



Remote Accessibility to Diabetes Management and Therapy in
Operational Healthcare Networks

REACTION (FP7 248590)

D2-9 Updated requirements report (Appendix)

Date 2013-06-11

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	0.4	F. Chiarugi	2013-05-19	Insertion of the complete list of requirements
	1.0	F. Chiarugi	2013-06-11	Addressed reviewers' comments (final version submitted to the EU commission)
Internal review history	Reviewed by	Date	Comments made	
	H. Udsen (IN-JET)	2013-05-23	Approved with minor formatting changes	
	P. Rosengren (CNET)	2013-06-07	Approved	

1 Complete Set of Requirements for the REACTION Platform

[REACTION-1] Internet communication between patient home and primary/secondary healthcare structures based on public wired or wireless network Created: 02/Jun/10 Updated: 04/Oct/12 Due: 30/Apr/11 Resolved: 02/Oct/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Communication		
Work package:	WP3, WP5		
Rationale:	A basic communication infrastructure has to be assumed		
Source/Originator:	Outpatient workshop		
Fit Criterion:	Tests will be based on this assumption		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		
Comment by Franco Chiarugi [07/Jul/10 2:54 PM]			
Main impact is on WP5			
Comment by Franco Chiarugi [30/Apr/12 2:31 PM]			
Partially implemented			

[REACTION-3] Support for IEEE 11073 medical device standards Created: 02/Jun/10 Updated: 01/Nov/12 Due: 10/Jul/12 Resolved: 28/Feb/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend is depended by REACTION-406 IEEE 11073 support Closed		
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Communication		
Work package:	WP4		
Rationale:	To support a wide variety of medical devices, the selected subsets of the IEEE 11073 medical device standards should be supported. An architecture supporting standards will enable flexibility in adding new sensors (plug and play interoperable).		
Source/Originator:	WP4 technical meeting 1, London		
Fit Criterion:	Show that REACTION device proxies can be developed for at least 2 different devices from different manufacturers.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Comment by Matts Ahlsen [09/Jun/10 9:22 AM]			
Which relevant subset ? need to be more specific			
Comment by Matts Ahlsen [16/Jun/11 10:57 AM]			
implemented for WP4 prototype 1 components			
Comment by Matts Ahlsen [12/Aug/11 10:38 AM]			
Adding more IEEE devices.			

Comment by [Stefan Asanin](#) [28/Feb/12 12:22 PM]

IEEE 11073 handling is implemented.

[REACTION-6] [Any REACTION device should have an associated semantic model \(description\)](#) Created: 02/Jun/10 Updated: 01/Nov/12 Due: 10/Jul/12 Resolved: 28/Feb/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Portable devices		
Work package:	WP4		
Rationale:	To facilitate device discovery and application development, a device ontology should be part of the architecture.		
Source/Originator:	WP4 Technical meeting, London.		
Fit Criterion:	New devices can be matched against descriptions in the device ontology.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Matts Ahlsen](#) [12/Aug/11 1:14 PM]

Most suitable the Hydra Device Ontology could be used to fulfill this requirement. It might be necessary with modifications to grasp medical terms/descriptions by the use of IEEE 11073.

Comment by [Jira Administrator](#) [20/Oct/11 12:22 PM]

RQ was marked QC Passed

Comment by [Stefan Asanin](#) [28/Feb/12 12:24 PM]

Medical Device class in the Device Connectivity Kit allows all underlying device classes to inherit the Hydra semantic model.

[REACTION-8] [User interface for manual entry of lifestyle data](#) Created: 07/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Context management		
Work package:	WP3, WP4, WP10		
Rationale:	To supply and support feedback on effectiveness of lifestyle behaviour and therapies to clinicians and patients.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	User interface exists.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	none		
Dependencies:	none		

Comment by [Franco Chiarugi](#) [07/Jul/10 2:52 PM]

Main impact is on WP10

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 9:58 AM]

Required only for primary care applications (DONE)

Comment by [Matts Ahlsen](#) [12/Aug/11 12:56 PM]

First Web Application was presented on the review and this models the user interface for underlying data in REACTION. To be

continued.
Comment by Franco Chiarugi [30/Apr/12 2:31 PM]
Partially implemented
Comment by Stefan Asanin [24/Sep/12 3:34 PM]
Available both in nutrition app and patient portal.

[REACTION-9] [Formalized feedback model](#) Created: 07/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Portable devices		
Work package:	WP4		
Rationale:	A model describing which parameters to be collected, the frequency of collection, and target users of the data		
Source/Originator:	WP4		
Fit Criterion:	System is able to provide feedback in satisfactory time		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matts Ahlsen [12/Aug/11 12:55 PM]
Parameters, frequency and target users must be set within some ranges and defined first.
Comment by Stefan Asanin [24/Sep/12 3:05 PM]
Implemented by the nutrition app, patient application and service orchestration.

[REACTION-12] [Automatic update on lifestyle data](#) Created: 07/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Context management		
Work package:	WP4		
Rationale:	Automatic update of lifestyle data based on sensors such as pedometers but also retrieval from health and lifestyle services and databases.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	At least one external service is supported.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

Comment by Matts Ahlsen [12/Aug/11 10:56 AM]
Various types of life style sensors and appliances are being implemented into REACTION and automatic updates are being reviewed alongside.

[REACTION-14] [Persistent local/global data storage](#) Created: 07/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Context management, Portable devices		
Work package:	WP4		
Rationale:	Configurable storage architecture allowing both local (in PAN) and global storage (in WAN).		
Source/Originator:	WP4 CNet focus group		
Fit Criterion:	At least global storage is supported.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

Comment by [Matts Ahlsen](#) [12/Aug/11 12:28 PM]

First version of global storage is implemented that stores ePatch data. To be further developed. Confusion regarding PAN storage - how is to be done? Wearable storage mechanisms or should it be rather applied to a WAN environment?

Comment by [Stefan Asanin](#) [28/Feb/12 12:34 PM]

Measurement Web Service component is built and will allow both local and global storage handling.

Comment by [Stefan Asanin](#) [24/Sep/12 3:33 PM]

Support by the LinkSmart Storage Manager and local storage in Android nutrition app.

[REACTION-17] [Configurable data transfer frequency](#) Created: 07/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Communication		
Work package:	WP4		
Rationale:	Possibility to configure the periodical transfer of the collected sensor data to external services such as WAN devices.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	Lowest periodical transfer is once per day.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	none		
Dependencies:	none		

Comment by [Matts Ahlsen](#) [12/Aug/11 12:29 PM]

Current version is pushing data through events generated by sensor. Needs be implemented as configurable to meet this requirements rationale.

