			
		Mobše:			
		Manifial Status: Next of Kin 1:	Single		
		Next of Rin 21			
		Monitoring Statue	Active 💌		
		Procision -		Next	



Test ID	testAddNewDeviceToClinicalPortal			
Test Result	PASSED			
Description	The user with administrator account attempts to add a new device to the REACTION Clinical Portal, by providing detailed device information. Upon success the device is added to the list, and can be assigned to the patient of the REACTION Clinical Portal.			
Initial Screenshot	Toom Add New Partient All Patients Admin Global Add New Partient All Patients Admin Global Add GR Code Dence D (EUII4) Selet Devce type Device marufacture: Device madel Device madel Device madel Device sensi number: Reset	I Settings Personali New device: 801687000100102 Guesse montar		

VERSION 1.1

Screenshot of result							
		0)evice Ma	nagement:			
	Device EUI-64	Device Type	Device Sub-type	Patient	Status	Unassign	Delete
	801687000100102	Glucose Monitor			Not Allocated	Unassign	Delete
	0000073901141100	Glucose Monitor			Not Allocated	Unassign	<u>Delete</u>
	0000073902440629	Glucose Monitor		Mr Test02 CNet	Allocated	Unassign	Delete
	0000073902764671	Glucose Monitor		Mr Jonathon Reynolds	Allocated	<u>Unassign</u>	<u>Delete</u>
	0000073902764682	Glucose Monitor		Mrs Penny Lawrence	Allocated	<u>Unassign</u>	Delete
	0000073902764701	Glucose Monitor			Not Allocated	<u>Unassign</u>	<u>Delete</u>
	0000073902764708	Glucose Monitor		Mr John McDaid	Allocated	Unassign	<u>Delete</u>
	00091FFFFE80018F	BP Monitor			Not Allocated	Unassign	<u>Delete</u>
	00091FFFFE800628	BP Monitor		Mrs Penny Lawrence	Allocated	Unassign	<u>Delete</u>
	00091FFFFE800AC4	Weighing Scale		Mrs Penny Lawrence	Allocated	Unassign	<u>Delete</u>
	00091FFFFE801295	Weighing Scale		Mr Jonathon Reynolds	Allocated	<u>Unassign</u>	<u>Delete</u>
	00091FFFFE80133F	Weighing Scale			Not Allocated	<u>Unassign</u>	<u>Delete</u>
	00091FFFFE8013B2	Weighing Scale		Mr Test02 CNet	Allocated	Unassign	<u>Delete</u>
	00091FFFFE8018F1	BP Monitor		Mr John McDaid	Allocated	<u>Unassign</u>	<u>Delete</u>
	00091FFFFE8018F8	BP Monitor		Mr Jonathon Reynolds	Allocated	<u>Unassign</u>	Delete
	all rights reserved, Version:					Dis	ext Last

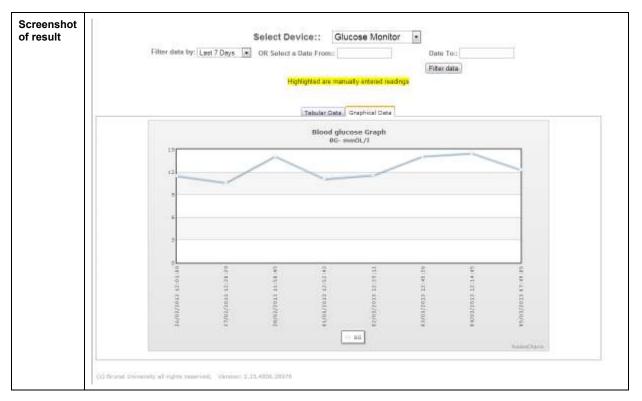
Test ID	testViewBloodPressureTabulardata				
Test Result	PASSED				
Description	The clinician wants to check the blood pressure measurements of a patient. He/She clicks on the patient name from the home page, resulting in the individual patient measurements page to be displayed. The clinician selects 'Blood pressure' from the Device drop down menu to view the BP data in tabular format.				
Initial Screenshot	View Add New Patient Admin Global Setting Personal lized Setting Aarms Handling Project Haungage Name Add New Patient All Patients Admin Global Setting Personallized Setting Aarms Handling Project Haungage Name Add New Patient All Patients Admin Global Setting Personallized Setting Aarms Handling Project Haungage Name Mark Kating Smith - Nume States States December December				

result	Filter data by: Last 7 Days 💌	OR Select a Date From::		Date To::		
		Highlighted are man	ually entered readings			
		Export tab Tabular Data	ular data Graphical Data			
	Date	Time	Systolic	Diastolic	Pulse	
	26/02/2013	12:03	126	70	64	*
	27/02/2013	12:22	125	67	70	
	28/02/2013	12:00	131	68	73	
	01/03/2013	12:55	146	75	66	
	02/03/2013	12:25	128	72	71	
	03/03/2013	12:48	128	66	67	
	04/03/2013	12:16	127	70	66	
	05/03/2013	09:59	134	66	71	

Test ID	testViewBloodPressureGraphicaldata			
Test Result	PASSED			
Description	The clinician wants to check the graphical blood pressure measurements of a patient. From the individual patient measurements page. He/ She selects 'Blood pressure' from the devices drop down menu, and then selects Graphical data. The graphical BP data is displayed.			
Initial Screenshot	None			
	Fitter data: Highlighted are manually entered readings			
	Export tabular data Tabular Data Blood Pressure graph Systolic/Diastolic			
	Export tabular data Tabular Data Blood Pressure graph Systolic/Biastolic			

Test ID	testViewBloodGlucoseTa	abulardata			
Test Result	PASSED				
Description	The clinician wants to check the blood glucose measurements of a patient. From the individual patient measurements page, he/she selects 'Glucose monitor' from the Device drop down menu. The tabular Blood glucose data is displayed.				
Initial Screenshot	None				
Screenshot of result	Filter data by: Lest 7 Days 💽		entered readings	ate To::	
	Date	Time	Blood Gluco (mmol/L)	se Intake Status	
	26/02/2013	12:01	11.5	Device	
	27/02/2013	12:20	10.6	Device	
	28/02/2013	11:58	14.1	Device	
	01/03/2013	12:52	11.1	Device	
	02/03/2013	12:23	11.6	Device	
	03/03/2013	12:45	14.1	Device	
	04/03/2013	12:14	14.5	Device	
	05/03/2013	07:49	12.3	Device	
	(c) Brunel University all rights reserved, Version: 2.	.15,4806,28976		*	

Test ID	testViewBloodGlucoseGraphicaldata
Test Result	PASSED
Description	The clinician wants to check the graphical blood glucose measurements of a patient. From the individual patient measurements page. He/She selects 'Glucose monitor' from the devices drop down menu, and then selects Graphical data. The graphical BG data is displayed.
Initial Screenshot	None



Test ID	testViewSPO2Tabulardata
Test Result	PASSED
Description	The clinician wants to check the pulse oxymeter measurements of a patient. From the individual patient measurements page, he/she selects 'Pulse Oxymeter' from the Device drop down menu. The tabular SpO ₂ and pulse data is displayed.
Initial Screenshot	None

Filter data by: Last 7 Days 💌	Highlighted are manually e	Date To Filter da		
	Export tabular of Tabular Data Graph			
Date	Time	SPO2	Pulse	
26/02/2013	08:33	78	122	*
27/02/2013	08:34	90	70	
28/02/2013	08:04	88	74	
01/03/2013	15:36	93	84	
02/03/2013	10:47	88	141	
03/03/2013	08:19	92	70	
04/03/2013	08:10	89	72	
05/03/2013	08:11	89	63	
05/03/2013	08:13	90	71	
				×

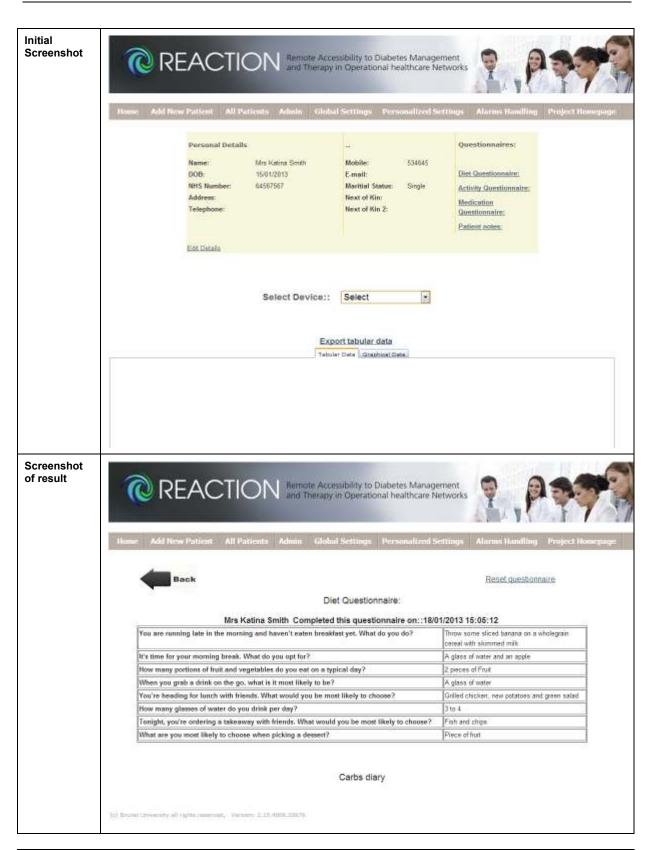
Test ID	testViewSPO2Graphicaldata			
Test Result	PASSED			
Description	The clinician wants to check the graphical oxymeter measurements of a patient. From the individual patient measurements page. He/she selects 'Pulse Oxymeter' from the devices drop down menu, and then selects Graphical data. The graphical SpO ₂ and pulse data is displayed.			
	None			
Initial Screenshot of result	Select Device:: Pulse Oxymeter Filter data by: Last 7 Days OR Select a Date From: Date To::			

Test ID	testViewWeighingScaleTabulardata		
Test Result	PASSED		
Description	The clinician wants to check the weighing scale measurements of a patient. From the individual patient measurements page, he/she selects 'Weighing scale' from the Device drop down menu. The tabular Weight data is displayed.		
Initial Screenshot	None		
	Exi	irom::: Date To::: Filter data Filter data d are manually entered readings port tabular data User Data Graphical Data Time Weight BMI 2 77.1 6 78.7 2 77.2 9 78.9	
	(c) Brunel University all rights reserved, Version: 2.15.4806.28976	-	

Test ID	testViewWeighingScaleGraphicaldata
Test Result	PASSED
Description	The clinician wants to check the graphical weighing scale measurements of a patient. From the individual patient measurements page. He/ She selects 'Weighing scale' from the devices drop down menu, and then selects Graphical data. The graphical WS data is displayed.
Initial Screenshot	None



Test ID	testViewPatientDietQuestionnaireData
Test Result	PASSED
Description	The clinician wants to check the answers to patient's diet questionnaire. He/She clicks on the patient name from the home page. The individual patient measurements page is displayed. The clinician selects the 'Diet Questionnaire' link, and the answers to patient's diet questionnaire are shown.



Test ID	testViewPatientActivityQuestionnaireData
Test Result	PASSED
Description	The clinician wants to check the answers to patient's activity questionnaire. He/She clicks on the patient name from the home page. The individual patient measurements page is displayed. The clinician selects the 'Activity Questionnaire' link, and the

	answers to patient's activity questionna	aire are shown.								
Initial Screenshot	REACTION Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks									
	Home Add New Patient All Patients Admin Global Settings Personalized Settings Alarms Handling Project Homepage									
	Personal Details Nome: Mrs Katina Smith DOB: 15/01/2013 MHS Number: 04567667 Address: Telephone:	↔ Mobile: 534645 E-mail: Maritial Status: Single Next of Kim Next of Kim 2:	Questionnaires: Dec Questionnaire: Activity Questionnaire: Medication Questionnaire: Patient notes:							
	Select Device::	Select								
	Export tabular data									
Screenshot of result	REACTION Remote Acce	essibility to Diabetes Managem in Operational healthcare Netv	ent P P P							
		vity Questionnaire:	Reset questionnaire							
	How old are you?	this questionnaire on::24/01/2	85 plus							
	The Department of Health recommends adults are modecately vigorously active for 75 minutes each week. In an average we shis?	You do around half of what's recommended								
	How many days a week do you do activities that strengthen yo	One Day								
	If you're not doing enough physical activity, which of the follo	wing best describes why?	I don't have time							
	How would you describe the way you feel after climbing a flig	ght of stairs?	Ok							
	How many of the following could you do easily?		10 sk-ups Touch your taes							
	(c) Brand Dreaming of rights removal, Variant 2.12,4002,20076									

Test ID	testViewPatientMedicationQuestionnaireData
Test Result	PASSED
Description	The clinician wants to check the answers to patient's medication questionnaire. He/She clicks on the patient name from the home page. The individual patient measurements

	page is displayed. The clinician selects the Medication									
	answers to patient's medication questionnaire are show	n.								
Initial Screenshot	REACTION Remote Accessibility to Diabetes Manage and Therapy in Operational healthcare in Home Add New Patient All Patients Admin Global Settings Personalized									
	Personal Details	Questionnaires:								
	Name: Mrs Katina Smith Mobile: 534645 DOB: 15/01/2013 E-mail: MHS Number: 04567567 Maritial Status: Single Address: Next of Kin: Telephone: Next of Kin 2:	Diet Questionnaire: Activity Questionnaire: Medication Questionnaire:								
	Est Ditals	Patient soles:								
	Select Device:: Select									
	Export tabular data									
Screenshot of result	REACTION Remote Accessibility to Diabetes Manag and Therapy in Operational healthcare to Home Add New Patient All Patients Admin Global Settings Personalized S	CALLET AN								
	Back									
	Medication Questionnaire:									
	Mrs Katina Smith Completed this guestionnaire on::24/	01/2013 15:20:66								
	Have you ever not filled an initial prescription?	NÖ								
	Have you ever not refilled a prescription that your health care provider wanted you to take?	NO								
	Have you ever stopped, skipped, or delayed taking a medication to save it for future use (e.g. case the condition it is used to treat reoccurs)?	in NO								
	Have your ever stopped taking your medication(s)?	NO								
	When do you feel better, do you sometimes stop or skip?	NO								
	Have you ever taken someone else's medication(s)?	NO								
	Insulin diary Medication taken									

6.1.3 Patient portal unit tests

The current version of the patient portal is 1.2.2 located in the FTP repository. The unit tests are composed into screenshots representing a specific test case. The result corresponds to another page or displayed results and determines if the page is the expected one, thus if the test is passed or failed.

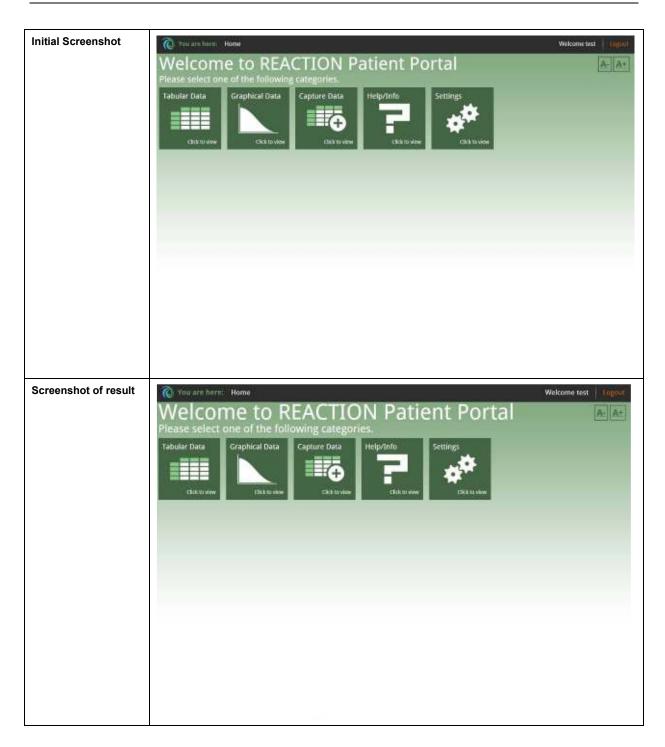
The results are reported below:

Test ID	testLoginToPatientPortal
Test Result	PASSED
Description	The user attempts to login to the REACTION Patient Portal web application, by providing his/hers credentials. Upon success the user is redirected to the main page of the Patient Portal.
Initial Screenshot	Chorlegwood Health Centre Health Centre Pessword Health Health Centre Heavend
Screenshot of result	Total in theme Notice to be Notice to be Places select one of the following categories: Image: Categories Image: Categories Bubbler Data Image: Categories Image: Categories Image: Categories Bubbler Data Image: Categories Image: Categories Image: Categories Image: Categories Bubbler Data Image: Categories Image: Categories Image: Categories Image: Categories Image: Categories Bubbler Data Image: Categories Image: Cat

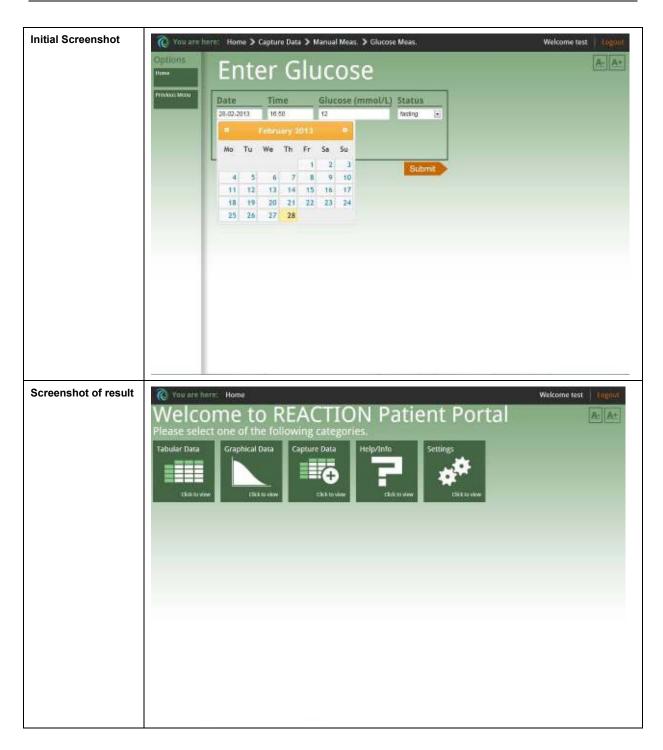
Test ID	testChangeLanguageContent						
Test Result	PASSED						

Description	The user access patient portal from a browser that has English and Greek settings. Each time the translated content is delivered through the client.
English content	Valuation Streem: Notice Streem Valuation Streem Valuation Streem: Welcome to REACTION Patient Portal Image: Streem: Image: Streem:
Greek content	<text></text>

Test ID	testChangeFontSize
Test Result	PASSED
Description	The user selects the preferred font size (normal or large) and the current page is re-displayed using the selected font size.



Test ID	testCaptureManualMeasurementGlucose							
Test Result	PASSED							
Description	The user inserts manually a glucose measurement. Upon success, the REACTION Patient Portal redirects the user to the main page of the manual measurements (which is the previous page) in order to simplify the procedure of adding another measurement.							



Test ID	testCaptureManualMeasurementPressure						
Test Result	PASSED						
Description	The user inserts manually a blood pressure measurement. Upon success, the REACTION Patient Portal redirects the user to the main page of the manual measurements (which is the previous page) in order to simplify the procedure of adding another measurement.						

Initial Screenshot	🔞 You are here: Home > Capture Data > Manual Meas. > Pressure Meas.								Welcome test	lingan	
	Options	Pres	ssure Measurement						A- A+		
		ate 8-02-2013	Time 1653	_	Syste 115	olic (mmH	<u>5)</u> 7	iastolic (mmHg) a		
		Т		me 16:53		llsoone Tiinin					
			00 Minute 00	04 10	08 20	12 30	16	20 50	Submit		
			Now	10	20		10543	Done			
Screenshot of result	The same as	s in the	test c	as	e wi	ith I	D te	estC	CaptureManualN	leasurementG	lucose

Test ID	testCaptureManualMeasurementWeight						
Test Result	PASSED						
Description	The user inserts manually a weight measurement. Upon success, the REACTION Patient Portal redirects the user to the main page of the manual measurements (which is the previous page) in order to simplify the procedure of adding another measurement.						
Initial Screenshot							
Screenshot of result	The same as in the test case with ID testCaptureManualMeasurementGlucose						

Test ID	testCaptureManualMeasurementOxygenSaturation					
Test Result	PASSED					
Description	The user inserts manually an oxygen saturation measurement. Upon success, the REACTION Patient Portal redirects the user to the main page of the manual measurements (which is the previous page) in order to simplify the procedure of adding another measurement.					
Initial Screenshot						
Screenshot of result	The same as in the test case with ID testCaptureManualMeasurementGlucose					

Test ID	testViewTabularDataGlucose
Test Result	PASSED
Description	The user wants to check the blood glucose measurements that have been submitted to the platform. Thus he/she navigates to the corresponding section of the REACTION Patient Portal (Home->Tabular Data ->Glucose) where the data are presented in tabular format.
Initial Screenshot	None

Options		Glucos	o Dr	ota		A- A+
Graphical Data		Glucos	e Da	ala		
Hore		Date	Time	Blood Glucose (mmol/L)	Intake Status	Blood Glucose Level
Previou: Mersi		08-01-2013	13:51	10	preprandial	To provide enough fuel (energy) for every cell in the body to work
Other		18-12-2012	16:30	25	casual	properly, a constant supply of glucose keeps drculating round in
misure		18-12-2012	16:27	18	preprandial	the blood. The level of glucose needs to be controlled carefully. Too little
Wright	_	14-12-2012	12:18	15	casual	glucose can make you feel very unwell (hypoglycaemia). Too much
	1	14-12-2012	12:08	16	fasting	glucose can eventually cause health problems (for example, it can
Organi Saturation	54	03-12-2012	17:58	10	cesual	damage your eyes). A level between 4 and 7 millimoles of
	21 28 01					mimol(1) before meals means your blood glucose is under good control. A tost below 4 mimol(1 may make you feel unwell (hypo). A level above 7 mmol/L before a meal is known as hyperglycaemia and can cause health problems in the long term.
						Target Blood Sugar should always be less than TOmmol/L
						more on the Internet

Test ID	testViewTabu	testViewTabularDataPressure					
Test Result	PASSED						
Description	The user wants to check the blood pressure measurements that have been submitted to the platform. Thus he/she navigates to the corresponding section of the REACTION Patient Portal (Home->Tabular Data ->Pressure) where the data are presented in tabular format.						
Initial Screenshot	None						
Screenshot of result	Coptions Options Graphed bas	Pressi		Data		Welcome patient Ligned	
	Hone.	Date	Time	Systolic (mmHg)	Diastolic (mmHg)	Blood Pressure	
	Trovicuo Menu	08-01-2013	13:52	130	120	Research has shown that controlling	
		19-12-2012	15:44	120	110	blood pressure is at least as important in diabetes as controlling blood sugar.	
	Other	19-12-2012	12:11	120	100	High blood pressure can be lowered	
	Wretz 7 Graypr dataration 21 20 21	14-12-2012	12:08	130	120	by stopping smaking, losing excess weight, regular excessive and avoiding added salt in the diet. There are also many medications available for lowering blood pressure. Target blood pressure should be less than 130/80. more on the Internet	

Test ID	testViewTabularDataWeight					
Test Result	PASSED					
Description	The user wants to check the weight measurements that have been submitted to the platform. Thus he/she navigates to the corresponding section of the REACTION Patient Portal (Home->Tabular Data ->Weight) where the data are presented in tabular format.					
Initial Screenshot	None					
Screenshot of result	nou are here: Ho	me 🗲 Tabular Data 🗲 Weight			Welcome patient	
	Options	Weight I	Data	A: A+		
	HORE	Date	Time	Weight (kgs)	Weight	
	Provinces Micros	08-01-2013	13:52	88	Regular exercise is good for us all. It	
		19-12-2012	13:21	95	helps lower blood pressure and heart disease risk, and helps us to achieve and maintain a healthy weight.	
	Other	19-12-2012	12:11	76		
	Pressure 7	14-12-2012	12:09	95	Mass Index (BMI) which is calculated from your weight in kilograms divided by your beight in meters squared. The healthy range for BMI is 19 - 25.	
	2111/100 21 21				Dverweight people with diabetes have more trouble keeping their blood glucose down and are also at increased risk of cardiovascular disease, so weight control through exercise and attention to diet is particularly important when the BMI is more than 25.	
					Regular, moderate exercise such as swimming ur brisk walking 5 times per week for at least 30 minutes is ideal. An exercise assistin longer than 20 minutes is likely to significant lower your blood sugar (glucose), and you may need to top it up with a quick acting carbohydrate such as fruit julios.	
					more on the Internet	

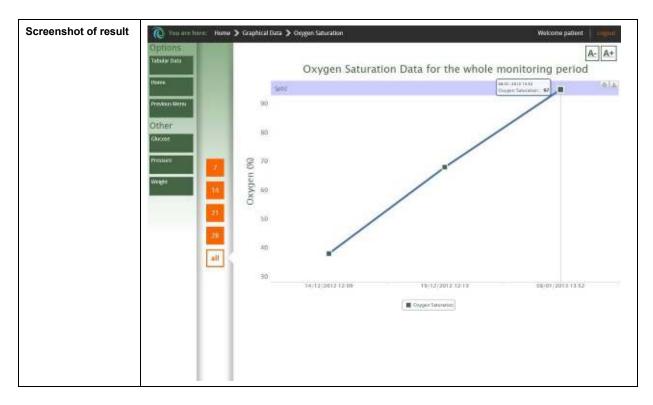
Test ID	testViewTabularDataOxygenSaturation
Test Result	PASSED
Description	The user wants to check the oxygen saturation measurements that have been submitted to the platform. Thus he/she navigates to the corresponding section of the REACTION Patient Portal (Home->Tabular Data ->Oxygen Sat.) where the data are presented in tabular format.
Initial Screenshot	None

Screenshot of result	🔞 fou are here: Home	🕽 Tabular Data 🏅 Oxygen	Saturation		Welcome patient
	Options Grankations	Oxyger	n Satu	iration Data	A- A+
	Hutte	Date	Time	Oxygen Saturation (%)	Oxygen Saturation
	Prindeaus Mierau	08-01-2013	13:52	97	
		19-12-2012	12:13	70	
	Other	14-12-2012	12:09	40	
	GARTER		TO SHOW		
	Pressure				
	WW 8/4				
	21				
	28				
	all				

Test ID	testViewGraphicalDataGlucose					
Test Result	PASSED					
Description	The user wants to check the blood glucose measurements that have been submitted to the platform. Thus he/she navigates to the corresponding section of the REACTION Patient Portal (Home->Graphical Data ->Glucose) where the data are presented in graphical format.					
Initial Screenshot	None					
Screenshot of result	Protocol Protocol <td< td=""></td<>					

Test ID	testViewGraphicalDataPressure						
Test Result	PASSED						
Description	The user wants to check the blood pressure measurements that have been submitted to the platform. Thus he/she navigates to the corresponding section of the REACTION Patient Portal (Home->Graphical Data ->Pressure) where the data are presented in graphical format.						
Initial Screenshot	None						
Screenshot of result							

Test ID	testViewGraphicalDataOxygenSaturation
Test Result	PASSED
Description	The user wants to check the oxygen saturation measurements that have been submitted to the platform. Thus he/she navigates to the corresponding section of the REACTION Patient Portal (Home->Graphical Data ->Oxygen Sat.) where the data are presented in graphical format.
Initial Screenshot	None



Test ID	testViewGraphicalDataWeight					
Test Result	PASSED					
Description	The user wants to check the weight measurements that have been submitted to the platform. Thus he/she navigates to the corresponding section of the REACTION Patient Portal (Home->Graphical Data ->Weight) where the data are presented in graphical format.					
Initial Screenshot	None					
Screenshot of result						

6.1.4 Integration testing

The integration testing procedure involves the combination of all the software components in a "real world" deployment. In case of primary care the following software components need to be deployed:

- Back end database schema
- Home gateways (including the set of devices)
- Clinical portal web application
- Patient portal web application

The integration testing procedure involves the running of various test cases (i.e. scenarios of use). For the device management and gateway measurements the integration testing was performed on section 6.1.1. The integration testing procedure includes tests at the following context:

- Consistency between the back end (database) and the front end (portals).
- Security issues (e.g., authentication of users)
- Data acquisition and monitoring issues (e.g., manual measurements)
- Localization issues (e.g., date formats)
- Accessibility issues

The results of the main integration tests performed on the primary care prototype are listed below.

Test ID	testDatabaseInitialization
Test Result	PASSED
Description	A new database needs to be initialized with pre-defined lookup tables. Specific SQL scripts located on FTP repository has been run in order to create the database schema as well as some populated data.
Issues	There were some problems related to the date format which hampered the acquisition of manual measurements
Solution	The proper configuration (locale) setting for the date format was made in the database engine

Test ID	testClinicianPortalLoginLogout			
Test Result	PASSED			
Description	In order to evaluate the authentication mechanism the first thing is to perform a login/logout on clinical portal. A pre-defined user "admin" has been created with a user name and password.			
Issues	A critical issue has been emerged with the security mechanism that if a patient knows the URL of the clinical portal then he can access to it with his credentials as well. There is no role based mechanism on clinical portal. Although the URL may not be known this issue has to be resolved in order to avoid security vulnerabilities in clinical portal.			
Solution	Since this issue has been discovered after the start of clinical trials, it will be resolved at the extended version of primary care prototype.			

Test ID	testClinicianAddNewPatient				
Test Result	PASSED				
Description	The admin user attempts to add a new patient to the system. The patient				

	demographics are entered first and user credentials (i.e. username and password) for the patient portal secondly. The patient should be then created as a new record on the database.				
Issues	An issue has been emerged on entering the NHS number of the patient. If the NHS number was 11 digits then the patient was not created successfully. This caused a side effect on Patient portal when this patient tried to access from it.				
Solution	The issue has been resolved by modifying the maximum number of digits on this text-field. Now the NHS number can be entered without this restriction.				

Test ID	testPatientPortalPatientAccess				
Test Result	PASSED				
Description	The newly created patient has been tested on the patient portal. His credentials has been entered on the login page the ne new patient can access the patient portal.				
Issues	None				
Solution	None				

Test ID	testPatientPortalEditPatientCredentials				
Test Result	PASSED				
Description	The patient tries to change his username and password from patient portal settings. The patient enters a new password twice in order to verify the correctness. The new credentials have been stored on database and the changes are visible from the clinical portal.				
Issues	None				
Solution	None				

Test ID	testMonitoringPatientMeasurements				
Test Result	PASSED				
Description	The patient enters manually his measurements on a daily base. These measurements are stored on the back end component. All measurement types are visible on both patient and the clinical portals in tabular as well as in graphical view.				
Issues	None				
Solution	None				

Test ID	testMonitoringPatientMedication
Test Result	PASSED
Description	The patient enters manually his medication. Then the measurement is visible on the clinical portal in tabular and graphical view. Medication is visible from both patient and clinical portal.
Issues	None

None

Test ID	testMonitoringQuestionnaireAnswers			
Test Result	PASSED			
Description	The patient fills up all the questionnaire types. The questionnaire answers are then being saved on the back end (database). Answers from each patient are can then be visible from clinical portal.			
Issues	None			
Solution	None			

6.1.5 System tests

The primary care prototype system testing follows the same principles as the in-hospital prototype, i.e. a comparison at four satisfaction levels of all functional requirements. These requirements were initially specified in *ID2-6-2 Prototype Application Specification 2* and subsequently inserted and maintained in the JIRA requirements database. These requirements were filtered to include only the ones impacting on the third year primary care prototype. All requirements resolved as Duplicate or Out of Scope have been omitted.

The levels of satisfaction for each of the functional requirements are listed below:

- Fully satisfied
- Partially satisfied
- Improperly satisfied
- Not satisfied

Figure 27 and Figure 28 show the system testing results for the basic and extended version of primary care prototype. These results are detailed in Appendix DAppendix .

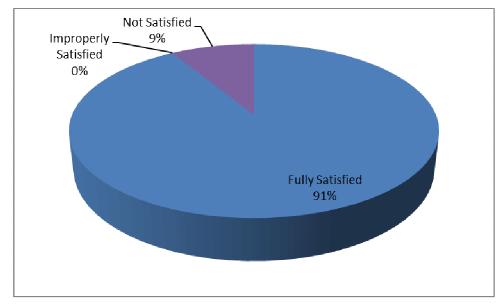


Figure 27: Satisfaction of requirements for the basic primary care prototype

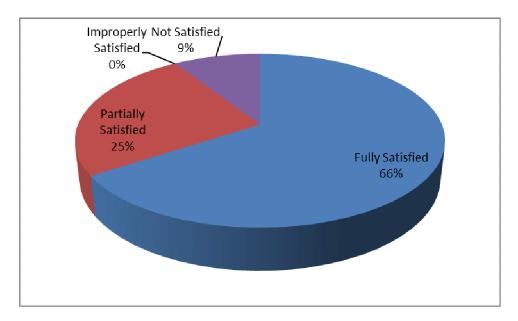


Figure 28: Satisfaction of requirements for the extended version of primary care prototype

6.2 Summary of validation results

CHC has conducted a series of field trials and user testing of devices and software in order to prepare for the primary care field trials. This work has consisted of testing:

- Devices provided by UBRUN/Acute Technology (HMPG home gateway)
- Devices provided by CNET (MPV home gateway)
- Patient Portal provided by FORTH-ICS
- Clinical Portal provided by UBRUN/Acute Technology

CHC has worked closely with technical partners in the development of the devices and clinical and patient portal prototypes. Prior to commencing the Primary Care field trial, a series of tests were completed. The testing process was undertaken in two stages, friends and family testing and field testing.