Comment by [Stefan Asanin](#) [24/Sep/12 3:37 PM]

Configurable on client side how often and when data is to be transferred.

[REACTION-18] [Monitoring devices must be discoverable by existing network infrastructure](#) Created: 07/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved
Project:	REACTION requirements

Component/s:	Network management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Communication		
Work package:	WP4, WP5		
Rationale:	Device must be discovered in order to be able to communicate with other devices and platforms.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	At least to automatically discover devices using protocols supported in the Hydra middleware such as BT, ZigBee etc.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Conflicts:	none		
Dependencies:	none		

Comment by [Matts Ahlsen](#) [12/Aug/11 12:53 PM]

Currently there is manual pairing of Bluetooth devices supporting Continua but the idea is to make this automatic in REACTION after initial pairing. Hydra Network Manager manages the discovery of these devices. ZigBee protocols will follow.

Comment by [Stefan Asanin](#) [28/Feb/12 12:36 PM]

Also part of WP4 device discovery by Hydra.

Comment by [Franco Chiarugi](#) [13/Jun/12 2:43 PM]

Main impact is on WP4

[REACTION-23] [Clinician generated feedback to patient](#) Created: 07/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Architecture, Communication, Context management		
Work package:	WP10		
Rationale:	It should be possible for clinician/staff to submit additional information to patients, e.g. for educational or encouragement purposes.		
Source/Originator:	WP4 CNet focus group.		
Fit Criterion:	At least to provide a two way communication, e.g. shared white board.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	none		
Dependencies:	none		

Comment by [Matts Ahlsen](#) [12/Aug/11 1:23 PM]

It is necessary to differ between educational feedback, therapy related feedback and remote counselling feedback such as white board. All of these impose different levels of implementation efforts.

Comment by [Stefan Asanin](#) [24/Sep/12 2:31 PM]

Implemented by the Alarm Handling & SMS service plus ALL's InformationExtraction WS.

[REACTION-24] [Logging of events from components](#) Created: 09/Jun/10 Updated: 01/Nov/12 Due: 18/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		

Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Sub-Component/s:	Architecture		
Work package:	WP4, WP5, WP10		
Rationale:	All software components shall keep a detailed activity log, which will support the tracing and debugging of possible functioning errors, security holes, mis-configurations and other implementation issues.		
Source/Originator:	Dow, WP10 Objectives (p. 121)		
Fit Criterion:	A log file will be available for each component, containing data which will be defined by the design process.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [09/Jun/10 3:07 PM]

It is suggested that logging be performed by all components using available logging tools and techniques (such as log4j) so that we can keep track of the logs, define common patterns for many components, connect logs with automated procedures etc.

Comment by [Franco Chiarugi](#) [07/Jul/10 2:48 PM]

Main impact is on WP4 (design of components)

Comment by [Matts Ahlsen](#) [12/Aug/11 10:23 AM]

What is meant with "all software components" and to what extent may real-time logging affect performance? Further, test logging is already supported in most development environments and therefore this issue should maybe not be emphasized at this level.

Comment by [Jira Administrator](#) [19/Oct/11 7:56 PM]

RQ was marked Incomplete

Comment by [Stefan Asanin](#) [28/Feb/12 12:38 PM]

Measurement Web Service component keeps a log of all web service calls to it.

Comment by [Stefan Asanin](#) [18/Sep/12 11:04 AM]

Errors and measurements not sent are logged in local SQLite database. To be extended to include component activity.

[REACTION-25] [Fault tolerance to network malfunctioning](#) Created: 09/Jun/10 Updated: 05/Oct/12 Due: 30/Apr/13

Status:	In progress		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Stelios Louloudakis
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Networking, PAN/BAN		
Work package:	WP10, WP4, WP5		
Rationale:	All software components which use network communication (of any kind) shall be capable to cope with sudden network problems, without crashing or stop responding. Due to the distributed nature of devices and services, it is expected that network availability will be limited in many cases, so all software components should be designed in a manner which does not assume 100% network availability.		
Source/Originator:	Dow, WP5 Objectives (p. 85)		
Fit Criterion:	A software component should keep functioning when we unplug the network or otherwise limit its connectivity.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [09/Jun/10 3:12 PM]

Software components should take actions so that no data is lost due to sudden network malfunctioning. When possible, data should be cached locally for later acquisition.

Comment by [Franco Chiarugi](#) [01/Jul/10 4:27 PM]

Highest impact should be on WP5

Comment by [Stelios Louloudakis](#) [04/Oct/12 4:17 PM]

With regards to the NMS component this has been resolved.

If other components affected by this requirement (e.g. Hydra, Data mgmt & Service orchestration components (?)) have addressed it then it can be considered resolved.

[REACTION-26] Embedded intelligence Created: 09/Jun/10 Updated: 02/Oct/12 Due: 31/Dec/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Networking, PAN/BAN		
Work package:	WP4, WP5, WP10		
Rationale:	Applications or software components which incorporate embedded intelligence techniques shall not take actions based on assumptions which are not written or specified in published deliverables or manuals. The applications shall not rely to "default" actions, or fall-back scenarios in exceptional cases, unless these are based on agreed scenarios or models.		
Source/Originator:	DoW, WP10, Task T10.1 (p. 122)		
Fit Criterion:	For any "intelligent" action of software component, a properly published manual shall exist justifying its purpose.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [09/Jun/10 3:22 PM]

The embedded intelligence techniques should not be hardwired actions into the source code, but as extensively as possible, should be configurable.

Comment by [Franco Chiarugi](#) [01/Jul/10 4:30 PM]

Main impact is on WP10.

Comment by [Franco Chiarugi](#) [08/Aug/11 5:13 PM]

In progress for the in-hospital prototype

Comment by [Franco Chiarugi](#) [02/Oct/12 2:51 PM]

In progress for the primary care prototype as well (almost completed for the field trial version of the in-hospital prototype)

[REACTION-28] Network interoperability Created: 09/Jun/10 Updated: 01/Nov/12 Due: 12/Apr/12 Resolved: 16/Apr/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Communication, Networking		
Work package:	WP5, WP4, WP10		
Rationale:	The communication between applications running in different devices will be based on SOAP messages.		
Source/Originator:	Dow, WP5, Task T5.4 (p. 89)		
Fit Criterion:	Communication with a service should be feasible by SOAP tools and standards, based on a service's published interface.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 2:47 PM]

Main impact is on WP4

Comment by [Matts Ahlsen](#) [12/Aug/11 1:25 PM]

Device P2P communication is handled by Hydra Middleware. Other service communication between applications are to be implemented.