6.2.1 Friends and family

Friends and family testing involved users that were not from the target population, they included researchers, friends and neighbours of those working within the study. The main objectives of the friends and family phase have been to:

- Test reliability and robustness in a non-lab environment
- Test functionality of the equipment in a non-lab environment
- Test usability and functionality of patient portal
- Test usability and functionality of clinical portal
- Receive usability feedback

Tests were performed using the two different gateways.

HMPG Home Gateway

Three people were provided with a mix of equipment provided by UBRUN and Acute Technology and asked to take a measurement each day and use the patient portal each day, see Table 19. Users undertook this testing for 7 days.

	Gateway	Blood Sugar	Blood Pressure	Weight	SpO ₂
User 1	Х	Х	Х		Х
User 2	Х	Х		Х	
User 3	Х	Х	Х		

Table 19: Equipment mix

Each user was given a test script which was designed to test functionality of the patient portal and of the devices. Once per day each user walked through the test script and completed the actions on the devices and patient portal. Users were asked to log the results against expected outcomes, see Figure 29.

Patient data was viewed on the clinical portal. Data was matched with manual logs to ensure data accuracy and transmission reliability. In the event that data was missing, the technical team were alerted. Patients were called to determine if technical, training support was required.

Results from the testing were logged in an action log and in JIRA, see Figure 30. Actions were reviewed regularly via meetings with the technical partners and actions were updated and closed as necessary.

				Mon		Tues		Wed		Thur		Fri	
Task	Navigation	Action	Expected Outcome	Comp	pleted	Comp	pleted	Com	pleted	Com	pleted	Com	pleted
				Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Enter Blood	Home Page	Click on Capture	Capture data page										
Glucose		Data	appears										
Enter Blood	Capture Data	Click on Manual	Manual										
Glucose		Measurement	Measurement page										
			appears										
Enter Blood	Manual	Click on Glucose	Enter Glucose page										
Glucose	Measurement	Measure	appears										
Enter Blood	Glucose page	Enter Date	Date is entered										
Glucose													
Enter Blood	Glucose Page	Enter Time	Time is entered										
Glucose													
Enter Blood	Glucose Page	Enter Glucose Level	Glucose level is										
Glucose			entered										
Enter Blood	Glucose Page	Select status	Yes / No is										
Glucose			displayed										
Enter Blood	Glucose Page	Click on Submit	Retuned to Manual										
Glucose			Measurement Page										
Notes:													

Figure 29: Test script

· Descent of a	COMPANY -	-	the second s	Channel and Channe	-	Characteristics and a second s		
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Figure 30: Action log

MPV Home Gateway

We were provided with one MPV home gateway kit to test. The kit consisted of a black box, blood pressure meter, SpO_2 meter, blood glucometer and weight. Testing was slightly erratic and not consistent. Issues with internet connectivity meant that testing was not consistent.

6.2.2 Field Testing

Following the friends and family testing, a number of patients from the target sample were approached and asked to take part in a series of field tests. The main objectives of the pre-pilot field testing phase were to:

- Test functionality of the equipment in a patient home environment
- Test installation procedures in a home environment
- Provide feedback to the technical teams on additional requirements
- Train clinical users on equipment and clinical interface
- Refine monitoring and clinical protocols
- Use information gained to inform the ethical approval

Six patients were recruited to take part, three for the HMPG home gateway and three for the MPV home gateway. Patients were asked if they had access to their own PC and if connections were wired or wireless. All six patients had a PC or a tablet and had a basic level of PC literacy, see Table 20.

User	Age	Gender	Diabetes	Blood	Blood	Tablet	Own PC
				Sugar	Pressure		
Patient 1	72	Male	Type 2	Х	Х		Х
Patient 2	56	Male	Type 1	Х	Х	Х	
Patient 3	66	Female	Type 1	Х	Х		Х
Patient 4	72	Male	Type 2	Х	Х		Х
Patient 5	62	Male	Type 2	Х	Х		Х
Patient 6	61	Male	Type 2	Х	Х		Х

Table 20: Demographics and device provided to patient

MPV Home Gateway

Installation, training and consent taking were conducted by the CHC research team. Each installation took between 40 and 60 minutes to complete.

Patients were provided with a blood glucose monitor and blood pressure. One patient was provided with a tablet despite having access to a PC in order to test and get feedback. All were asked to complete a minimum of 1 blood glucose measurement per day and a blood pressure measurement.

The tasks assigned to each patient are listed in Table 21.

User	Activity Questionnai re	Diet Questionnaire	Manual Readings*	Insulin Dose	Medication Compliance Questionnaire	Medication Compliance Daily
Patient 1	Х	Х	X		Х	X
Patient 2	Х	Х	X	Х	Х	
Patient 3	Х	Х	X	Х	Х	
Patient 4	Х	Х	X		Х	Х
Patient 5	Х	Х	X	Х	Х	
Patient 6	Х	Х	X	Х	Х	

Table 21: Information captured via patient portal

As an outcome of the friends and family testing, it was decided that technical support would be provided for the installations of home gateways. It was arranged that 2 kits would be installed using

WIFI connectivity and another would using wired internet connectivity. Clinicians from CHC were accompanied by 2 technical people from CNET.

Clinical Portal

Clinicians and researchers from CHC monitored incoming patient data on the clinical portal and patient portals. Patients completed between 7 and 28 days on the system. Patients were asked about their experiences using the device and portal.

Patient Portal

Patients were also provided with a user name and password for the patient portal. Patients were asked to log onto the patient portal and enter information based on their need.

Results from the testing were logged in an action log and in JIRA. Actions were reviewed regularly via meetings with the technical partners and actions were updated and/or closed as necessary.

6.2.3 Major findings and recommendations

6.2.3.1 Home gateways and devices

HMPG Home Gateway and device functionality

Devices worked as expected in relation to taking readings. Battery power which had been a problem in earlier testing periods was not found to be an issue. A number of device issues were identified during both phases of the testing. These have since been solved.

- Loss of connectivity between gateway and device (indicated by red light on device).
- Loss of GSM connectivity on gateway (indicated by red light)

Device usability

None of the patients reported any usability issues with the devices. The patients indicated a liking for the LEDs as this enabled feedback that data had been sent.

MPV Home Gateway

Devices worked as expected, with none of the patients reporting any issues. WIFI installation required a portable screen, keyboard and mouse in order to connect to the WIFI. We required an additional router for the patient who used wired connections as his router only had one port. On one occasion blood sugar readings stopped appearing on the clinical portal. The technical team were informed and the black box was remotely rebooted and readings transmitted.

- Need to identify wired or wireless connectivity prior to installation
- Need to bring screen, keyboard and mouse for wireless connectivity

Device Usability

None of the patients reported any usability issues with the devices. One patient called to enquire about the blood glucometer as it flashed continuously when it was plugged into the black box even when fully charged.

6.2.3.2 Patient Portal

Patient Portal Functionality

All patients were able to gain access to the patient portal on both the tablet and their own PC. There was one functional error reported by one of the patients using a PC. This was to do with the date range when entering manual readings, and the problem was solved in a new version of the patient portal.

Patient Portal Usability - PC

Patients generally reported that the patient portal was easy to use. It was simple to log onto and was quick to navigate and complete the tasks. The usability issues that were raised are as follows:

- Screen resolution: If the screen resolution was increased (due to patient requiring larger font), the patient portal screen would become distorted and not all options were viewable. This was resolved in version 1.2.2.
- Patient entry of data: One patient was using a very old version of the web browser and was not able to use the slider functions on the questionnaires. The patient was not aware of how to update their browser settings.

During the testing period the patient portal was updated to use https. After this, every user was confronted with a security message asking about the display of secure and non-secure data each time they selected an option on the patient portal. We are still waiting for this to be investigated and remedied.

Patient Portal Usability – Tablet PC

The patient using the tablet had a level of reduced mobility in his hands and reported that he sometimes found it difficult to enter in data on the tablet, e.g., user name and password and manual readings.

6.2.3.3 Clinical Portal

The clinicians had previously used the clinical portal for other monitoring and so were used to the navigation and basic functionality. The clinicians were able to access the portal when required at their work stations and view data from each of the patients. At the time of testing there were still some functionality that had not been implemented and as such has not been tested.

Functionality

- Ability to capture blood glucose context data, e.g., pre meal, post, ad hoc reading
- Display of questionnaire data
- Resetting patient questionnaire
- Assign patient username and password
- Assigning equipment
- Sorting of patient data
- Rules and notifications
- Prioritisation of incoming data
- Reports

Usability

During initial testing phases the clinicians reported that the clinical portal was easy to use and to navigate. However as more patients were added to the system it became apparent that the management of data was not optimum. As a result a new set of updated requirements have been written for the clinical portal to help manage and prioritise incoming data. These updated requirements include:

- Reducing the number of steps to view data
- Display of patient specific data
- Graphical display of data
- Making it easier to assign patient equipment
- Ability to distinguish manually entered readings on the patient portal to those sent via the device.
- Improve terminology used on the portal

Accuracy of Data

There have been a number of issues where data transmitted from the device and patient entered manually from the patient portal was not accurately reflected in the clinical portal. Most of the problems seem to have been related to the Blood Glucose measurements.

- Device data missing
- Duplicate data same reading and timestamp
- Transmission of stored data from Blood Glucometer
- Display of blood glucose data in mgl as opposed to the requirement of mmol/L

6.2.4 Technology Survey of patients

As an extension of the pre-pilot, we also undertook a survey of diabetes patients on the CHC disease register. The aim of the survey was to better understand the device requirements as well as any constraints.

To date 25% of patients on the diabetes register at CHC have been asked to complete the survey. The survey has been conducted via phone calls and in person at the health centre.

No. of patients who have a PC

69% have access to PC

17% do not have access to PC

14% other

Type of Operating System

17% Vista

21% XP

24% Windows 7

38% don't know

Age of PC

Less than 2 years 21%

Greater than 2 years 48%

Do not know 31%

Type of Connectivity

Wired 35%

Wireless 41%

Both 10%

Do not know 14%

6.2.5 Summary

Following the period of testing of the devices we have now begun deployment within the clinical trials. The user testing phases have identified a number of areas that need improvement and these are being fed back into the next iteration of user requirements.

- Improved management of patient information on the clinical portal
- Improved user manuals for both the home and patient Gateway that will enable drop ship of equipment to patients
- Improved understanding of which system (HMPG or MPV Home Gateway) should be used for which patient demographic

• Improvements to the usability of the patient portal

7 Impact assessment

7.1 Impact on architecture

During the third iteration we have successfully tested the flexibility and openness of the REACTION platform. In the primary care scenario the concept of two types of gateways was introduced – HMPG home gateway and MPV home gateway. The distinction is in how they are clinically used. The purpose of the HMPG home gateway is to allow screening of all patients during a two-week period to determine their individual needs. The purpose of the MPV home gateway is to support patients with special needs. During the trial two different solutions have been tested – a single-protocol hardware-based gateway and a multi-protocol software-based gateway – to explore advantages and disadvantages. The multi-protocol gateway was developed using the REACTION DCK. The Patient Portal is also based on REACTION software and adds user interaction through a touch screen and possibly video-conferencing capabilities.

The use of the two gateways in combination with a variety of commercial off-the-shelf devices as well as experimental research devices has shown that the REACTION platform is able to support a wide range of remote monitoring applications.

During the third iteration it became apparent that we need a service layer between REACTION components and the underlying database. This was already foreseen in the original REACTION architecture as "Internal interface adaptors", and our experiences have shown that it would be beneficial for several reasons to implement such a layer. Firstly, it will further extend the service-oriented architecture of REACTION and allow full use of concepts like service orchestration. Secondly it will also facilitate the exploitation and use of the REACTION platform in new applications beyond the trials of the project.

Furthermore, the initial work on integration with emergency services will also require implementation of interfaces with these types of services. This has also been foreseen in the original architecture as "External interface adaptors", and now we need to instantiate this layer with support for common protocols in the emergency field

7.2 Compliance with Medical Device Directive

Compliance with the Medical Device Directive is described in Section 7.2 of the previous version of this document, *ID2-8-3 Change request and re-engineering report 2*. This information will be updated in internal deliverable *ID6-6 REACTION solutions and the Medical Device Directive*, which is due in M42 (August 2013).

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9 Appendix A

In-hospital domain tests (back end) - Summary of domain tests

Group name	Methods
AuditTrailDao	AuditTrailDaoTransformTest.testToAuditTrailVO_GlucoManUser_ empty()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDaoTransformTest@5a92668c] AuditTrailDaoTransformTest.testToAuditTrailVO_GlucoManUser_li nked()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDaoTransformTest@5a92668c] AuditTrailDaoOperationTest.testCreateAuditTrail()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDaoOperationTest@4b7f1841] AuditTrailDao_createAuditTrailTest.testCreateAuditTrail_userExist s()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDao_createAuditTrailTest.testCreateAuditTrail_userExist s()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDao_createAuditTrailTest.testCreateAuditTrail_principal Null()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDao_createAuditTrailTest.testCreateAuditTrail_principal Null()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDao_createAuditTrailTest@669a4cb] AuditTrailDao_createAuditTrailTest.testCreateAuditTrail_principal NameNull()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDao_createAuditTrailTest.testCreateAuditTrail_principal NameNull()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDao_createAuditTrailTest.testCreateAuditTrail_userNotE xists()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDao_createAuditTrailTest@669a4cb] AuditTrailDao_createAuditTrailTest@669a4cb] AuditTrailDao_createAuditTrailTest@669a4cb] AuditTrailDao_reateAuditTrailTest@669a4cb] AuditTrailDaoTransformTest.testAuditTrailVOToEntity()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.A uditTrailDaoTransformTest@5392668c]
DrugDao	DrugDaoTransformTest.testDrugVOToEntity_entity_exists() DrugDaoTransformTest.testDrugVOToEntity() DrugDaoTransformTest.testToDrugVO() DrugDao_findByCriteriaTest.testSuccessPath()
DssCalculationDao	EnrolmentRecordDaoTransformTest.testToEnrolmentRecordDetail VO()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.E nrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest.testEnrolmentRecordDetailV OToEntity()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.E nrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest.testEnrolmentRecordVOToE ntity()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.E nrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest.testToRecentActivityVO()[pri: 0, instance:eu.reaction.prototype.glucosemanagement.domain.test.E nrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest@92696c2] EnrolmentRecordDaoTransformTest@92696c2]

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	userName_exists()
	GlucoManUserDaoTransformTest.testUserVOToEntity_no_user_
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	GlucoManUserDaoTransformTest.testUserListVOToEntity()
	GlucoManUserDao_findByPhraseTest.testSuccessPath_only_phr
	ase() GlucoManUserDaoTransformTest.testToUserListVO()
	GlucoManUserDaoTransformTest.testToUserVO()
	GlucoManUserDao_findByPhraseTest.testSuccessPath_only_dea
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	instance:eu.reaction.prototype.glucosemanagement.domain.test.In
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	InsulinDoseAdjustmentRecordDaoTransformTest.testInsulinDose
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	sulinDoseAdjustmentRecordDaoTransformTest@370a5c21]
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	VO()[pri:0,
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	MeasurementRecordDaoTransformTest.testMeasurementRecord
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	ntActivityVORecord()[pri:0,
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	easurementRecordDaoTransformTest@2929e5e9]
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	MeasurementRecordDaoTransformTest.testToMeasurementRecor
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	MeasurementTypeDaoOperationTest.testCheckMeasurmentType
	Aliases_one_set()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.domain.test.M
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	dVOToEntity()[pri:0,
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	NutritionRecordDaoTransformTest.testToNutritionRecordDetailVO
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	utritionRecordDaoTransformTest@44739f3f]
	NutritionRecordDaoTransformTest.testUpdateNutritionRecordVOT
	oEntity()[pri:0,
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	NutritionRecordDaoTransformTest.testAddNutritionRecordVOToE
	ntity()[pri:0,
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	Entity()[pri:0,
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	currentPatientLocation()[pri:0,
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	PatientDaoTransformTest.testToPatientVO_all_populated()[pri:0,
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ecordDaoOperationTest@1766bfd8]
NutritionRecordDaoOperationTest.testCreate()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.N
utritionRecordDaoOperationTest@38d0357a]
RecordDaoOperationTest.testCreateAndAuditRecord_emptyRecor
dComment()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoOperationTest@1766bfd8] RecordDao findByPatientIDTest.testFindRecordsForPatient ok()[
pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R ecordDao_findByPatientIDTest@6bd38b87]
RecordDaoOperationTest.testUpdateAndAuditRecordCriticalRecord
d()[pri:0,
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ecordDaoOperationTest@1766bfd8]
RecordDaoOperationTest.testDeactivateAndAuditRecord_instrum
entationTest()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoOperationTest@1766bfd8]
RecordDao_findByCriteriaTest.testRecordTypes()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByCriteriaTest@338e18a3]
RecordDao_findByEnrolmentIDTest.testFindByEnrolmentID_sort_
order_measurements()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByEnrolmentIDTest@5117a20]
RecordDaoOperationTest.testCreateAndAuditRecord()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoOperationTest@1766bfd8]
RecordDaoOperationTest.testCreateAndAuditRecord_instrumenta
tionTest()[pri:0,

instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoOperationTest@1766bfd8] RecordDao_findByCriteriaTest.testEventDateTimeFromEqual()[pri
:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByCriteriaTest@338e18a3]
RecordDao_findByCriteriaTest.testWardID()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByCriteriaTest@338e18a3]
RecordDao_getActiveByRecordIDTest.testSuccessPath()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_getActiveByRecordIDTest@6d66f9b9]
RecordDao_findByCriteriaTest.testChangeable()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByCriteriaTest@338e18a3]
RecordDao_findByCriteriaTest.testEnrolmentEndDateFrom()[pri:0,
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ecordDao_findByCriteriaTest@338e18a3]
RecordDaoOperationTest.testDeactivateAndAuditRecord_recordN
otActive()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R ecordDaoOperationTest@1766bfd8]
RecordDao_findByCriteriaTest.testEventDateTimeToEqual()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByCriteriaTest@338e18a3]
RecordDaoOperationTest.testUpdateAndAuditRecord_eventDateT
imeNotSet()[pri:0,
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ecordDaoOperationTest@1766bfd8]
RecordDaoOperationTest.testCreateAndAuditRecord_recordIdSet ()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoOperationTest@1766bfd8]
RecordDao_findByCriteriaTest.testPatientIDWrong()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByCriteriaTest@338e18a3]
RecordDao_findByCriteriaTest.testRecordIDWrong()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R ecordDao_findByCriteriaTest@338e18a3]
RecordDao_getActiveByRecordIDTest.testWithDeactivatedRecord
()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_getActiveByRecordIDTest@6d66f9b9]
RecordDao_findByPatientIDTest.testfindRecordsForPatient_no_p
atientID()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao findByPatientIDTest@6bd38b87]
RecordDaoOperationTest.testDeactivateAndAuditRecord()[pri:0,
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ecordDaoOperationTest@1766bfd8]
RecordDao_findByPatientIDTest.testfindRecordsForPatient_ok2()[
pri:0,
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ecordDao_findByPatientIDTest@6bd38b87] RecordDaoOperationTest.testCreateAndAuditRecord_recordType
Set()[pri:0,
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ecordDaoOperationTest@1766bfd8]
RecordDaoTransformTest.testRecentActivitiesVOToEntity()[pri:0,
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ecordDaoTransformTest@30d58ce2]
RecordDaoOperationTest.testCreateAndAuditRecord_emptyEvent
DateTime()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoOperationTest@1766bfd8]
RecordDaoTransformTest.testToRecentActivitiesVO()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoTransformTest@30d58ce2]
RecordDaoOperationTest.testUpdateAndAuditRecord_recordIsNot
Changeable()[pri:0,
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RecordDao_getAllVersionsByRecordIDTest.testSuccessPath()[pri:
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_getAllVersionsByRecordIDTest@3e68cd79]
RecordDao_findByCriteriaTest.testEnrolmentStartDateTo()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao findByCriteriaTest@338e18a3]
RecordDao findByCriteriaTest.testEventDateTimeFromAfter()[pri:
0,
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ecordDao_findByCriteriaTest@338e18a3]
RecordDao_findByCriteriaTest.testSuccessPath()[pri:0,
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ecordDao_findByCriteriaTest@338e18a3]
RecordDaoOperationTest.testUpdateAndAuditRecord_changeable
TypeNotSet()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoOperationTest@1766bfd8]
RecordDaoOperationTest.testDeactivateAndAuditRecord_recordT
ypeNotSet()[pri:0,
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ecordDaoOperationTest@1766bfd8]
RecordDao_findByCriteriaTest.testEnrolmentStartDateFromEqual(
)[pri:0,
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RecordDao findByPatientIDTest.testFindByPatientID sort order()
[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByPatientIDTest@6bd38b87]
RecordDao_findByEnrolmentIDTest.testFindByEnrolmentID_ok()[
pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByEnrolmentIDTest@5117a20]
RecordDao_findByCriteriaTest.testEnrolmentEndDateTo()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByCriteriaTest@338e18a3]
RecordDao_findByCriteriaTest.testRecordType()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByCriteriaTest@338e18a3]
RecordDaoOperationTest.testCreateAndAuditRecord_recordActiv
e()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDaoOperationTest@1766bfd8] RecordDao_findByEnrolmentIDTest.findByEnrolmentID_no_enrol
mentId()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.domain.test.R
ecordDao_findByEnrolmentIDTest@5117a20]

	RecordDaoOperationTest.testCreateAndAuditRecord_emptyChan geableType()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.domain.test.R
	ecordDaoOperationTest@1766bfd8] RecordDaoOperationTest.testDeactivateAndAuditRecord_recordIs
	NotChangeable()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.domain.test.R ecordDaoOperationTest@1766bfd8]
	RoomDaoTransformTest.testRoomVOToEntity_entity_exists()
RoomDao	RoomDaoTransformTest.testToRoomVO()
	RoomDaoTransformTest.testRoomVOToEntity()
	StopEnrolmentRecordDaoTransformTest.testStopEnrolmentRece ntActivityVOToEntity()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.domain.test.S
	topEnrolmentRecordDaoTransformTest@10980e7]
	StopEnrolmentRecordDao_findByCriteriaTest.testSuccessPath()[p
StopEnrolmentDao	ri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.S
	topEnrolmentRecordDao_findByCriteriaTest@40b86944]
	StopEnrolmentRecordDaoTransformTest.testToStopEnrolmentRe
	centActivityVO()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.S
	topEnrolmentRecordDaoTransformTest@10980e7]
	TaskDao_findByCriteriaTest.testSuccessPath()
TaskDao	TaskDaoTransformTest.testTaskDetailVOToEntity()
	TaskDaoTransformTest.testToTaskDetailVO()
	TherapySettingsRecordDaoTransformTest.testTherapySettingsDe tailVOToEntity()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.domain.test.T
	herapySettingsRecordDaoTransformTest@235f4a7f]
	TherapySettingsRecordDaoTransformTest.testToTherapySettings DetailVO()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.domain.test.T
	herapySettingsRecordDaoTransformTest@235f4a7f]
	TherapySettingsRecordDaoTransformTest.testTherapySettingsVO
TherapySettingsRecordDao	ToEntity()[pri:0, instance:eu.reaction.prototype.glucosemanagement.domain.test.T
	herapySettingsRecordDaoTransformTest@235f4a7f]
	TherapySettingsRecordDaoTransformTest.testToTherapySettings
	VO()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.domain.test.T herapySettingsRecordDaoTransformTest@235f4a7f]
	TherapySettingsRecordDao_findByCriteriaTest.testSuccessPath()[
	pri:0,
	instance:eu.reaction.prototype.glucosemanagement.domain.test.T herapySettingsRecordDao_findByCriteriaTest@7a9300cc]
	TherapyMedicationDaoTransformTest.testToTherapyMedicationV
TherapyMedicationDao	O()
Therapywealoation.buo	TherapyMedicationDaoTransformTest.testTherapyMedicationVOT
	oEntity() VisitTest.testGetEnrolmentStatus_stoped_oneEnrolment()
	VisitTest.testGetEnrolmentStatus_started_stopStartEnrolment()
VisitDao	VisitTest.testGetEnrolmentStatus_unknown()
	VisitTest.testGetEnrolmentStatus_stoped_stopStopEnrolment()
	VisitTest.testGetEnrolmentStatus_started_oneEnrolment() WardDaoTransformTest.testWardVOToEntity()
WardDao	WardDaoTransformTest.testWardVOToEntity()
	WardDaoTransformTest.testToWardVO()

Default test

Tests run: 191, Failures: 0, Skips: 0

10 Appendix B

In hospital unit tests (back end)

Service tests

DSS tests

	yRegimenHandlerService_getNewDailyInsulinDoseTest.test
BasalBolusTherapyRegi 7] BasalBolusTherapyRegi	n-porotype.glucosemanagement.service.regimen.test.Basal menHandlerService_getNewDailyInsulinDoseTest@4b85c1 yRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 yRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 yRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 yRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 yRegimenHandlerService_getPartialInsulinDoseRecommen PartialInsulinDoseRecommendationBloodGlucoseZero()[pri: n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getPartialInsulinDoseRecommen PartialInsulinDoseRecommendationBloodGlucoseZero()[pri: n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getPartialInsulinDoseRecommendation yRegimenHandlerService_getInitialDailyInsulinDoseTest.test inDoseCreatininLessThanZero()[pri:0, n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getInitialDailyInsulinDoseTest.test inDoseDateOfBirthAfterToday()[pri:0, n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getInitialDailyInsulinDoseTest@7bafb0 yRegimenHandlerService_getPartialInsulinDoseRecommen PartialInsulinDoseRecommendationRecordIDAndDateTimeV n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getPartialInsulinDoseRecommen PartialInsulinDoseRecommentTypeBloodGlucose()[pri:0, n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getNewDailyInsulinDoseTest.test nDoseDailyInsulinDoseNotSet()[pri:0, n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getNewDailyInsulinDoseTest.test nDoseDailyInsulinDoseNotSet()[pri:0, n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getNewDailyInsulinDoseTest.test nDoseDailyInsulinDoseNotSet()[pri:0, n.prototype.glucosemanagement.service.regimen.test.Basal menHandlerService_getPartialInsulinDoseRecommen PartialInsulinDoseRecommendationDailyInsulinDoseRecommen PartialInsulinDoseRecommendationDailyInsulinDoseRecommen PartialInsulinDoseRecommendationDailyInsulinDoseRecommen

instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation Test@4513e9fd]
BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test GetNewDailyInsulinDoseManyMeasurementsWithDssCalculation()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 7]
BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test GetNewDailyInsulinDoseNoTherapyAdjustments()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 7]
BasalBolusTherapyRegimenHandlerService_workflowTest.testNegativeTotalB olusDoseErrorSubject113()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_workflowTest@5c4b82d2] BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test
GetNewDailyInsulinDoseLotsMeasurementsWithDssCalculation()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 7]
BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommen dationTest.testGetPartialInsulinDoseRecommendationNotBasalBolus()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation Test@4513e9fd]
BasalBolusTherapyRegimenHandlerService_getCurrentDailyInsulinDoseTest.t estGetCurrentDailyInsulinDose_remainderDose_greaterEqual3()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getCurrentDailyInsulinDoseTest@1b5b 8520]
BasalBolusTherapyRegimenHandlerService_getCurrentDailyInsulinDoseTest.t estGetCurrentDailyInsulinDose_remainderDose_greaterEqual2()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getCurrentDailyInsulinDoseTest@1b5b 8520]
BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommen dationTest.testGetPartialInsulinDoseRecommendationInsulinResistanceNotSet
()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation Test@4513e9fd]
BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommen dationTest.testGetPartialInsulinDoseRecommendationInsulinResistanceSensiti ve()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation
Test@4513e9fd] BasalBolusTherapyRegimenHandlerService_getCurrentDailyInsulinDoseTest.t estGetCurrentDailyInsulinDose_remainderDose_greaterEqual1()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getCurrentDailyInsulinDoseTest@1b5b
8520] BasalBolusTherapyRegimenHandlerService_workflowTest.testDoubleDailyInsu linDoseErrorSubject112()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_workflowTest@5c4b82d2]
BasalBolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest.test GetInitialDailyInsulinDose_successPath_creatinine_greater_2()[pri:0,

instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getInitialDailyInsulinDoseTest@7bafb0 c7] BasalBolusTherapyRegimenHandlerService getInitialDailyInsulinDoseTest.test GetInitialDailyInsulinDoseWeightNotChanged()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest@7bafb0 c7] BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test AfterMorningZoneWithActualMorningMeasurement()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getNewDailyInsulinDoseTest@4b85c1 71 BasalBolusTherapyRegimenHandlerService getNewDailyInsulinDoseTest.test GetNewDailvInsulinDose measurements before therapvAdjustment()[pri:0. instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getNewDailyInsulinDoseTest@4b85c1 7] BasalBolusTherapyRegimenHandlerService getInitialDailyInsulinDoseTest.test GetInitialDailyInsulinDose successPath age greater 70()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getInitialDailyInsulinDoseTest@7bafb0 c7] BasalBolusTherapyRegimenHandlerService getInitialDailyInsulinDoseTest.test GetInitialDailyInsulinDoseNoElementRecord()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getInitialDailyInsulinDoseTest@7bafb0 c7] BasalBolusTherapyRegimenHandlerService getPartialInsulinDoseRecommen dationTest.testGetPartialInsulinDoseRecommendationWithBolusInsulinAdminis tered()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getPartialInsulinDoseRecommendation Test@4513e9fd] BasalBolusTherapyRegimenHandlerService getPartialInsulinDoseRecommen dationTest.testGetPartialInsulinDoseRecommendationRecordIDNoMeasureme nt()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getPartialInsulinDoseRecommendation Test@4513e9fd] BasalBolusTherapyRegimenHandlerService getNewDailyInsulinDoseTest.test GetNewDailyInsulinDoseNoEnrolment()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getNewDailyInsulinDoseTest@4b85c1 7] BasalBolusTherapyRegimenHandlerService getNewDailyInsulinDoseTest.test GetNewDailyInsulinDoseManyMeasurements()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getNewDailyInsulinDoseTest@4b85c1 7] BasalBolusTherapyRegimenHandlerService getCurrentDailyInsulinDoseTest.t estGetCurrentDailyInsulinDose remainderDose less0()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService getCurrentDailyInsulinDoseTest@1b5b 85201 BasalBolusTherapyRegimenHandlerService getNewDailyInsulinDoseTest.test GetNewDailyInsulinDose eveningMeasurement missing()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 7]

BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test GetNewDailyInsulinDoseNoMeasurement()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 7]
BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test GetNewDailyInsulinDoseManyTherapyAdjustments()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 7]
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instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest@7bafb0 c7]
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$Basal Bolus Therapy Regimen Handler Service_get New Daily Insulin Dose Test.test Get New Daily Insulin Dose_morning Blood Glucose Value_greater 181_evening Blood Glucose Value_greater 180_evening Blood Glucose Value_greater 180_eveningreater 18$
odGlucoseValue_greater181_successPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1
7] BasalBolusTherapyRegimenHandlerService_getCurrentDailyInsulinDoseTest.t
estGetCurrentDailyInsulinDose_regimenType_not_supported()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getCurrentDailyInsulinDoseTest@1b5b
8520] BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.testI nMorningZoneWithoutActualMorningMeasurement()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1
7] BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommen dationTest.testGetPartialInsulinDoseRecommendationDssDailyInsulin()[pri:0,
$instance: eu.reaction.prototype.glucosemanagement.service.regimen.test.BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation$
Test@4513e9fd] BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test GetNewDailyInsulinDose_dssDailyInsulinDose_negative()[pri:0,
$instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1$
7] BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test GetNewDailyInsulinDoseDailyInsulinDoseZero()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 7]
BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test GetNewDailyInsulinDoseMoreMeasurementsAtATimeZone()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1 7]
$BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendationTest.testGetPartialInsulinDoseRecommendationInsulinResistanceResist$
ant()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal

BolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation
Test@4513e9fd] BasalBolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest.test
GetInitialDailyInsulinDoseNoMeasurementTypeCreatinin()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest@7bafb0 c7]
BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommen
dationTest.testGetPartialInsulinDoseRecommendationRecordID()[pri:0,
instance: eu.reaction. prototype. glucosemanagement. service. regimen. test. Basal
BolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation Test@4513e9fd]
$BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test$
GetNewDailyInsulinDose_morningBloodGlucoseValue_greater141_eveningBlo
odGlucoseValue_greater141_successPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1
7]
$BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test$
GetNewDailyInsulinDoseDssCalculation()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1
7]
BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test
GetNewDailyInsulinDose_morningBloodGlucoseValue_hypo_eveningBloodGlu
coseValue_hypo()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1
7]
BasalBolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest.test
GetInitialDailyInsulinDose_successPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest@7bafb0
c7]
BasalBolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest.test
GetInitialDailyInsulinDoseVisitIsNotCurrent()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getInitialDailyInsulinDoseTest@7bafb0
c7]
$BasalBolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest.test$
GetNewDailyInsulinDose_morningMeasurement_missing()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getNewDailyInsulinDoseTest@4b85c1
7]
BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommen
dationTest.testGetPartialInsulinDoseRecommendationWithBasalInsulinAdminis
tered()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal
BolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation
Test@4513e9fd]
BasalBolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommen
dationTest.testGetPartialInsulinDoseRecommendationNoMeasurements()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.regimen.test.Basal BolusTherapyRegimenHandlerService_getPartialInsulinDoseRecommendation
Test@4513e9fd]