Comment by [Jira Administrator](#) [20/Oct/11 12:20 PM]

RQ was marked QC Passed

[REACTION-30] [Power budget of wearable sensor platform](#) Created: 11/Jun/10 Updated: 07/Mar/13 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Portable devices, Sensors		
Work package:	WP3		
Rationale:	Depending on the measuring intervals (tbd) power must be available for autarkic operation of sensor platform		
Source/Originator:	Ines Frese (IMM)		
Fit Criterion:	Definition of total power budget		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 2:30 PM]

Old components relevant: Portable Devices, Sensors

Comment by [Thomas Klotzbuecher](#) [07/Mar/13 4:02 PM]

Should be resolved within D3-9, due M36. Since no integration of the glucose sensors into the e-patch is made so far the power budget should be made for each single sensor.

[REACTION-32] [The architecture should support the Continua WAN interface \(WAN-IF\)](#) Created: 11/Jun/10 Updated: 06/Nov/12 Resolved: 18/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Malcolm Clarke
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Communication		
Work package:	WP4		
Rationale:	Need to support Continua		
Source/Originator:	London tech meeting, CNET WP4 Focus group		
Fit Criterion:	The REACTION system implements at minimum the IHE PCD01 format		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Malcolm Clarke](#) [06/Nov/12 12:07 PM]

Recent work has resolved minor differences between Continua and the Reaction implementation

[REACTION-33] [Sensor data as concrete values and CONTINUA compatible](#) Created: 11/Jun/10 Updated: 20/Feb/13 Due: 07/Jan/13 Resolved: 20/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0

Requirement Type:	Functional - REACTION platform
Sub-Component/s:	Data management
Work package:	WP3
Rationale:	No raw sensor-data processing on REACTION platform
Source/Originator:	Ines Frese (IMM)
Fit Criterion:	Definition of data transfer protocol compatible to CONTINUA
Customer Satisfaction:	Uninterested
Customer Dissatisfaction:	Very Low Unhappiness

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 9:59 AM]

CONTINUA compatibility might not be required for the first demonstrators

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 2:29 PM]

Old components relevant: Data Management

Comment by [Thomas Klotzbuecher](#) [27/Sep/12 11:19 AM]

We should think of having the Continua standard as a requirement, as far as I understood CNET it is not a "must have" but a "nice to have". A decision should be made within 2012.

Comment by [Thomas Klotzbuecher](#) [20/Feb/13 10:53 AM]

The sensor raw data is processed on the internal microprocessor after calibration and a glucose value in [mg/dl] is communicated via ModbusASCII protocol either via Blue Tooth or USB. Since no available standard for continuous glucose sensors exist right now in CONTINUA, compatibility can currently not be achieved but implemented later.

[REACTION-34] [Define "black box" to be used in primary care environment](#) Created: 11/Jun/10 Updated: 30/Nov/12 Due: 31/Oct/12 Resolved: 04/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Basic Primary care prototype , REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stelios Louloudakis	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Communication, Networking, Portable devices		
Work package:	WP5		
Rationale:	Define the hardware to be used in primary care environment for acquiring and transmitting sensor data to the REACTION middleware (use a mobile device or a "home-pc").		
Source/Originator:	None		
Fit Criterion:	None		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	None		
Dependencies:	REACTION-19		

Comment by [Franco Chiarugi](#) [30/Apr/12 2:32 PM]

Partially implemented

[REACTION-35] [Usage Data \(Information about elder and juvenile usage of the platform and resources shall be available\)](#) Created: 14/Jun/10 Updated: 11/Mar/13 Due: 30/Sep/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Interface with HIS/EPR		
Work package:	WP8, WP10		

Rationale:	Reports shall be generated in a way that summarizes the use of the platform to meet the expectations of its users.
Source/Originator:	DoW & Technical meeting in London
Fit Criterion:	A survey shall show the percent of the users that regularly use the platform.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Franco Chiarugi](#) [07/Jul/10 2:43 PM]

Main impact is on WP8

[REACTION-37] [Applications guidelines \(guidelines for formal carers, in-formal carers and patients\) have to be clearly defined](#) Created: 14/Jun/10 Updated: 02/Oct/12 Due: 31/Oct/12 Resolved: 02/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Interface with HIS/EPR, Portable user interface, Web user interface		
Work package:	WP8, WP10		
Rationale:	To ensure that the applications will run with the best possible way.		
Source/Originator:	DoW		
Fit Criterion:	To demonstrate the full functionality of the REACTION platform.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [08/Aug/11 5:12 PM]

Detailed specifications have been provided for the in-hospital prototype

Comment by [Franco Chiarugi](#) [23/Aug/11 3:05 PM]

Main impact is on WP8

Comment by [Franco Chiarugi](#) [02/Oct/12 2:54 PM]

User manuals have been released for in-hospital and primary care prototype

[REACTION-38] [Integration plan \(combining the various components\)](#) Created: 14/Jun/10 Updated: 04/Oct/12 Due: 29/Feb/12 Resolved: 09/Mar/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Operational		
Sub-Component/s:	Backend middleware, Networking, PAN/BAN, Portable devices, Sensors		
Work package:	WP10		
Rationale:	To describe how the different sensors, subsystems, networks and software modules will be integrated into a complete and functioning whole.		
Source/Originator:	DoW		
Fit Criterion:	For each interface/interconnection specify the data content and physical material content.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [20/Jul/11 5:36 PM]

An integration plan for sensors and PAN/BAN has already been released, the remaining integration plan (for the back-end) in under

development.

[REACTION-40] [The sensors/devices developed by the consortium which communicate with the platform wirelessly, must be able to connect swiftly to platform and maintain that connection without interruptions, even in a fragmented space from wireless devices.](#) Created: 14/Jun/10 Updated: 07/Mar/13 Due: 31/Dec/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Communication		
Work package:	WP3, WP10		
Rationale:	To guarantee the operation of the portable devices under any circumstances. Consortium developed wireless devices must be able to pair in an acceptable time and maintain connectivity in a electromagnetic interfering environment.		
Source/Originator:	DoW		
Fit Criterion:	Multiple trials in a real life environment (not only in the fully controlled environment of the laboratory) using multiple WiFi and Bluetooth devices, to ensure the ability of the sensor/device to connect and operate.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 2:35 PM]

Main impact is on WP3

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 2:28 PM]

Old components relevant: communication

[REACTION-41] [The tools developed by the consortium must be properly documented in such a way that the end user can understand them and use them for the intended purpose.](#) Created: 14/Jun/10 Updated: 02/Oct/12 Due: 31/Oct/12 Resolved: 02/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Sub-Component/s:	Interface with HIS/EPR, Portable user interface, Web user interface		
Work package:	WP10		
Rationale:	Depending on the tool and its use, the "end user" could be one or a combination from the following: patient, clinician or developer. The well documented tools will allow the users to make full use of their functions and capabilities and will also provide a complete test of the platform's functionality. Design history file is necessary not only for the end user but also for regulatory approval by the authorities which is mandatory for medical devices.		
Source/Originator:	DoW		
Fit Criterion:	Writing complete and understandable manuals for each tool of the platform. The manuals should be shared with the tools and should be widely available and easily accessible via the website.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [28/Jul/10 11:06 AM]

Changed the rationale in order to address Lukas's comments

Comment by [Franco Chiarugi](#) [20/Jul/11 5:35 PM]

Documentation for the in-hospital prototype has been done in accordance with the amended MDD (very accurate) and the manuals have been made available since the first-year prototype (in-hospital).

Comment by Franco Chiarugi [10/Apr/12 2:22 PM]
Fully implemented for the in-hospital prototype.
Comment by Franco Chiarugi [02/Oct/12 3:01 PM]
A user manual has been released for all tools integrated in the first version of the in-hospital and primary care prototypes (in case further tools will be added, they should be clearly documented for the end users)

[REACTION-42] [The technical interfaces to the platform must be documented and in such a way that the stakeholders can understand it and use it for integration.](#) Created: 14/Jun/10 Updated: 13/Mar/13 Due: 30/Apr/13 Resolved: 13/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Application development kit (ADK)		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Validated	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Sub-Component/s:	Architecture		
Work package:	WP4, WP10		
Rationale:	Developers can develop better applications faster. The platform thus could also provide easy access to third party developers.		
Source/Originator:	DoW		
Fit Criterion:	Writing sufficient documentation for the technical interfaces and also by providing examples and if available simulators.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 2:34 PM]
Main impact is on WP4
Comment by Matts Ahlsen [12/Aug/11 1:27 PM]
Modelling a Device Connectivity Kit to be used together with Hydra SDK and DDK in order to enhance seamless application development by all possible users in REACTION.
Comment by Stefan Asanin [13/Mar/13 2:26 PM]
Documented in D10.3.2. May include future documentation as development progress.

[REACTION-44] [Protection against unintended user actions](#) Created: 14/Jun/10 Updated: 05/Feb/13 Due: 30/Jun/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend is depended by REACTION-338 All data entered must be checked for ... In Progress		
Requirement Type:	Non-functional - Security		
Sub-Component/s:	Portable user interface, Security, Web user interface		
Work package:	WP4, WP7, WP10		
Rationale:	Unintended user actions should not harm data integrity and the overall functioning of the platform. Unintended user actions may not cause the system to close down, neither on the client nor on the server. All data entered must be checked for format, consistency and validity. In case of doubt, the user must be warned and asked what to do. The user must be able to correct mistakes easily. The user must be able to interrupt long functions (e.g. waiting for a remote data transfer).		
Source/Originator:	DoW		
Fit Criterion:	The functional test should include specific tests in order to verify such circumstances		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 6:20 PM]
This seems to be more an issue with appropriate data interfaces for users, thus WP4 and WP10 should be involved instead of WP7.
Comment by Franco Chiarugi [07/Jul/10 2:32 PM]
Addressed Matthias's comments. Main impact is on WP10.
Comment by Franco Chiarugi [08/Aug/11 5:10 PM]
In progress for the in-hospital prototype
Comment by Franco Chiarugi [10/Apr/12 2:20 PM]
Implemented for the in-hospital prototype.
Comment by Franco Chiarugi [04/Dec/12 1:31 PM]
Implementd also in patient portal v1.17

[REACTION-45] [Protection against threats](#) Created: 14/Jun/10 Updated: 06/Nov/12 Resolved: 22/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Security		
Work package:	WP7, WP10		
Rationale:	Medical data are sensible data and protection against threats and and unauthorized access should be provided. The system must protect against: *Unauthorized persons obtaining manager rights through the internet (hacking). *Unauthorized persons getting access to personal data. *The system must conform to Law on Handling of Personal Data.		
Source/Originator:	DoW		
Fit Criterion:	The functional test should include specific tests in order to verify such circumstances		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [01/Jul/10 6:17 PM]
Rights elevation is often a problem of poorly designed user interfaces, thus WP10 should probably also be involved.
Comment by Franco Chiarugi [07/Jul/10 2:30 PM]
Main impact is on WP7
Comment by Matthias Enzmann [22/Oct/12 5:36 PM]
Functional tests are part of the development life cycle. For in-hospital, test cases are described as part of the documents required to satisfy MDD and to get ethical approval. Penetration tests to simulate hacker attacks are out of scope.

[REACTION-46] [Error messages must be understandable and helpful](#) Created: 14/Jun/10 Updated: 05/Feb/13 Due: 31/Dec/12 Resolved: 05/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Minor
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Sub-Component/s:	Architecture		
Work package:	WP4, WP10		
Rationale:	When an application fails this must happen gracefully while providing sufficient and easy to understand messages to the user. In this way the user will not get panicked during a failure, while able to understand what happened or whom to contact to report or resolve the problem.		
Source/Originator:	DoW		
Fit Criterion:	For each application, developers must ensure that error messages should be brief, easy to read, understood even by non-specialists and should also provide some short help (of course they must include the error code and/or description that will allow to understand exactly what is wrong).		
Customer Satisfaction:	Very Pleased		

Customer Dissatisfaction:	Neutral Unhappiness
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Comment by [Franco Chiarugi](#) [14/Jun/10 2:01 PM]

This issue is related to the architecture because all the error messages (the ones encountered by users, and also the developers) must actually mean something and must be documented.

Comment by [Franco Chiarugi](#) [07/Jul/10 2:30 PM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [08/Aug/11 5:10 PM]

This requirement has been considered at this moment in the in-hospital prototype

Comment by [Franco Chiarugi](#) [10/Apr/12 2:19 PM]

Implemented for the in-hospital prototype.