Default suite

Total tests run: 109, Failures: 0, Skips: 0

Medication tests

Service name	Methods
DrugService	DrugService_loadDrugsTest.testLoadDrugsTest_SuccessPath()
LocalDrugService	LocalDrugService_loadDrugsTest.testLoadDrugsTest_SuccessPath()
MedicationService	MedicationService_addMedicationRecordsTest.testAddMedicationRecordWith NutritionMocked()[pri0, instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M edicationService_addMedicationRecordsTest@d522de2] MedicationService_addMedicationRecordsTest@d522de2] MedicationService_addMedicationRecordsTest@d522de2] MedicationService_addMedicationRecordsTest.testAddMedicationRecordNoC urrentEnroImentForPatient()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M edicationService_addMedicationRecordsTest@d522de2] MedicationService_addMedicationRecordsTest@d522de2] MedicationService_addMedicationRecordTest.testAddMedicationRecordMoC urrentEnroImentForPatient()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.medicationRecord MedicationService_updateMedicationRecordTest.testUpdateMedicationRecord MedicationService_deactivateMedicationRecordTest.testDeactivateMedication RecordSuccesPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M edicationService_deactivateMedicationRecordTest_testDeactivateMedication RecordSuccesPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M edicationService_updateMedicationRecordTest_testUpdateMedicationRecord Test_testUpdateMedicationRecordTest_testUpdateMedicationRecord WithNutritionNoMedicationLpdate()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M edicationService_addMedicationRecordTest_testAddMedicationRecordDss Calculation()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M edicationService_addMedicationRecordTest_de522de2] MedicationService_addMedicationRecordSTest@d522de2] MedicationService_addMedicationRecordTest_de522de2] MedicationService_deadtMedicationRecordTest_de522de2] MedicationService_indMedicationRecordTest@d522de2] MedicationService_indMedicationRecordTest_de527a4bd4] MedicationService_updateMedicationRecordTest_de571a4bd4] MedicationService_updateMedicationRecordTest.testUpdat

essPath()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_addMedicationRecordsTest@d522de2]
MedicationService_updateMedicationRecordTest.testUpdateMedicationRecor
dEnrolmentStopped()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_updateMedicationRecordTest@571a4bd4]
MedicationService_deactivateMedicationRecordTest.testDeactivateMedication
RecordWithNutrition()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_deactivateMedicationRecordTest@7b283052]
MedicationService_updateMedicationRecordTest.testUpdateMedicationRecor
dEventDateTimeUpdateUnit()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_updateMedicationRecordTest@571a4bd4]
MedicationService_updateMedicationRecordTest.testUpdateMedicationRecor
dOnePreviousMedicationRecord()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_updateMedicationRecordTest@571a4bd4]
MedicationService_deactivateMedicationRecordTest.testDeactivateMedication
RecordMedicationCritical()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_deactivateMedicationRecordTest@7b283052]
MedicationService_deactivateMedicationRecordTest.testDeactivateMedication
RecordMedicationRecordDeactivated()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_deactivateMedicationRecordTest@7b283052]
MedicationService_updateMedicationRecordTest.testUpdateMedicationRecordEventDateTimeUpdate()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_updateMedicationRecordTest@571a4bd4]
MedicationService_updateMedicationRecordTest.testUpdateMedicationRecord
dWithNutrition()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService updateMedicationRecordTest@571a4bd4]
MedicationService updateMedicationRecordTest.testUpdateMedicationRecor
dWithNutritionNotLinked()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService updateMedicationRecordTest@571a4bd4]
MedicationService_addMedicationRecordsTest.testAddMedicationRecordTher
apyMedicationNotSet()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_addMedicationRecordsTest@d522de2]
MedicationService_addMedicationRecordsTest.testAddMedicationRecordRes
olveTaskMocked()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_addMedicationRecordsTest@d522de2]
$Medication Service_deactivate Medication Record Test.test Deactivate Medication$
RecordMedicationRecordNotFound()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.medication.test.M
edicationService_deactivateMedicationRecordTest@7b283052]

Default suite

Total tests run: 27, Failures: 0, Skips: 0

Nutrition tests

Service

Methods

name	
	NutritionService_findNutritionsTest.testSuccessPath()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionSe
	rvice_findNutritionsTest@239c7c21] NutritionService_deactivateNutritionTest.testSuccessPath()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionSe
	rvice_deactivateNutritionTest@76996cca]
	NutritionService_addNutritionTest.testSuccessPath()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionSe rvice addNutritionTest@98adae2]
	NutritionService_updateNutritionTest.testSuccessPath()[pri:0,
	instance: eu.reaction. prototype. glucosemanagement. service. nutrition. test. Nutrition Service. test. Nutrition Servi
	rvice_updateNutritionTest@52b57e9a] NutritionCoreService_updateNutritionTest.testBreadUnitsZero()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_updateNutritionTest@7f6877f8]
	NutritionCoreService_updateNutritionTest.testUpdateOnlyOneField()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_updateNutritionTest@7f6877f8] NutritionCoreService_deactivateNutritionTest.testSuccessPath()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_deactivateNutritionTest@b7c96a9]
	NutritionCoreService_findNutritionsTest.testOperationsCalled()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService findNutritionsTest@168e4805]
	NutritionCoreService_addNutritionTest.testBreadUnitsZero()[pri:0,
	instance: eu.reaction. prototype. glucosemanagement. service. nutrition. test. Nutrition Control of the service of the servi
	reService_addNutritionTest@d34eb84] NutritionCoreService_addNutritionTest.testBreadUnitsHundred()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
NutritionService	reService_addNutritionTest@d34eb84]
	NutritionCoreService_deactivateNutritionTest.testRecordAlreadyDeactivated()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService deactivateNutritionTest@b7c96a9]
	NutritionCoreService_findNutritionsTest.testSuccessPath()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_findNutritionsTest@168e4805]
	NutritionCoreService_updateNutritionTest.testRecordDoesNotExist()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService updateNutritionTest@7f6877f8]
	NutritionCoreService_findNutritionsTest.testCriteriaParameterSet()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_findNutritionsTest@168e4805] NutritionCoreService_updateNutritionTest.testNutritionLinkedWithMedication()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_updateNutritionTest@7f6877f8]
	NutritionCoreService_addNutritionTest.testMethodCalls()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService addNutritionTest@d34eb84]
	NutritionCoreService_deactivateNutritionTest.testDeactivateComment()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_deactivateNutritionTest@b7c96a9]
	NutritionCoreService_deactivateNutritionTest.testDeactivateCommentNull()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_deactivateNutritionTest@b7c96a9]
	NutritionCoreService_addNutritionTest.testBreadUnitsHundredPOne()[pri:0,
	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo
	reService_addNutritionTest@d34eb84] NutritionCoreService_updateNutritionTest.testSuccessPath()[pri:0,

	instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService_updateNutritionTest@7f6877f8] NutritionCoreService_addNutritionTest.testBreadUnitsZeroPOne()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService_addNutritionTest@d34eb84] NutritionCoreService_deactivateNutritionTest.testRecordDoesNotExist()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService_deactivateNutritionTest@b7c96a9] NutritionCoreService_addNutritionTest.testSuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService_addNutritionTest@d34eb84] NutritionCoreService_addNutritionTest.testNonExistentEnrolment()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService_addNutritionTest.testNonExistentEnrolment()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService_addNutritionTest.testNonExistentEnrolment()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo reService_addNutritionTest.testNonExistentEnrolment()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.nutrition.test.NutritionCo	

Default suite

Total tests run: 24, Failures: 0, Skips: 0

Patient tests

Service name	Methods
PatientDataManagement Service	PatientDataManagementService_cancelDischargeTest.testSuccessPath_a nother_active_visit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_cancelDischargeTest@35f38fc6] PatientDataManagementService_cancelDischargeTest.testSuccessPath_n o_other_active_visit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_cancelDischargeTest@35f38fc6] PatientDataManagementService_cancelAdmissionTest.testCancelAdmissio n_no_enrollment_linked_to_visit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_cancelAdmissionTest@1c20eb7] PatientDataManagementService_dischargePatientTest.testDischargePatie nt_no_patient()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_dischargePatientTest@606f8b2b] PatientDataManagementService_cancelAdmissionTest.testCancelAdmissio n_stopped_enrolment()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_cancelAdmissionTest@1c20eb7] PatientDataManagementService_admitPatientTest.testAdmitPatient_secon d_visit_first_visit_discharged()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_admitPatientTest@5c3a835d] PatientDataManagementService_mergePatientInformationTest.testMergeP atientDataManagementService_mergePatientInformationTest@212b19c5] PatientDataManagementService_cancelAdmissionTest.testCancelAdmission n_active_enrolment()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_cancelAdmissionTest.testSuccessPath_p atientDataManagementService_cancelAdmissionTest.testSuccessPath_p atientDataManagementService_cancelAdmissionTest.testSuccessPath_p instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_dischargePatientTest.testSuccessPath_p atientDataManagementService_di

PatientDataManagementService_mergePatientInformationTest.testMergeP atientInformation_nonSurvivingPatient_does_not_exist()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat
ientDataManagementService_mergePatientInformationTest@212b19c5] PatientDataManagementService_mergePatientInformationTest.testMergeP atientInformation survivingPatient does not exist()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_mergePatientInformationTest@212b19c5]
PatientDataManagementService_transferPatientTest.testTransferPatient_lo cation_variations(java.lang.String, java.lang.String, java.lang.String)[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_transferPatientTest@3efd66a5] PatientDataManagementService_admitPatientTest.testAdmitPatient_new_p atient()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_admitPatientTest@5c3a835d] PatientDataManagementService_admitPatientTest.testAdmitPatient_updat
e_patient_update_admission()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_admitPatientTest@5c3a835d]
PatientDataManagementService_dischargePatientTest.testDischargePatie nt_no_visit()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_dischargePatientTest@606f8b2b] PatientDataManagementService_updatePatientInformationTest.testUpdate PatientUnterservice_actionService_updatePatientInformationTest.testUpdate
PatientInformation_successPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_updatePatientInformationTest@39320a41] PatientDataManagementService_dischargePatientTest.testSuccessPath_p
atient_not_enrolled()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat
ientDataManagementService_dischargePatientTest@606f8b2b] PatientDataManagementService_cancelAdmissionTest.testCancelAdmissio n_no_patient()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_cancelAdmissionTest@1c20eb7] BatientDataManagementService_cancelDischargeTest testCancelDischarg
PatientDataManagementService_cancelDischargeTest.testCancelDischarg e_no_visit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat
ientDataManagementService_cancelDischargeTest@35f38fc6] PatientDataManagementService_cancelAdmissionTest.testCancelAdmissio
n_no_visit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_cancelAdmissionTest@1c20eb7] DetiintDataManagementService_cancelAdmissionTest@1c20eb7]
PatientDataManagementService_admitPatientTest.testAdmitPatient_updat e_patient_first_visit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat
ientDataManagementService_admitPatientTest@5c3a835d] PatientDataManagementService_admitPatientTest.testAdmitPatient_secon
d_visit_first_visit_active_patient_enrolled()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_admitPatientTest@5c3a835d]
PatientDataManagementService_admitPatientTest.testAdmitPatient_secon d_visit_first_visit_active()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_admitPatientTest@5c3a835d] PatientDataManagementService_transferPatientTest.testTransferPatient_vi
sit_with_assigned_pl_exists()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat

	ientDataManagementService_transferPatientTest@3efd66a5] PatientDataManagementService_admitPatientTest.testAdmitPatient_visit_d ischarged()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_admitPatientTest@5c3a835d] PatientDataManagementService_transferPatientTest.testTransferPatient_tr anfer_to_same_pl()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_transferPatientTest@3efd66a5] PatientDataManagementService_updatePatientInformationTest.testUpdate PatientDataManagementService_updatePatientInformationTest.testUpdate PatientInformation_patient_does_not()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_updatePatientInformationTest@39320a41] PatientDataManagementService_cancelDischargeTest.testCancelDischarg e_no_patient()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientDataManagementService_cancelDischargeTest@35f38fc6]
PatientService	PatientService_loadPatientEnrolmentTest.testLoadPatientEnrolmentTest_S uccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientService_loadPatientEnrolmentTest@7a20807c] PatientService_loadPatientEnrolmentTest.testLoadPatientEnrolmentTest_p atient_not_found()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientService_loadPatientEnrolmentTest@7a20807c] PatientService_findPatientsTest.testFindPatientsTest_SuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientService_findPatientsTest.testFindPatientsTest_SuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.patient.test.Pat ientService_findPatientsTest@49198ff2]

Recent activities tests

Service name	Methods
RecentActivitiesService	RecentActivitiesService_loadRecentActivitiesTest.testLoadRecentActivities MockSearchParam()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.activities.test.R ecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest.testLoadRecentActivities UpdatedRecord()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.activities.test.R ecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest.testLoadRecentActivities OtherCreator()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.activities.test.R ecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest.testLoadRecentActivities TwoDifferentCreator()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.activities.test.R ecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest@7db5391b] RecentActivitiesService_loadRecentActivitiesTest.testLoadRecentActivities ()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.activities.test.R ecentActivitiesService_loadRecentActivitiesTest@7db5391b]

Default suite

Total tests run: 5, Failures: 0, Skips: 0

Task manager tests

Service name	Methods				
TaskManagementCoreS ervice	TaskManagementCoreService_resolveTaskTest.testResolveTask_resolve_ task_no_exc_if_not_found()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_resolveTaskTest@14a8e586] TaskManagementCoreService_resolveTaskTest@14a8e586] TaskManagementCoreService_cancelTaskTest@14a8e586] TaskManagementCoreService_cancelTaskTest@14a8e586] TaskManagementCoreService_cancelTaskTest@14a8e586] TaskManagementCoreService_cancelTaskTest.testCancelTask_cancel_re minder_task_all_patients()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_cancelTaskTest@524c71d2] TaskManagementCoreService_cancelTaskTest.testCancelTask_cancel_ac tivity_task()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_cancelTaskTest@524c71d2] TaskManagementCoreService_generateTaskIDTest.testSuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_generateTaskIDTest@52c24193] TaskManagementCoreService_resolveTaskTest.testResolveTask_resolve_ reminder_task_all_patients()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_resolveTaskTest.testResolveTask_resolve_ reminder_task_all_patients()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_findTasksTest.testFindTasks_scheduledSta rDateTimeFrom_To()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_findTasksTest.testFindTasks_scheduledSta rDateTimeFrom_To()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_findTasksTest.testFindTasks_scheduledEn dDateTimeFrom_To()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCoreService_findTasksTest.testFindTasks_scheduledEn dDateTimeFrom_To()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementCore				
TaskManagementServic e	TaskManagementService_cancelTaskTest.testSuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementService_cancelTaskTest@3c3228a1] TaskManagementService_findTasksTest.testSuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementService_findTasksTest@56278e83] TaskManagementService_resolveTaskTest.testSuccessPath()[pri:0,				

	instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementService_resolveTaskTest@59e2afb2] TaskManagementService_createTaskTest.testSuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.task.test.Task ManagementService_createTaskTest@f79f36b]
TaskSchedulerService	

Therapy tests

Service name	Methods
TherapyService	TherapyService_findTherapySettingsTest.testSuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_getLatestInsulinDoseAdjustmentTest@44aea710] TherapyService_addNewTherapySettingsTest.testSuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_addNewTherapySettingsTest.testSuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_addNewTherapySettingsTest.testNo_active_visit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_findTherapySettingsTest.testNo_active_visit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest.testPatient_with_patientID_does _not_exist()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest.testNo_active_enrolment()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_getLatestInsulinDoseAdjustmentTest.testWithInsulinDose AdjustmentToOtherTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest.testDecending_order()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_findTherapySettingsTest@57c8b24d] TherapyService_addNewInsulinDoseAdjustmentTest.tes

-	nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_getCurrentTherapySettingsTest@729b1670] TherapyService_addNewTherapySettingsTest.testAddNewTherapySettings _getCurrentEnrolment()[pri:0,
i	nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_addNewTherapySettingsTest@9bad5a] TherapyService_addNewInsulinDoseAdjustmentTest.testPatient_with_patie
	ntID_does_not_exist()[pri:0,
e	nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.TherapyService_addNewInsulinDoseAdjustmentTest@472462b3]
	TherapyService_addNewInsulinDoseAdjustmentTest.testSuccessPath()[pri:),
i	nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.TherapyService_addNewInsulinDoseAdjustmentTest@472462b3]
	TherapyService_updateCurrentTherapySettingsTest.testSuccessPath()[pri:),
	nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_updateCurrentTherapySettingsTest@5a940f82]
	TherapyService_findTherapySettingsTest.testOther_current_enrolmentID()[pri:0,
	nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_findTherapySettingsTest@57c8b24d]
i	TherapyService_getLatestInsulinDoseAdjustmentTest.testSuccessPath()[pr :0,
e	nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th erapyService_getLatestInsulinDoseAdjustmentTest@44aea710]
1	TherapyService_addNewInsulinDoseAdjustmentTest.testInputParameterVa idation(boolean, java.lang.String, java.lang.String, java.lang.Float,
ĺ	ava.lang.Float, java.lang.Long, java.lang.String, java.lang.Class)[pri:0, nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th
	erapyService_addNewInsulinDoseAdjustmentTest@472462b3] TherapyService_addNewInsulinDoseAdjustmentTest.testOther_current_enr
i	blmentID()[pri:0, nstance:eu.reaction.prototype.glucosemanagement.service.therapy.test.Th
	erapyService_addNewInsulinDoseAdjustmentTest@472462b3]