Comment by [Franco Chiarugi](#) [04/Dec/12 1:31 PM]

Implemented also in patient portal v1.17

[REACTION-48] [Support for multilingual user interface](#) Created: 14/Jun/10 Updated: 04/Dec/12 Due: 31/Dec/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Web user interface, Portable user interface		
Work package:	WP10		
Rationale:	Users from different countries should have access to services.		
Source/Originator:	DoW		
Fit Criterion:	Any type of text in any graphical user interfaces that will be developed (labels, text fields, labels, etc.) must be able to easily configured and changed using a easily configurable localization file. A first version of the file will be created in English language, and then it will be distributed to the partners. Once decided which languages will be supported, partners must contribute to the localization of the components, by translating them to its native language (if in the set of supported languages)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [20/Jul/11 5:31 PM]

Partly implemented for the in-hospital prototype.

Comment by [Franco Chiarugi](#) [10/Apr/12 2:18 PM]

Implemented for the in-hospital prototype.

Comment by [Franco Chiarugi](#) [02/Oct/12 3:06 PM]

Which languages must be supported? Is this still a requirement?

Comment by [Franco Chiarugi](#) [04/Oct/12 4:41 PM]

The configuration for multi-language with a configurable localization file is a requirement (Helene Hudson).

Comment by [Franco Chiarugi](#) [04/Dec/12 1:16 PM]

Implemented also in the patient portal v1.2

[REACTION-49] [The touch/tablet/phone device must allow the execution of processes in the background](#) Created: 14/Jun/10 Updated: 27/Sep/12 Due: 31/Dec/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Portable devices, Portable user interface		

Work package:	WP3
Rationale:	The applications developed for the portable devices should start and stop only when the user wants. If the portable device is a mobile phone when the user receives a phone call or SMS then the application should continue in the background without closing (preventing data loss). Therefore the portable devices should allow applications running in the background.
Source/Originator:	DoW & Technical meeting in London
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by [Lhoucine Ben Mohammadi](#) [08/Aug/11 4:20 PM]

This requirement should be assigned to WP3.5, Franco Chiarugi

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 2:26 PM]

Old components relevant: Portable Devices, Portable User Interface

Comment by [Franco Chiarugi](#) [10/Apr/12 2:17 PM]

Implemented for the in-hospital prototype.

[REACTION-50] [The touch/tablet/phone device must support notification messages](#) Created: 14/Jun/10 Updated: 27/Sep/12 Due: 31/Dec/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Portable devices, Portable user interface		
Work package:	WP3		
Rationale:	The portable device must have the ability to show alert messages to the user. This will allow the device to report promptly to the user if any measurement is not good, if it presents a problem, or even whether to take a medicine, or whether he has an appointment with the doctor.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement. The reception of alarm and alerts will be checked on the portable device.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-106		

Comment by [Helene Udsen](#) [29/Jun/10 6:45 PM]

This appears to be a duplicate of issue 106 /Helene

Comment by [Franco Chiarugi](#) [07/Jul/10 2:23 PM]

#106 is a duplicate of this requirement

Comment by [Lhoucine Ben Mohammadi](#) [08/Aug/11 4:17 PM]

This requirement should be assigned to WP3.5, Franco Chiarugi

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 2:19 PM]

Old components relevant: Portable Devices, Portable User Interface

Comment by [Franco Chiarugi](#) [10/Apr/12 2:16 PM]

Active alarms and alerts do not seem to be used in the in-hospital prototype. If confirmed this requirement will be out of scope for the purposes of the in-hospital prototype.

Comment by [Thomas Klotzbuecher](#) [27/Sep/12 11:27 AM]

This requirement could be considered as duplicate of [REACTION-128](#) which is more general.

[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.](#) Created: 14/Jun/10 Updated: 27/Sep/12 Due: 31/Dec/13

Status:	In Progress
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Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Portable devices		
Work package:	WP3		
Rationale:	It is likely that outside the home, the user will not have access to a wireless network. In such a case the mobile device will continue to take measurements but will not be able to transmit them. Therefore in order not to lose the measurements, the device should be able to store them internally (the device must have a decent amount of internal storage, or accept memory cards, and be able to store the measurements there). When the device reconnects to a wireless network then it will send the stored measurements to the database.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement. The functional test should include specific tests in order to ensure that data are always stored correctly in case of a battery-forced shut down.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-119 & REACTION-120		

Comment by [Tamas Toth](#) [01/Jul/10 10:47 AM]

Also a duplicate of #119

Comment by [Franco Chiarugi](#) [07/Jul/10 2:21 PM]

#119 and #120 are duplicates of this requirement

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 2:16 PM]

Old components relevant: Portable Devices

Comment by [Franco Chiarugi](#) [30/Apr/12 2:33 PM]

Partially implemented

Comment by [Thomas Klotzbuecher](#) [27/Sep/12 3:27 PM]

Portable devices to just display information to the patients or the physicians is beyond the scope of WP3. I suggest to address the requirement to WP5!

[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 the platform.](#) Created: 14/Jun/10 Updated: 05/Mar/13 Due: 31/Dec/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Minor
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Communication, Portable devices		
Work package:	WP3		
Rationale:	If no wireless network is available at the user's home environment, then he/she must be given the opportunity to send the measurements from the portable device to database, using the local connection (wired) of the home gateway.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	Creation of a service for the home gateway that upon USB connection with the portable device, the service will transmit the cached data of the portable device to the database. The whole procedure must be easy for the user. For this case an internet connection is mandatory for the home gateway.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Low Unhappiness		
Dependencies:	REACTION-108		

Comment by [Franco Chiarugi](#) [14/Jun/10 2:03 PM]

To examine if this is supported by any portable touch device. If not then this has no meaning. If it is supported an extra service must be implemented to handle the connection and the uploading of the data.
Comment by Franco Chiarugi [21/Jul/10 3:26 PM]
#108 is a duplicate of this requirement
Comment by Thomas Klotzbuecher [20/Feb/12 2:15 PM]
Old components relevant: communication, Portable Devices
Comment by Thomas Klotzbuecher [27/Sep/12 3:23 PM]
Portable devices to just display information to the patients or the physicians is beyond the scope of WP3. I suggest to address the requirement to WP5!
Comment by Franco Chiarugi [05/Mar/13 4:55 PM]
Probably out-of-scope

[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. Created: 14/Jun/10 Updated: 27/Sep/12 Due: 31/Dec/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Portable devices		
Work package:	WP3		
Rationale:	The device must support the latest and most widespread communication protocols. The presence of specialized sensors like the accelerometer, and the GPS will improve the usability of the device, and will allow the collection of additionally useful information.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-121		

Comment by Helene Udsen [29/Jun/10 5:49 PM]
This is (another) duplicate of issue 121 /Helene
Comment by Franco Chiarugi [01/Jul/10 3:03 PM]
this statement is similiar to N-121 (Lukas)
Comment by Franco Chiarugi [07/Jul/10 2:15 PM]
#110 & #121 are duplicates of this requirement
Comment by Thomas Klotzbuecher [20/Feb/12 2:13 PM]
Old components relevant: Portable Devices
Comment by Franco Chiarugi [10/Apr/12 2:13 PM]
Implemented for the in-hospital prototype.
Comment by Thomas Klotzbuecher [27/Sep/12 3:22 PM]
Portable devices to just display information to the patients or the physicians is beyond the scope of WP3. I suggest to address the requirement to WP5!

[REACTION-54] Network & system monitoring Created: 14/Jun/10 Updated: 04/Oct/12 Due: 30/Jun/12 Resolved: 28/May/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stelios Louloudakis	Assignee:	Stelios Louloudakis

Resolution:	Implemented	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Communication, Data management, Networking, Portable devices		
Work package:	WP5		
Rationale:	Ensure that servers, networks and devices used in the Reaction project will allow Active Measurements using ICMP, Passive Measurements using SNMP and Netflow Records for network monitoring, in order to verify QoS, as well as network and systems' monitoring services.		
Source/Originator:	WP5		
Fit Criterion:	none		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	None		
Dependencies:	Heterogenous networks		

[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. Created: 14/Jun/10 Updated: 27/Sep/12 Due: 31/Dec/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Portable devices		
Work package:	WP3		
Rationale:	A device with smaller screen estate will compromise its usability, and will make the interaction with user an unattractive and difficult experience. A multitouch display dramatically improves the user interaction. Displays that make use of capacitive technology provide a much better multitouch operation.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-111		

Comment by [Franco Chiarugi](#) [01/Jul/10 3:05 PM]

This statement is similar to N-111 (Lukas)

Comment by [Franco Chiarugi](#) [02/Jul/10 3:58 PM]

This statement is similar to N-121 (Thomas, IMM)

Comment by [Franco Chiarugi](#) [07/Jul/10 2:12 PM]

#111 is a duplicate of this requirement

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 2:12 PM]

Old components relevant: Portable Devices

Comment by [Franco Chiarugi](#) [10/Apr/12 2:11 PM]

Implemented for the in-hospital prototype.

Comment by [Thomas Klotzbuecher](#) [27/Sep/12 3:10 PM]

Portable devices to just display information to the patients or the physicians is beyond the scope of WP3. I suggest to address the requirement to WP5!

[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. Created: 14/Jun/10 Updated: 27/Sep/12 Due: 31/Dec/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		

Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Portable devices		
Work package:	WP3		
Rationale:	The portable device will have to be operated continuously. The small size and weight of the device allows the user to move freely, but the battery life can be a problem. For this reason, the life of the device when powered only by battery should be sufficient to allow the user to leave the house. The portable touch device should be able to operate while the sensors receive measurements simultaneously with the application and its services, for at least five consecutive hours (it is acceptable if the display is not turned on for the whole duration). The extended battery life will allow the user to continue his daily program with a minimal intervention (or no intervention at all), until he/she returns home, where he/she can then charge the portable device.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	All devices, those used in the field of testing and those that will eventually be selected, must comply with this mandatory requirement.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-122		

Comment by Franco Chiarugi [02/Jul/10 3:52 PM]
this statement is similar to N-111 (Thomas, IMM)
Comment by Franco Chiarugi [07/Jul/10 2:10 PM]
#122 is a duplicate of this requirement
Comment by Lhoucine Ben Mohammadi [08/Aug/11 4:21 PM]
This requirement should be assigned to WP3.5, Franco Chiarugi
Comment by Thomas Klotzbuecher [20/Feb/12 2:09 PM]
Old components relevant: Portable Devices
Comment by Franco Chiarugi [10/Apr/12 2:09 PM]
Implemented for the in-hospital prototype.
Comment by Thomas Klotzbuecher [27/Sep/12 3:10 PM]
Portable devices to just display information to the patients or the physicians is beyond the scope of WP3. I suggest to address the requirement to WP5!

[REACTION-57] Performance and Scalability Created: 14/Jun/10 Updated: 02/Oct/12 Due: 31/Oct/12 Resolved: 02/Oct/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Performance		
Sub-Component/s:	Communication		
Work package:	WP4, WP10		
Rationale:	Responsive enough to integrate with the clinician workflow. The response to the users action should be acceptable, depending on how time-critical is the action's response. Each component should scale well when increasing the users and the data that is stored and processed.		
Source/Originator:	DoW		
Fit Criterion:	Criteria are different depending on the user action. For time-critical actions the response should be almost instant.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 1:32 PM]
Main impact is on WP10

Comment by Franco Chiarugi [08/Aug/11 5:07 PM]
In progress for the in-hospital prototype
Comment by Franco Chiarugi [21/Oct/11 2:08 PM]
Time-critical actions in the various prototype should be defined by the end-users
Comment by Franco Chiarugi [02/Oct/12 6:03 PM]
Both in-hospital and primary care prototypes have satisfactory response times to the various functionalities

[REACTION-60] Restore from malfunctioning Created: 14/Jun/10 Updated: 11/Mar/13 Due: 30/Nov/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Sub-Component/s:	Architecture		
Work package:	WP4, WP8, WP10		
Rationale:	System should be able to restore its previous state and the data when an unexpected problem occurred (wrong usage, hardware error, etc).		
Source/Originator:	DoW		
Fit Criterion:	There should be no corrupted data or loss of information whatever the action of the user is or whenever the system stops working for any reason.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 1:49 PM]
Main impact is on WP8

[REACTION-63] Security and privacy related to patient data Created: 14/Jun/10 Updated: 22/Oct/12 Resolved: 22/Oct/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-415	Each person MAY only perform actions ... Resolved
	depends	REACTION-403	Each entity in the Reaction platform ... Resolved
Requirement Type:	Functional - REACTION platform		
Work package:	WP7, WP10		
Rationale:	Privacy concerns are of utmost importance. The patient data should be transfer and maintained in a secure way while any access to them should be monitored and logged (getting advantage of a login mechanism available in the applications).		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	Verify that any access to patient data is logged and is performed in a secure way		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	REACTION-103		