User tests

Service name	Methods				
UserService	UserService_findUsersTest.testFindUsersTest_SuccessPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.user.test.User Service_findUsersTest@21fb3211]				

Default suite

Total tests run: 1, Failures: 0, Skips: 0

Enrolment tests

Service name	Methods				
EnrollmentService	EnrolmentService_startEnrolmentTest.testStartEnrolment_No_ActiveVisit()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test. EnrolmentService_startEnrolmentTest@4d480ea] EnrolmentService_updateEnrolmentTest.testUpdateEnrolment_SuccessPa				

th()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_updateEnrolmentTest@2dc0435]
EnrolmentService updateEnrolmentTest.testEnrolmentAlreadyStopped()[pr
i:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_updateEnrolmentTest@2dc0435]
EnrolmentService_stopEnrolmentTest.testStopEnrolment_SuccessPath()[p
ri:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_stopEnrolmentTest@74002515]
EnrolmentService_startEnrolmentTest.testStartEnrolment_EnrolmentExists ()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_startEnrolmentTest@4d480ea]
EnrolmentService updateEnrolmentTest.testStartEnrolment NoEnrolment
Exists()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService updateEnrolmentTest@2dc0435]
EnrolmentService_startEnrolmentTest.testStartEnrolment_SuccessPath()[p
ri:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_startEnrolmentTest@4d480ea]
EnrolmentService_stopEnrolmentTest.testStopEnrolment_NoEnrolmentExi sts()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_stopEnrolmentTest@74002515]
EnrolmentService_startEnrolmentTest.testStartEnrolment_NoPatientFound
()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_startEnrolmentTest@4d480ea]
EnrolmentService_updateEnrolmentTest.testStartEnrolment_DataintegrityC
heck()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_updateEnrolmentTest@2dc0435]
EnrolmentService_stopEnrolmentTest.testEnrolmentAlreadyStopped()[pri:0
,
instance:eu.reaction.prototype.glucosemanagement.service.enrolment.test.
EnrolmentService_stopEnrolmentTest@74002515]

Default suite

Total tests run: 11, Failures: 0, Skips: 0

Measurement tests

Service name	Methods
MeasurementService	MeasurementService_addMeasurementTest.testAddMeasurement_no_enr olment()[pri:0,instance:eu.reaction.prototype.glucosemanagement.service.measurement.test.MeasurementService_addMeasurementTest@6b541147]MeasurementService_findMeasurementTest.testSuccessPath()[pri:0,instance:eu.reaction.prototype.glucosemanagement.service.measurement.test.MeasurementService_findMeasurementsTest@5abd09e8]MeasurementService_addMeasurementTest.testAddMeasurementSuccessPath()[pri:0,instance:eu.reaction.prototype.glucosemanagement.service.measurement.test.MeasurementService_addMeasurementTest.testAddMeasurementSuccessPath()[pri:0,instance:eu.reaction.prototype.glucosemanagement.service.measurement.test.MeasurementService_addMeasurementTest@6b541147]MeasurementService_addMeasurementTest@6b541147]MeasurementService_addMeasurementTest.testAddMeasurement_measurement_measurement_type_not_set()[pri:0,

instance:eu.reaction.prototype.glucosemanagement.service.measurement.t est.MeasurementService_addMeasurementTest@6b541147]
MeasurementService_updateMeasurementRecordTest.testUpdateMeasure mentRecordSuccessPath()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t est.MeasurementService_updateMeasurementRecordTest@336d8196]
MeasurementService_updateMeasurementRecordTest.testUpdateMeasure
mentRecord_updateCritical()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.measurement.t
est.MeasurementService_updateMeasurementRecordTest@336d8196] MeasurementService_deactivateMeasurementTest.testDeactivateMeasure mentRecord measurement deactivated()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t
est.MeasurementService_deactivateMeasurementTest@7d56b386] MeasurementService_deactivateMeasurementTest.testDeactivateMeasure mentPeaserd_superservert()[pri:0]
mentRecord_successPath()[pri:0, instance:eu.reaction.prototype.glucosemanagement.service.measurement.t
est.MeasurementService_deactivateMeasurementTest@7d56b386] MeasurementService_loadMeasurementTypesTest.testSuccessPath()[pri:0
,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t est.MeasurementService_loadMeasurementTypesTest@23de4dd8]
MeasurementService_updateMeasurementRecordTest.testUpdateMeasure
mentRecord_measurement_deactivated()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t est.MeasurementService_updateMeasurementRecordTest@336d8196]
MeasurementService_updateMeasurementRecordTest.testUpdateMeasure mentRecord_measurement_not_found()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t
est.MeasurementService_updateMeasurementRecordTest@336d8196] MeasurementService_deactivateMeasurementTest.testDeactivateMeasure mentRecord_critical()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t
est.MeasurementService_deactivateMeasurementTest@7d56b386] MeasurementService_addMeasurementTest.testAddMeasurement_measur
ement_type_deactivated()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t est.MeasurementService_addMeasurementTest@6b541147]
MeasurementService_updateMeasurementRecordTest.testUpdateMeasure
mentRecordEnrolmentStopped()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t est.MeasurementService updateMeasurementRecordTest@336d8196]
MeasurementService_updateMeasurementRecordTest.testUpdateMeasure
mentRecordEventDateTime()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t est.MeasurementService_updateMeasurementRecordTest@336d8196]
MeasurementService_deactivateMeasurementTest.testDeactivateMeasure
mentRecord_measurement_not_found()[pri:0,
instance:eu.reaction.prototype.glucosemanagement.service.measurement.t est.MeasurementService_deactivateMeasurementTest@7d56b386]

Default suite Total tests run: 16, Failures: 0, Skips: 0

11 Appendix C

In-hospital prototype – details of system tests

The table below represents the level of the satisfaction for the 3^d year in-hospital prototype after performing system testing.

11.1 Functional requirements

Requirement Key	Summary	Release 1	Release 2	Release 3	Status
		1 st year in- hospital prototype (release- 1.0)	2 nd year in- hospital prototype (release- 1.2.1)	3 rd year in- hospital prototype (release- 1.4.1)	
REACTION-501	Second Prototype of the Glucose Control Algorithm (GCA 2) - Matlab GUI	No	No	Yes	Partially Satisfied
REACTION-497	Management Functionality for the Identities used in the In-Hospital-Scenario	No	No	Yes	Partially satisfied
REACTION-492	Components should reflect national requirements, policies, guidelines or provisions	No	No	Yes	Partially Satisfied
REACTION-485	GCS – Interface for online model optimization	No	No	Yes	Fully Satisfied
REACTION-484	GCS – Interface for semi-automatic online glucose control	No	No	Yes	Fully Satisfied
REACTION-483	GCS – Interface for Model Initialization	No	No	Yes	Fully Satisfied
REACTION-482	GCS – Interface to create individual model file	No	No	Yes	Fully Satisfied
REACTION-481	Glucose Control Suite (GCS) – Matlab GUI	No	No	Yes	Fully Satisfied
REACTION-472	A portable sensor patch should have as reduced visibility as is technically feasible	No	No	Yes	Not Satisfied
REACTION-467	Semantics based data management	No	Yes	Yes	Fully Satisfied
REACTION-466	(Web) Service to present decision support for glucose control to clinicians	No	Yes	Yes	Fully Satisfied
REACTION-465	Clinical evaluation report	No	Yes	Yes	Fully Satisfied
REACTION-463	Context management for clinical (lab) values.	No	Yes	Yes	Fully Satisfied

REACTION-462	Interface for user				
	inputs from portable				
	computer in order to	No	Yes	Yes	Fully Satisfied
	store data in In-				
	hospital data storage				
REACTION-460	Measurements of				
	HbA1c				Partially
		No	No	Yes	Satisfied
REACTION-459	Ontologies and data				
	management designed				
	for the storage and				
	multi-user availability	No	No	Yes	Fully Satisfied
	of all relevant				,
	information, actions,				
	treatments, events				
REACTION-456	Nutrition information				
	has to be stored in the	No	Yes	Yes	Fully Satisfied
	data management	110	105	105	Tuny Sutisfied
REACTION-455	REACTION data storage	Yes	Yes	Yes	Fully Satisfied
	-				
REACTION-451	In-hospital prototype	No	No	Yes	Partially
	communication with				Satisfied
	REACTION platform				De utie II. :
REACTION-443	Data exchange with	No	No	Yes	Partially
	third party systems				Satisfied
REACTION-441	Basic workflow in In-	Yes	Yes	Yes	Fully Satisfied
	hospital environment				,
REACTION-439	Information should be				
	cashed in local storage				
	to prevent loss in case	No	No	Yes	Fully Satisfied
	of a node or				
	communication failure.				
REACTION-432	Special				
	examinations/treatmen	No	Yes	Yes	Fully Satisfied
	ts to be registered in	110	100	100	r any batisfied
	fever chart				
REACTION-428	Drug administration				
	data (OAD and/or	No	Yes	Yes	Fully Satisfied
	insulin)				
REACTION-421	Models and rules for				
	insulin dose prediction	No	Yes	Yes	Fully Satisfied
	(In-hospital)				
REACTION-402	Measurements of				
	blood glucose and	Yes	Yes	Yes	Fully Satisfied
	insulin injections in In-	163	105	162	i uny satisfied
	hospital environment				
REACTION-388	Insulin sensitivity and	Na	Vaa	V	Fully and i f i d
	insulin resistance	No	Yes	Yes	Fully satisfied
REACTION-387	Information related to	No	No	No	Not Satisfied
	informed consent				
	stored in the platform				
REACTION-375	Therapy scheme in In-				
	hospital environment	No	Yes	Yes	Fully Satisfied
REACTION-372	Context of				
	observations	No	No	Yes	Fully Satisfied
	1		1		

REACTION-363	Interface to Hospital				
	Information System for	No	Yes	Yes	Fully Satisfied
	clinical data	NO	165	165	Fully Satisfied
	import/export				
REACTION-362	Interface to patient	N	Nie	N -	Fully Catiofical
	demographic register	No	No	No	Fully Satisfied
REACTION-340	Storage of insulin	Yes	Yes	Yes	Fully Satisfied
	administration				
REACTION-336	HIS interfaces for				
<u></u>	patient demographic				
	data - Patient	No	No	Yes	Fully Satisfied
	enrolment (or	-	_		,
	recruitment)				
REACTION-285	User interface for the				
	clinical data stored in				
	the In-hospital	Yes	Yes	Yes	Fully Satisfied
	environment				
REACTION-284	Clinical data to be				
ILLACTION 204	stored in the In-	Yes	Yes	Yes	Fully Satisfied
	hospital environment	105	105	105	Tuny Sutisticu
REACTION-274	The cost of the sensor				
ILACTION-274	should be specified	No	No	Yes	Fully Satisfied
	The sensor safety				
REACTION-273	should follow the				
	device directive				
	93/42/EEC and	No	No	Yes	Fully Satisfied
		NO	NO	165	Fully Satisfied
	subsequent amending directives like the				
	directive 2007/47/EC				
REACTION-272	The body interface of the sensors should be	No	Yes	Yes	Fully Satisfied
	specified	NO	res	Tes	Fully Satisfied
	The calibration of the				
REACTION-271	sensors should be				
		No	Yes	Yes	Fully Satisfied
	specified (strategy,	NO	res	Tes	Fully Satisfied
	intervals, reference,				
	algorithms)				
REACTION-270	Operating temperature				
	of sensors should be specified and kept on				
		Yes	Yes	Yes	Fully Satisfied
	equal level for the IR GM sensor reference				
	and measuring channel				
REACTION-269	Working range of				
	sensors should be	Yes	Yes	Yes	Fully Satisfied
	specified (linearity and				
	detection limit)				
REACTION-268	Response time and	V		¥-	Fully Cast Cold
	drift of the sensors	Yes	Yes	Yes	Fully Satisfied
	should be specified				
REACTION-267	Accuracy/precision of			.,	
	sensors should be	Yes	Yes	Yes	Fully Satisfied
	specified				-
REACTION-266	Type of sensor/signal	Yes	Yes	Yes	Fully Satisfied
	should be specified			-	,

	The clinical normators				
REACTION-265	The clinical parameters to be measured must	Yes	Yes	Yes	Fully Satisfied
	be specified				
REACTION-263	Improve				
	documentation quality	No	No	Yes	Fully Satisfied
	and streamlined access				
	to information Automated transfer of				
REACTION-258	patient related data				
	from the hospital	No	Yes	Yes	Fully Satisfied
	information system				
REACTION-255	Management of				
ILLACTION 200	missing data	Yes	Yes	Yes	Fully Satisfied
REACTION-253	Data entry shall be				
	facilitated as much as	No	Yes	Yes	Not Satisfied
	possible				
REACTION-251	Creation of electronic				
	decision support rules	No	Yes	Yes	Fully Satisfied
	shall be supported				,
REACTION-250	Different				
	contextualization of the	Vac	Vec	Vac	Fully Satisfied
	patient clinical	Yes	Yes	Yes	Fully Satisfied
	information				
REACTION-247	Mobile access point in				
	wards of In-hospital	Yes	Yes	Yes	Fully Satisfied
	environment				
REACTION-246	Multi-user availability				Partially
	and display of the fever	Yes	Yes	Yes	Satisfied
	chart				
REACTION-245	Fever and infections				
	shall be registered in				
	the fever chart and	No	No	Yes	Fully Satisfied
	have an impact in the				
	insulin dosage calculation				
	Management of				
REACTION-241	hypoglycaemic				
	episodes in In-hospital	No	No	No	Not Satisfied
	environment				
REACTION-238	Update and entering of				
<u>ALACTION 250</u>	drug administration				
	(OAD and/or insulin)	No	Yes	Yes	Fully Satisfied
	data				
REACTION-237	Annotation of blood		l .		1
	glucose values,	Vac	Vac	Vac	Eully Cottofice
	especially in In-hospital	Yes	Yes	Yes	Fully Satisfied
	environment				
REACTION-236	Blood glucose				Partially
	measurements in In-	No	No	Yes	Satisfied
	hospital environment				Julished
REACTION-235	Therapy scheme in In-				
	hospital environment				
	registered immediately	Yes	Yes	Yes	Fully Satisfied
	after the patient				
	enrolment				

REACTION-234	Determination of				
	health status in In-	Yes	Yes	Yes	Fully Satisfied
	hospital environment				
REACTION-231	End of process for the				
	diabetic patient in the	Yes	Yes	Yes	Fully Satisfied
	In-hospital	105	105	105	Tuny Sutisfied
	environment				
REACTION-230	Therapy adjustment in				
	In-hospital	No	Yes	Yes	Fully Satisfied
	environment				
REACTION-229	Decision on therapy in				
	In-hospital	No	Yes	Yes	Fully Satisfied
	environment				
REACTION-228	Blood glucose				
	measurements have to				
	be contextualized (e.g.	Yes	Yes	Yes	Fully Satisfied
	before/after meal)				
REACTION-227	Initialization of the				
	fever/sugar chart	No	No	Yes	Fully Satisfied
REACTION-226	Electronic fever/sugar		1	<u> </u>	
ILLACTION 220	chart should be				
	modelled in the data	No	No	Yes	Fully Satisfied
	management system				
REACTION-225	PoC device for blood				
ILACTION-225	glucose measurement				
	will be used in the first-	No	No	Yes	Fully Satisfied
	year prototype Basic workflow is				
REACTION-224					
	repeated 4 times a day	No	Yes	Yes	Fully Satisfied
	in In-hospital				
	environment Basic workflow for				
REACTION-223		Na	Vee	Vee	Fully Catiofical
	insulin treatment in In-	No	Yes	Yes	Fully Satisfied
	hospital environment				
REACTION-220	Healthcare				
	professionals perform				
	the safe glycaemic	No	Yes	Yes	Fully Satisfied
	control in In-hospital				
	environment (not self-				
	management)				
REACTION-219	Safe Glycaemic Control	No	Yes	Yes	Fully Satisfied
	(SGC)	-			,
REACTION-214	Activity parameters				
	must be measured (e.g.				Partially
	pulse frequency, body	No	Yes	Yes	Satisfied
	temperature) by				Satisfied
	sensors				
REACTION-205	Docking station for the				Partially
	ePatch	No	No	Yes	
					Satisfied
REACTION-204	Wireless interfacing of				D
	other devices than	No	Yes	Yes	Partially
	ePatch				Satisfied
REACTION-188	Storage of events for				
112/10/10/1100	context of	No	Yes	Yes	Fully Satisfied
	measurements				, outoned
I			1		1

	1		1		
REACTION-183	The sensitivity of the glucose sensor should be high, the SNR must be large and changes of glucose concentration in the range 1-15 mM must be detectable	Yes	Yes	Yes	Partially Satisfied
REACTION-180	Measurement of glucose should be specific and the glucose sensor should be able to monitor glucose in complex media	Yes	Yes	Yes	Fully Satisfied
REACTION-174	The system must provide interfaces to HIS and implement data management and data structures for In- hospital scenario	No	No	Yes	Fully Satisfied
REACTION-173	Platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data)	No	No	Yes	Fully Satisfied
REACTION-172	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds	No	No	Yes	Fully Satisfied
REACTION-171	Data input application for In-hospital glucose control	Yes	Yes	Yes	Fully Satisfied
REACTION-170	Selection of a mobile device for In-hospital glucose control based on given requirements	Yes	Yes	Yes	Fully Satisfied
REACTION-169	Display and input of data should be possible at different locations simultaneously (centrally managed data repositories)	Yes	Yes	Yes	Fully Satisfied
REACTION-165	Error Messages	No	Yes	Yes	Fully Satisfied
REACTION-161	The system should remind caregivers to perform measurements.	Yes	Yes	Yes	Fully Satisfied
REACTION-156	The system should provide a regular backup of data	No	No	Yes	Fully Satisfied
REACTION-155	The System should keep an electronic paperless data record	Yes	Yes	Yes	Fully Satisfied

				1	
	of the data relevant for				
	Glucose Management				
REACTION-124	Portable device should				
	collect all the relevant	Yes	Yes	Yes	Fully Satisfied
	vital signs measured on	100	100	103	runy satisfied
	the patient				
REACTION-123	Define components	Yes	Yes	Yes	Fully Satisfied
	and services	105	105	105	Tuny Satisfied
REACTION-96	Visualization individual				
	patient data to support	Yes	Yes	Yes	Fully Satisfied
	glucose control	163	105	103	Tuny Satisfied
	(decision support)				
REACTION-83	Interface to clinical	No	Yes	Yes	Fully Satisfied
	data from "near" real-				
	time observations for				
	decision support				
REACTION-78	Mechanistic	No	No	Yes	Partially
	physiology-based				Satisfied
	models of insulin and				
	glucose kinetics				
REACTION-72	Provide decision				
	support for insulin	No	Yes	Yes	Fully Satisfied
	dosing for clinicians (in-	NO	Tes	res	Fully Satisfied
	hospital)				
REACTION-70	Processing of multi-				
	parametric clinical and	No	No	Yes	Fully Catiofied
	non-clinical data from	No	No	res	Fully Satisfied
	different sources				
REACTION-68	Component Versioning	Vee	Vac	Vee	Fully Catiofied
		Yes	Yes	Yes	Fully Satisfied
REACTION-66	Component Interface	Yes	Yes	Yes	Fully Satisfied
		163	165	Tes	Fully Satisfied
REACTION-65	System availability	No	No	Vac	Partially
		No	No	Yes	Satisfied
REACTION-63	Security and privacy		N N		
	related to patient data	No	Yes	Yes	Fully Satisfied
REACTION-40	The sensors/devices				
	developed by the				
	consortium which				
	communicate with the				
	platform wirelessly,				
	must be able to				
	connect swiftly to	No	No	Yes	Partially
	platform and maintain				Satisfied
	that connection				
	without interruptions,				
	even in a fragmented				
	space from wireless				
	devices.				
REACTION-33	Sensor data as				
	concrete values and	No	No	Yes	Fully Satisfied
	CONTINUA compatible	-	-		,
REACTION-30	Power budget of				
	wearable sensor	No	No	Yes	Partially
	platform				Satisfied
	piation				

REACTION-28	Network interoperability	Yes	Yes	Yes	Fully Satisfied
REACTION-26	Embedded intelligence	No	Yes	Yes	Partially Satisfied
REACTION-14	Persistent local/global data storage	Yes	Yes	Yes	Fully Satisfied

11.2 Non-functional requirements

Requirement Key	Summary	Release 1	Release 2	Release 3	Status
		1 st year in-hospital prototype (release- 1.0)	2 nd year in-hospital prototype (release- 1.2.1)	3 rd year in-hospital prototype (release- 1.4.1)	
REACTION-493	The user must be able to correct, rectify, block or erase personal data that has been disclosed - In-Hospital	No	No	Yes	Not Satisfied
REACTION-480	Access control mechanisms should be able to process context information	No	No	Yes	Partially Satisfied
REACTION-475	Log and log-in system	No	Yes	Yes	Fully Satisfied
REACTION-437	Each role MUST be assigned to a set of permissible actions.	No	Yes	Yes	Fully Satisfied
REACTION-415	Each person MAY only perform actions permitted by her role.	No	Yes	Yes	Fully Satisfied
REACTION-403	Each entity in the Reaction platform MUST be representable by a digital identity.	No	Yes	Yes	Fully Satisfied
REACTION-385	Digital identities for the Reaction platform MUST only be issued or revoked by trusted (third) parties, e.g., a certification authority (CA).	No	No	Yes	Fully Satisfied
REACTION-376	Integrity check for the stored data	No	No	Yes	Fully Satisfied
REACTION-356	Manual data insertion	Yes	Yes	Yes	Fully Satisfied
REACTION-344	Display of acquired measurements (values, time, context (if available))	No	No	Yes	Fully Satisfied
REACTION-343	Every person represented in the Reaction platform MUST be assigned to one or more roles.	No	Yes	Yes	Fully Satisfied

	T		1	r	
REACTION-341	Roles MUST be defined for stakeholders of the	No	Yes	Yes	Fully Satisfied
	Reaction platform, e.g.,				
	doctor, nurse, patient,				
	informal carer,				
	administrative personnel etc.				
	All data entered must	No	No	Vac	Dortially
REACTION-338	be checked for format,	NO	NO	Yes	Partially Satisfied
	consistency and validity				Satistieu
REACTION-321	Risk analysis	No	Yes	Yes	Partially
ILACHON-321		NO	163	163	Satisfied
REACTION-283	Qualification of the	No	No	Yes	Partially
	investigator for clinical				Satisfied
	trials				
REACTION-282	Insurance for clinical	No	No	Yes	Partially
	trials must be made				Satisfied
REACTION-281	Clinical trials CE-	No	No	Yes	Partially
	certification OR				Satisfied
	certification that the				
	medical device fulfils				
	the MDD 93/42/EEC				
	and subsequent				
	amending directives				
	like the directive				
	2007/47/EC				
REACTION-280	Device manual for	No	No	Yes	Fully Satisfied
	clinical trials				
REACTION-279	Clinical trials	No	No	Yes	Not Satisfied
	investigators brochure	NI-	NI-	No	Dautially
REACTION-278	Clinical trials case	No	No	Yes	Partially
	report form	No	No	Yes	Satisfied
REACTION-277	Clinical trials study protocol	NO	NO	res	Partially Satisfied
	Clinical trials, patient's	No	No	Yes	
REACTION-276	information sheet	NO	NO	res	Partially Satisfied
	including informed				Satistieu
	consent				
REACTION-275	Clinical trials, formal	No	No	Yes	Not Satisfied
ILLACTION 275	application		110	105	Not Satisfied
REACTION-262	Improve productivity	No	No	Yes	Not Satisfied
	and efficiency, reducing				
	cost				
REACTION-261	The platform shall not	No	No	Yes	Not Satisfied
	generate additional	-	-		
	workload for the				
	clinical staff				
REACTION-162	Documentation of user	No	No	Yes	Fully Satisfied
	interfaces				
REACTION-146	It should be possible to	No	No	Yes	Fully Satisfied
	configure the				
	application to different				
	socio-cultural settings				
REACTION-140	The platform shall	No	No	Yes	Fully Satisfied
	prevent incorrect data				
	from being introduced				

			1		
REACTION-139	The platform shall be able to be installed and configured at the field trial sites by the local technical partner without too much effort	No	No	Yes	Fully Satisfied
REACTION-138	The platform shall be expected to operate within reasonable maintenance effort for all the duration of the field trials	No	No	Yes	Partially Satisfied
REACTION-132	The platform shall help the user to avoid making mistakes	No	No	Yes	Fully Satisfied
REACTION-131	The platform shall appear authoritative	No	No	Yes	Fully Satisfied
REACTION-118	Assurance: the architecture and its implementation must provide assurance that it delivers the security and compliance properties it promises	No	No	Yes	Fully Satisfied
REACTION-116	Availability of security mechanisms to manage sensitive data	No	No	Yes	Fully Satisfied
REACTION-115	Transparency: Security configuration should be hidden from the user as far as possible	Yes	Yes	Yes	Fully Satisfied
REACTION-114	Modularity: the system has to be divided into components	Yes	Yes	Yes	Fully Satisfied
REACTION-109	Scalability: the security must not materially impact the performance of the system	No	No	Yes	Fully Satisfied
REACTION-104	Need-to-know Basis: Stakeholders processing information should only learn what is necessary to carry out their specific task	No	Yes	Yes	Fully Satisfied
REACTION-100	Access control: Access to sensitive information should only by given to authorised personnel	No	Yes	Yes	Fully Satisfied
REACTION-99	Authorisation: Stakeholders must be authorised before they are allowed to perform	No	Yes	Yes	Fully Satisfied

	relevant actions				
REACTION-95	Accountability:	No	No	Yes	Fully Satisfied
	Stakeholders should be				
	held accountable for				
	relevant actions				
REACTION-94	Availability: Patient	No	No	Yes	Fully Satisfied
	data and other				
	resources must be				
	available to ensure				
	proper treatment				
REACTION-93	Confidentiality:	No	No	Yes	Partially
	Sensitive information				Satisfied
	must not be readable				
	by unauthorised				
	persons	No	Vac	Voc	
REACTION-92	Integrity: Information, in particular health	No	Yes	Yes	Fully Satisfied
	data, must be				
	protected from any				
	kind of unintended				
	changes during				
	transport				
REACTION-91	Authenticity:	No	Yes	Yes	Fully Satisfied
	Processors of				
	information should be				
	able to determine				
	whether the data being				
	processed is authentic				
REACTION-90	Identifiability:	No	No	Yes	Fully Satisfied
	Recipients and senders				
	of information must be				
	identifiable, though not				
	necessarily personally				
	identifiable	Yes	Vac	Yes	Not Satisfied
REACTION-80	Only one or max two categories of different	Tes	Yes	162	NUL Salisileu
	mobile operating				
	systems will be				
	considered for the				
	portable devices				
REACTION-76	Portability	No	Yes	Yes	Fully Satisfied
REACTION-71	Simulators for the	No	Yes	Yes	Fully Satisfied
	internal tests				
REACTION-67	Component Repository	Yes	Yes	Yes	Fully Satisfied
REACTION-64	Friendly applications	Yes	Yes	Yes	Fully Satisfied

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REACTION-60	Restore from malfunctioning	No	Yes	Yes	Partailly Satisfied
REACTION-57	Performance and Scalability	No	No	Yes	Fully Satisfied
REACTION-56	The portable touch device must have a satisfactory operational time. The battery must be able to support the device for at least half a day. If the device supports exchangeable battery that would be an advantage.	Yes	Yes	Yes	Partially Satisfied
REACTION-55	The portable touch device must have a display of sufficient screen size & resolution (more than a 3,5" display, more than 320px*480px). If not a stylus operating device then the display must be of capacitive technology & with support for multitouch.	Yes	Yes	Yes	Partially Satisfied
REACTION-53	*The portable touch device must have at least the following connectivity options: WiFi (802.11g or 802.11n), Bluetooth, USB; *Also it must have built in at least the following sensors: GPS, accelerometer; *If mobile phone it must support 3G networks.	Yes	Yes	Yes	Partially Satisfied
REACTION-52	If the portable touch device is not capable to connect wirelessly and send the data, then it should be able to connect via USB to a host gateway with connectivity to the Internet & upload the measurement file to	No	No	No	Not Satisfied

	the platform.				
	the platform.				
REACTION-50	The	No	No	Yes	Partially
	touch/tablet/phone				Satisfied
	device must support				
	notification messages				
REACTION-49	The	Yes	Yes	Yes	Partially
	touch/tablet/phone				Satisfied
	device must allow the				
	execution of processes				
	in the background				
REACTION-48	Support for	Yes	Yes	Yes	Fully Satisfied
	multilingual user				
	interface				
REACTION-46	Error messages must	No	Yes	Yes	Fully Satisfied
	be understandable and				
	helpful				
REACTION-45	Protection against	No	Yes	Yes	Fully Satisfied
	threats				
REACTION-44	Protection against	Yes	Yes	Yes	Fully Satisfied
	unintended user				
	actions				
REACTION-41	The tools developed by	Yes	Yes	Yes	Fully Satisfied
	the consortium must				
	be properly				
	documented in such a				
	way that the end user				
	can understand them				
	and use them for the				
	intended purpose.				
REACTION-38	Integration plan	No	No	Yes	Fully Satisfied
	(combining the various				
	components)				
REACTION-37	Applications guidelines	No	Yes	Yes	Fully Satisfied
	(guidelines for formal				
	carers, in-formal carers				
	and patients) have to				
	be clearly defined				
REACTION-35	Usage Data	No	No	Yes	Not Satisfied
	(Information about				
	elder and juvenile				
	usage of the platform				
	and resources shall be				

11.3 Constraints

Requirement Key	Summary	Release 1	Release 2	Release 3	Status
		1 st year in-hospital prototype	2 nd year in-hospital prototype	3 ^ª year in-hospital prototype	
REACTION-391	Data fields for the In- hospital glucose control prototype (eDSS).	No	Yes	Yes	Fully Satisfied
REACTION-79	Off-the-Shelf Devices	No	No	Yes	Fully Satisfied

12 Appendix D

Primary Care requirements

12.1 Functional requirements

Requirement Key	Summary	Release 1	Release 2	Release 3	Status
		1 st year primary care prototype	2 nd year primary care prototype	3 rd year primary care prototype	
REACTION-492	Components should reflect national requirements, policies, guidelines or provisions	No	No	Yes	Partially Satisfied
REACTION-479	Support identification of "patients at risk" for need for insulin treatment in primary care	No	No	Yes	Not Satisfied
REACTION-468	Provide regular update of data model for Health Care profil	No	No	Yes	Fully Satisfied
REACTION-467	Semantics based data management	No	Yes	Yes	Fully Satisfied
REACTION-460	Measurements of HbA1c	No	No	Yes	Partially Satisfied
REACTION-455	REACTION data storage	Yes	Yes	Yes	Fully Satisfied
REACTION-454	Content formatter	No	Yes	Yes	Fully Satisfied
REACTION-453	Communication interface between REACTION Client and REACTION Server	No	Yes	Yes	Fully Satisfied
REACTION-451	In-hospital prototype communication with REACTION platform	No	No	Yes	Partially Satisfied
REACTION-449	Personalized care plan	No	No	Yes	Not Satisfied
REACTION-448	Alert / notification messages should be short enough in order to be delivered as SMS messages if necessary	No	No	Yes	Fully Satisfied
REACTION-444	6-month clinical checks	No	No	Yes	Partially Satisfied

	Data ayahanga yuith				
REACTION-443	Data exchange with third party systems	No	No	Yes	Partially Satisfied
REACTION-442	Management of complications	No	No	Yes	Not Satisfied
REACTION-439	Information should be cashed in local storage to prevent loss in case of a node or communication failure.	No	No	Yes	Fully Satisfied
REACTION-435	Outcomes of regular visits at primary healthcare centres	No	No	Yes	Not Satisfied
REACTION-426	Comorbidities have to be registered	No	No	Yes	Partially Satisfied
REACTION-425	Set of action rules	No	No	Yes	Fully Satisfied
REACTION-419	Set of event rules	No	No	Yes	Fully Satisfied
REACTION-416	Patient education	No	No	Yes	Partially Satisfied
REACTION-413	Connection with external services like MS HealthVault	No	No	Yes	Fully Satisfied
REACTION-409	Risk assessment models and rules	No	No	No	Not Satisfied
REACTION-408	Non-pharmacological and/or pharmacological treatment	No	No	Yes	Fully Satisfied
REACTION-404	Service Orchestration Manager	No	No	Yes	Fully Satisfied
REACTION-399	Ongoing management	No	No	No	Not Satisfied
REACTION-397	The patient shall be registered to the sytem manually and all patient monitorered data will be followed.	No	No	Yes	Fully Satisfied
REACTION-392	Personal Health Status Profiles	No	No	Yes	Partially Satisfied
REACTION-387	Information related to informed consent stored in the platform	No	No	No	Not Satisfied