Comment by Matthias Enzmann [01/Jul/10 5:50 PM]
The implications of the Title/Summary are much wider than the Rationale and the Fit Criterion.
Comment by Franco Chiarugi [07/Jul/10 1:44 PM]
Changed summary, rationale and fit criterion in order to address Matthias's comments
Comment by Franco Chiarugi [07/Jul/10 1:44 PM]

Main impact is on WP7
Comment by Stefan Asanin [22/Dec/11 11:45 AM]
Re-opened REACTION-63 after request by Frederik Franke.
Comment by Matthias Enzmann [22/Oct/12 5:13 PM]
Basic log functionality has been implemented

[REACTION-64] [Friendly applications](#) Created: 14/Jun/10 Updated: 19/Mar/13 Due: 31/Dec/12 Resolved: 05/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Web user interface		
Work package:	WP10		
Rationale:	The use of end-user applications and the devices both in the in-hospital but also (and most importantly perhaps) in the primary care cases should be intuitive, efficient, and of minor disturbance to the patients, requiring minimal interactions and engagement.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	No complex user interfaces, the user should be familiar with the applications in short time (training is foreseen)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Helene Udsen [29/Jun/10 6:15 PM]
Compare with issue 133 'One day of training' /Helene
Comment by Franco Chiarugi [07/Jul/10 1:36 PM]
#133 and this requirement complement each other, but #133 is focused on the quality of training while this requirement is focused on easy and user-friendly user interface
Comment by Franco Chiarugi [20/Jul/11 5:29 PM]
Mock-up and usability tests of the user interfaces have been used with the end-users for the in-hospital prototype. Similar approach is recommended also for the primary care.
Comment by Franco Chiarugi [02/Oct/12 6:14 PM]
Usability tests have been performed for the in-hospital and the primary care prototypes. Retrofits have been used in order to improve the UI and it is reasonable to think the iterative procedure will be finalized by the fixed due date.

[REACTION-65] [System availability](#) Created: 14/Jun/10 Updated: 02/Oct/12 Due: 31/Dec/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware		
Work package:	WP4, WP8, WP10		
Rationale:	The system should be continually monitoring and gathering data about the patients status with no excessive down time. Support for patients and doctors should be continuous. Availability here means that the vital components of the REACTION platform will be in functioning state in order for the patient safety to be supported.		
Source/Originator:	DoW & Technical meeting in London		
Fit Criterion:	The end user applications and the devices in the vicinity of the patient should always operable		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [14/Jun/10 2:48 PM]
To better achieve this requirement standard software engineering practices like for example replication of the data and distribution of the computations among worker components with load balancing and failover should be followed.
Comment by Franco Chiarugi [07/Jul/10 1:34 PM]
Main impact is on WP10
Comment by Franco Chiarugi [08/Aug/11 5:05 PM]
This requirement has been considered at this moment only for the in-hospital prototype

[REACTION-66] Component Interface Created: 14/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware		
Work package:	WP4, WP10		
Rationale:	Interoperability among components should be guaranteed by the use of standard interfaces.		
Source/Originator:	DoW & Technical Meetings		
Fit Criterion:	The test facility will be based on the implemented standard		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:31 PM]
Main impact is on WP4.
Comment by Matts Ahlsen [12/Aug/11 2:56 PM]
IEEE, HL7, WS, and so on.
Comment by Stefan Asanin [24/Sep/12 3:32 PM]
IEEE, HL7, WS, and so on.

[REACTION-67] Component Repository Created: 14/Jun/10 Updated: 04/Oct/12 Due: 31/Oct/10 Resolved: 04/Oct/12			
Status:	Closed		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Sub-Component/s:	Architecture		
Work package:	WP10		
Rationale:	A repository for the binary components has to be set-up in order to ease the integration and the internal test		
Source/Originator:	Technical Meetings		
Fit Criterion:	A server for the containment of the components will be set-up		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [20/Jul/11 5:27 PM]
An FTP secure repository and an SVN repository have been made available to all project partners. FORTH-ICS is hosting and managing these services.

[REACTION-68] Component Versioning Created: 14/Jun/10 Updated: 18/Oct/12 Due: 31/Dec/12 Resolved: 18/Oct/12	
Status:	Resolved

Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Malcolm Clarke
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Backend middleware		
Work package:	WP4, WP10		
Rationale:	In order to facilitate the software development cycle (especially the testing phase) all components and mainly the applications should contain the version number (e.g. in the about menu). In this way we should be able to reduce misunderstandings in setting up various testing configurations at different partners' premises and minimize signalling of "false bugs".		
Source/Originator:	Technical Meetings		
Fit Criterion:	The test facility will take into account also the version of components including in the feedback to the developers (test reports) also the version number of the various applications/components.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [14/Jun/10 2:52 PM]
This issue was also suggested by CNET.
Comment by Franco Chiarugi [01/Jul/10 4:33 PM]
Main impact is on WP4.
Comment by Matts Ahlsen [12/Aug/11 1:29 PM]
For example, SVN could be hosted in CNET's premises.
Comment by Jira Administrator [20/Oct/11 12:18 PM]
RQ was marked QC Passed
Comment by Stefan Asanin [28/Feb/12 12:53 PM]
SVN host
Comment by Franco Chiarugi [02/Oct/12 6:19 PM]
Versioning is implemented in the in-hospital and patient portal applications. Same should be done for the clinician portal. At component level, this is recommended but not so necessary like in case of the main applications.
Comment by Franco Chiarugi [04/Oct/12 4:28 PM]
Version, as agreed during the 6th PBM meeting in Mainz should be included also in the UI of the clinician portal in order to facilitate the test configurations.