REACTION-383	Self-management and lifestyle support	No	No	Yes	Partially Satisfied
REACTION-381	Definition of a common ontology to refer to data, metadata, interfaces and models	No	No	Yes	Partially Satisfied
REACTION-380	Set of alerts and reminders	No	No	Yes	Fully Satisfied
REACTION-374	Annual clinical checks	No	No	Yes	Partially Satisfied
REACTION-372	Context of observations	No	No	Yes	Fully Satisfied
REACTION-371	Use of activity patterns for context annotations	No	No	Yes	Partially Satisfied
REACTION-367	Insertion of baseline physiological measurements at the first visit	No	No	Yes	Fully Satisfied
REACTION-365	Data should be stored in proper way in order to be easily transmitted over mobile networks in case that broadband network is not available.	No	No	Yes	Fully Satisfied
REACTION-358	Network manager for hosting client	Yes	Yes	Yes	Fully Satisfied
REACTION-351	Telemonitoring data should be visualized to patients and professionals in a flexible and performant way	No	No	Yes	Fully Satisfied
REACTION-348	High-level data fusion	No	Yes	Yes	Fully Satisfied
REACTION-346	Knowledge Discovery from unstructured clinical text information	No	No	Yes	Partially Satisfied
REACTION-345	Two-way communication between REACTION server and client	No	No	Yes	Fully Satisfied
REACTION-342	Low-level data fusion	No	Yes	Yes	Fully Satisfied
REACTION-340	Storage of insulin administration	Yes	Yes	Yes	Fully Satisfied

REACTION-337	Health status model	No	No	Yes	Partially Satisfied
REACTION-334	Devices should be able to operate anywhere in the home	No	No	Yes	Fully Satisfied
REACTION-333	Devices should be single communication technology	No	No	Yes	Partially Satisfied
REACTION-331	The patient portal's screen shall be easy to read and use	No	No	Yes	Fully Satisfied
REACTION-330	Patient access to a library of diseases with questionnaires which help the patient to better manage his lifestyle and disease	No	No	Yes	Partially Satisfied
REACTION-326	The registration of the enrolled patient on to the system shall be accured manually by the Care giver at the Primary Care	No	No	Yes	Fully Satisfied
REACTION-325	The possibility to manage user accounts by user name and password and secure log in and log out	No	No	Yes	Fully Satisfied
REACTION-323	Providing a complete audit trail for each user's data and action taken on the system	No	No	No	Partially Satisfied
REACTION-253	Data entry shall be facilitated as much as possible	No	Yes	Yes	Not Satisfied
REACTION-232	Continua Manager emulation	No	No	Yes	Partially Satisfied
REACTION-217	Acquired values in the alarm range	No	No	Yes	Fully Satisfied
REACTION-202	Set up remote patient monitoring scheme	No	No	Yes	Fully Satisfied
REACTION-197	Care spaces in the primary care environment	No	No	Yes	Fully Satisfied
REACTION-193	Alarm & alert generation	No	No	Yes	Partially Satisfied
REACTION-189	Other implications for type I diabetic patients	No	No	Yes	Fully Satisfied

REACTION-188	Storage of events for				
	context of measurements	No	Yes	Yes	Fully Satisfied
REACTION-186	The sensor platform should be robust and simple to be used, enabling the device to be operated by the patient himself	No	No	Yes	Partially Satisfied
REACTION-184	Risk values for HbA1c	No	No	No	Not Satisfied
REACTION-181	Decision on therapy in Primary care environment	No	No	Yes	Not Satisfied
REACTION-179	Daily data review by clinicians or telehealth support team	No	No	Yes	Fully Satisfied
REACTION-168	Remote Patient Monitoring (RPM)	No	No	Yes	Fully Satisfied
REACTION-160	Alerts for the annual and 6-month clinical checks	No	No	Yes	Partially Satisfied
REACTION-153	Symptoms of diabetes or hyperglycaemia	No	No	Yes	Partially Satisfied
REACTION-128	Portable device should allow the display of feedback to patient	No	Yes	Yes	Fully Satisfied
REACTION-127	Home gateway	No	No	Yes	Partially Satisfied
REACTION-126	Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake)	No	Yes	Yes	Fully Satisfied
REACTION-125	Home gateway should be easily extendable in order to receive data from environmental sensors	No	No	Yes	Fully Satisfied
REACTION-124	Portable device should collect all the relevant vital signs measured on the patient	No	Yes	Yes	Fully Satisfied
REACTION-123	Define components and services	Yes	Yes	Yes	Fully Satisfied

REACTION-89	Network management subsets	No	Yes	Yes	Fully Satisfied
REACTION-88	Define the provided input for SMS communication	No	No	Yes	Fully Satisfied
REACTION-86	Estimate short- and medium-term risk and identify successful therapy schemes for patient groups	No	No	No	Not Satisfied
<u>REACTION-85</u>	Present effectiveness of medication therapies to patients and carers	No	No	Yes	Fully Satisfied
REACTION-84	Interface to patients health history information from EPR/HIS	No	No	Yes	Partially Satisfied
REACTION-83	Interface to clinical data from "near" real- time observations for decision support	No	No	Yes	Fully Satisfied
REACTION-82	Contextualized and personalized feedback to patients and carers	No	No	Yes	Partially Satisfied
REACTION-81	Long-term risk calculation and health professional-oriented presentation	No	No	Yes	Partially Satisfied
REACTION-77	Browser Compatibility	No	No	Yes	Fully Satisfied
REACTION-75	Maintain and continuously update a patient health status profile	No	No	Yes	Fully Satisfied
REACTION-74	Formalization of pre- existing clinical data (semantic structure)	No	No	Yes	Not Satisfied
REACTION-73	Short-term risk management (primary care)	No	No	Yes	Partially Satisfied
REACTION-70	Processing of multi- parametric clinical and non-clinical data from different sources	No	No	Yes	Fully Satisfied
REACTION-68	Component Versioning	Yes	Yes	Yes	Fully Satisfied
REACTION-66	Component Interface	Yes	Yes	Yes	Fully Satisfied

REACTION-63	Security and privacy related to patient data	No	Yes	Yes	Fully Satisfied
REACTION-51	If the touch/tablet/phone device is not able to send the data to the platform (lack of connectivity), it should store them locally and then send them when the connectivity is re- established.	No	No	Yes	Partially Satisfied
REACTION-34	Define "black box" to be used in primary care environment	No	No	Yes	Fully Satisfied
REACTION-33	Sensor data as concrete values and CONTINUA compatible	No	No	Yes	Fully Satisfied
REACTION-32	The architecture should support the Continua WAN interface (WAN- IF)	No	Yes	Yes	Fully Satisfied
REACTION-28	Network interoperability	Yes	Yes	Yes	Fully Satisfied
REACTION-26	Embedded intelligence	No	Yes	Yes	Partially Satisfied
REACTION-25	Fault tolerance to network malfunctioning	No	No	Yes	Partially Satisfied
REACTION-14	Persistent local/global data storage	Yes	Yes	Yes	Fully Satisfied
REACTION-8	User interface for manual entry of lifestyle data	No	No	Yes	Fully Satisfied
REACTION-6	Any REACTION device should have an associated semantic model (description)	No	Yes	Yes	Fully Satisfied
REACTION-3	Support for IEEE 11073 medical device standards	No	Yes	Yes	Fully Satisfied
REACTION-1	Internet communication between patient home and primary/secondary healthcare structures based on public wired or wireless network	No	No	Yes	Fully Satisfied

12.2 Non-Functional requirements

Requirement Key	Summary	Release 1	Release 2	Release 3	Status
Key		1 st year primary care prototype	2 nd year primary care prototype	3 rd year primary care prototype	
REACTION-496	Documentation of user interfaces - primary care prototype	No	No	No	Partially Satisfied
REACTION-495	It should be possible to configure the application to different socio-cultural settings - Clinician portal	No	No	Yes	Fully Satisfied
REACTION-494	It should be possible to configure the application to different socio-cultural settings - Patient Portal	No	No	Yes	Fully Satisfied
REACTION-475	Log and log-in system	No	No	Yes	Fully Satisfied
REACTION-471	Individuals that suffer stigmatisation (including through conditions such as diabetes) often value the ability to socialise with others having a similar condition or sympathetic healthcare professionals. REACTION should not eliminate this possibility.	No	No	Yes	Not Satisfied
REACTION-470	The potential stigmatising effect of REACTION due to increased visibility should be decreased to a minimum.	No	No	Yes	Fully Satisfied
REACTION-452	Communication between the Reaction Device Hosting Server and the EPR/EHR System MUST be authentic (entity authentication), with integrity, and confidential.	No	No	Yes	Fully Satisfied
REACTION-438	Communication between the Reaction Device Hosting Server and the GP EPR MUST be authentic (entity	No	No	Yes	Fully Satisfied

	authentication), with integrity, and confidential.				
REACTION-431	Data/messages exchanged between the Reaction Device Hosting Server and the GP EPR SHOULD be authentic (message authentication), with integrity, and confidential.	No	No	Yes	Fully Satisfied
REACTION-423	Sensor quality parameters	No	No	Yes	Fully Satisfied
REACTION-414	Communication between the Reaction Hosting Client and the Reaction Device Hosting Server MUST be authentic (entity authentication), with integrity, and confidential.	No	No	Yes	Fully Satisfied
REACTION-403	Each entity in the Reaction platform MUST be representable by a digital identity.	No	No	Yes	Fully Satisfied
REACTION-401	Device specialization - A list of devices to be provided	No	No	Yes	Fully Satisfied
REACTION-400	Data/messages exchanged between the Reaction Device Hosting Server and the EPR/EHR System SHOULD be authentic (message authentication), with integrity, and confidential.	No	No	Yes	Fully Satisfied
REACTION-382	Privacy enhancing technology	No	No	Yes	Fully Satisfied
REACTION-376	Integrity check for the stored data	No	No	Yes	Fully Satisfied
REACTION-356	Manual data insertion	No	Yes	Yes	Fully Satisfied
REACTION-354	Data/messages exchanged between the Reaction Host Client and the Reaction Device Hosting Server MUST be authentic	No	No	Yes	Fully Satisfied

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	(message				
	authentication), with				
	integrity, and				
	confidential.	No	No	Vac	Fully Satisfied
REACTION-352	Scalable / easy to use solution for REACTION	No	No	Yes	Fully Satisfied
	software in GP surgery				
		NI-	NI-	No	r. II.
REACTION-349	Patient questionnaires (lifestyle, physio-	No	No	Yes	Fully Satisfied
	psychological				Satistieu
	conditiond, checking				
	medication				
	compliance, adherence				
	to clinical pathways,				
	education, self				
	management)				
REACTION-347	Continuous blood	No	No	Yes	Fully
	glucose monitoring				Satisfied
REACTION-344	Display of acquired	No	No	Yes	Fully
	measurements (values,				Satisfied
	time, context (if				
	available))				
REACTION-339	Communication	No	No	Yes	Fully
	between the Reaction				Satisfied
	Device Hosting Server				
	and the patient's/GP's				
	web browser MUST be				
	authentic (entity				
	authentication), with				
	integrity, and confidential.				
	All data entered must	No	No	Yes	Partially
REACTION-338	be checked for format,	NO	NO	165	Satisfied
	consistency and validity				Satisfied
REACTION-264	Increase accuracy and	No	No	Yes	Partially
REACTION-204	reduce errors	NO	NO	163	Satisfied
					Satisfied
REACTION-151	The user must be able	No	No	Yes	Not Satisfied
MERCINICITY 101	to correct, rectify,				
	block or erase personal				
	data that has been				
	disclosed - Primary care				
REACTION-145	The user must consent	No	No	Yes	Fully Satisfied
	to the collection of				
	personal data				
	whenever possible				
REACTION-141	The user should have	No	No	Yes	Fully Satisfied
	choices regarding all				
	data collection				
	activities concerning				
	his personal data				
REACTION-140	The platform shall	No	No	Yes	Fully Satisfied
	prevent incorrect data				
	from being introduced				

REACTION-139	The platform shall be able to be installed and configured at the field trial sites by the local technical partner without too much effort	No	No	Yes	Fully Satisfied
REACTION-138	The platform shall be expected to operate within reasonable maintenance effort for all the duration of the field trials	No	No	Yes	Partially Satisfied
REACTION-136	The platform shall cater for 20 simultaneous users in the field trials. In the end product this number is expected to grow to 100.	No	No	Yes	Fully Satisfied
REACTION-134	Any interface between an end-user and the platform shall have a reasonable maximum response time in condition of public network optimally working	No	No	Yes	Fully Satisfied
REACTION-133	A patient, informal or formal carers should be able to be productive within a short time (one day of training)	No	No	Yes	Fully Satisfied
REACTION-132	The platform shall help the user to avoid making mistakes	No	No	Yes	Fully Satisfied
REACTION-130	The platform shall be easily used by elderly people with no specific technological knowledge	No	No	Yes	Fully Satisfied
REACTION-117	Cross-platform usability: user experience should be the same on all platforms	No	No	Yes	Fully Satisfied
REACTION-116	Availability of security mechanisms to manage sensitive data	No	Yes	Yes	Fully Satisfied
REACTION-94	Availability: Patient data and other resources must be available to ensure proper treatment	No	No	Yes	Fully Satisfied
REACTION-93	Confidentiality: Sensitive information must not be readable	No	No	Yes	Partially Satisfied

	by unauthorised				
	persons				
REACTION-92	Integrity: Information, in particular health	No	Yes	Yes	Fully Satisfied
	data, must be				
	protected from any kind of unintended				
	changes during				
	transport				
REACTION-91	Authenticity:	No	Yes	Yes	Fully Satisfied
	Processors of information should be				
	able to determine				
	whether the data being				
	processed is authentic				
REACTION-90	Identifiability:	No	No	Yes	Fully Satisfied
	Recipients and senders of information must be				
	identifiable, though not				
	necessarily personally				
	identifiable				
REACTION-87	Define network architectural model	No	No	Yes	Fully Satisfied
	architecturarmoder				
REACTION-80	Only one or max two	Yes	Yes	Yes	Not Satisfied
	categories of different				
	mobile operating				
	systems will be considered for the				
	portable devices				
REACTION-76	Portability	No	No	Yes	Fully Satisfied
REACTION-71	Simulators for the	No	No	Yes	Fully Satisfied
	internal tests				
	Component Penecitory	Yes	Yes	Yes	Fully Satisfied
REACTION-67	Component Repository	res	res	res	Fully Satisfied
REACTION-64	Friendly applications	No	No	Yes	Fully Satisfied
REACTION-57	Performance and	No	No	Yes	Fully Satisfied
	Scalability			-	,
		••			
REACTION-56	The portable touch device must have a	No	No	Yes	Partially Satisfied
	satisfactory operational				Jausileu
	time. The battery must				
	be able to support the				
	device for at least half				
	a day. If the device supports exchangeable				
	battery that would be				
	an advantage.				

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REACTION-55	The portable touch device must have a display of sufficient screen size & resolution (more than a 3,5" display, more than 320px*480px). If not a stylus operating device then the display must be of capacitive technology & with support for multitouch. *The portable touch device must have at least the following	Yes	Yes	Yes	Partially Satisfied Partially Satisfied
	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.				
<u>REACTION-52</u>	If the portable touch device is not capable to connect wirelessly and send the data, then it should be able to connect via USB to a host gateway with connectivity to the Internet & upload the measurement file to the platform.	No	No	No	Not Satisfied
REACTION-50	The touch/tablet/phone device must support notification messages	Yes	Yes	Yes	Partially Satisfied
REACTION-49	The touch/tablet/phone device must allow the execution of processes in the background	Yes	Yes	Yes	Partially Satisfied
REACTION-48	Support for multilingual user interface	No	No	Yes	Partially Satisfied
REACTION-46	Error messages must be understandable and helpful	No	No	Yes	Fully Satisfied
REACTION-44	Protection against unintended user actions	No	No	Yes	Partially Satisfied
REACTION-42	The technical interfaces to the platform must be documented and in	No	No	Yes	Fully Satisfied

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	such a way that the				
	stakeholders can				
	understand it and use it				
	for integration.				
REACTION-41	The tools developed by	No	No	Yes	Fully Satisfied
	the consortium must				
	be properly				
	documented in such a				
	way that the end user				
	can understand them				
	and use them for the				
	intended purpose.				
REACTION-38	Integration plan	No	No	Yes	Fully Satisfied
	(combining the various				
	components)				
REACTION-37	Applications guidelines	No	No	Yes	Fully Satisfied
	(guidelines for formal				
	carers, in-formal carers				
	and patients) have to				
	be clearly defined				
REACTION-24	Logging of events from	No	No	Yes	Fully Satisfied
	components				

12.3 Constraint requirements

Requirement Key	Summary	Release 1	Release 2	Release 3	Status
		1 st year primary care prototype	2 nd year primary care prototype	3 ^ª year primary care prototype	
REACTION-395	A REACTION application needs to be executed in the patient surgery independent from the EPR	No	No	Yes	Fully Satisfied
REACTION-190	In the Primary care environment the medications are usually self-administered by the patient himself or by informal carers (rarely)	No	No	Yes	Fully Satisfied
REACTION-79	Off-the-Shelf Devices	No	No	Yes	Fully Satisfied