[REACTION-70] Processing of multi-parametric clinical and non-clinical data from different sources					
Created: 14/Jun/10 Updated: 13/Mar/13 Due: 01/May/13 Resolved: 13/Mar/13					
Status:	Resolved				
Project:	REACTION requirements				
Component/s:	Service orchestration				
Affects Version/s:	REACTION Platform				
Type:	Volere Requirement	Priority:	Blocker		
Reporter:	Peter Beck	Assignee:	Stefan Asanin		
Resolution:	Implemented	Votes:	0		
Sub-Tasks:	Key	Summary	Type	Status	Assignee
	REACTION-490	LTRM	Sub-task	In Progress	Stefan Asanin
	REACTION-491	STRM	Sub-task	In Progress	Stefan Asanin
Requirement Type:	Functional - REACTION platform				
Sub-Component/s:	PAN/BAN, Physiology models, Portable devices, Risk assessment, Architecture, Backend middleware, Communication, Context management, Data management, Interface with HIS/EPR, Networking, Ontology/Terminology				
Work package:	WP3, WP4, WP5, WP6, WP8, WP10				
Rationale:	The individualized health status profile is the initial point to support management of the disease and predict the risk for future health complications of diabetes patients. Therefore the REACTION platform has to provide personalized clinical and non-clinical data.				
	Four different applications have been identified in ID6-5 of WP6:				
	1) Decision Support for Insulin Dosing in Hospital				

	<ul style="list-style-type: none"> a. Decision Support for Insulin Dosing in Hospital for patients with type II diabetes b. Decision Support for Insulin Dosing in Hospital for patients with type 1 diabetes 2) Primary Care Risk Assessment Applications <ul style="list-style-type: none"> a. Long-term risk assessment application b. Short-term risk assessment application Details of the applications can be found in ID6-5.
Source/Originator:	Call, DoW, D2.1/MSG; revision based on ID6-5
Fit Criterion:	Platform flexibly supports processing of data from multiple sources
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by [Franco Chiarugi](#) [07/Jul/10 12:55 PM]

Main impact is on WP4

Comment by [Stefan Asanin](#) [13/Mar/13 2:25 PM]

The multi-protocol gateway and patient gateway do already flexibly support processing of data from multiple sources. The subtasks remain but are questionable if CNet should be the responsible partner.

[REACTION-71] [Simulators for the internal tests](#) Created: 14/Jun/10 Updated: 05/Feb/13 Due: 31/Dec/12 Resolved: 05/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Sub-Component/s:	Sensors, Backend middleware, Architecture		
Work package:	WP10		
Rationale:	The internal test is performed without real users (clinicians & patients) and therefore some interactions have to be simulated		
Source/Originator:	Technical Meetings		
Fit Criterion:	Simulated components performing the same operations with exactly the same interface have to be available		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [08/Aug/11 5:04 PM]

This requirement has been considered for the in-hospital prototype in order to allow the integration of the prototype

[REACTION-72] [Provide decision support for insulin dosing for clinicians \(in-hospital\)](#) Created: 14/Jun/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 10/Apr/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Peter Beck	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate is incorporated by REACTION-466 (Web) Service to present decision sup... Resolved is incorporated by REACTION-424 Models and rules for insulin dose pre... Resolved		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Alert & alarm subsystem, Architecture, Communication, Context management, Data management, Glucose control algorithm, Interface with HIS/EPR, Networking, Ontology/Terminology, Physiology models, Portable devices, Portable user interface, Risk assessment, Sensors, Web user interface		
Work package:	WP10, WP8, WP6, WP5		
Rationale:	Decision support for insulin dosing is an important requirement for the inpatient scenario. Based on various clinical and non-clinical parameters REACTION should provide an electronic decision support system		

	(eDSS) to suggest insulin dosing
Source/Originator:	DoW, D2.1 (p.62)/MSG
Fit Criterion:	eDSS is available for the REACTION platform
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Franco Chiarugi](#) [07/Jul/10 12:53 PM]

Main impact is on WP6

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:02 AM]

This should not be connected with the sensor itself but rather with platform behind, delete relevance for WP3 and shift to WP6 (DONE)

[REACTION-73] [Short-term risk management \(primary care\)](#) Created: 14/Jun/10 Updated: 19/Apr/13 Due: 30/May/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Issue Links:	Incorporate incorporates REACTION-360 Mechanistic model and rules for insul... Resolved		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Alert & alarm subsystem, Architecture, Backend middleware, Communication, Context management, Data management, Glucose control algorithm, Interface with HIS/EPR, Networking, Ontology/Terminology, PAN/BAN, Physiology models, Portable devices, Portable user interface, Risk assessment, Web user interface		
Work package:	WP6, WP8, WP10		
Rationale:	Identification of short-term risks would help to optimize the patient's management and to prevent the development or deterioration of complications.		
Source/Originator:	DoW, D2.1 (p.42)/MSG		
Fit Criterion:	A module is available for the identification of short-term risks (based on pattern management).		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:52 PM]

Main impact is on WP6

Comment by [Peter Beck](#) [28/Mar/12 2:28 PM]

Issue should be rephrase to be about short term risk management and linked to #360 (glucose algorithm)

Comment by [Peter Beck](#) [29/Mar/12 9:43 AM]

changed direction of "incorporates".

It's still not absolutely correct, as short-term risk management probably will be done by patterns or rules and #360 glucose prediction with a mechanistic model / an algorithm, but its the best way to express the relation.

Comment by [Franco Chiarugi](#) [30/Apr/12 2:33 PM]

Partially implemented

Comment by [Jira Administrator](#) [06/Nov/12 12:55 PM]

To be reviewed after the Stockholm Integration meeting

[REACTION-74] [Formalization of pre-existing clinical data \(semantic structure\)](#) Created: 14/Jun/10 Updated: 19/Mar/13 Due: 28/Jun/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Peter Beck	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0

Issue Links:	Incorporate is incorporated by REACTION-346 Knowledge Discovery from unstructured... In Progress
Requirement Type:	Functional - REACTION platform
Sub-Component/s:	Architecture, Backend middleware, Context management, Data management, Ontology/Terminology, Risk assessment
Work package:	WP6, WP4, WP10
Rationale:	The REACTION platform should provide a mechanism to formalize pre-existing clinical data from the EPR/HIS
Source/Originator:	DoW/MSG
Fit Criterion:	External data from EPR/HIS are available in a formalized manner
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Franco Chiarugi](#) [07/Jul/10 12:51 PM]

Main impact is on WP6

Comment by [Peter Beck](#) [08/Jul/10 6:08 PM]

According to the DOW this work should be mainly done in T6.4 (ALL). (WP6)

Comment by [Jira Administrator](#) [20/Oct/11 12:17 PM]

RQ was marked QC Passed

[REACTION-75] [Maintain and continuously update a patient health status profile](#) Created: 14/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate is incorporated by REACTION-468 Provide regular update of data model ... Resolved		
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Portable devices, Risk assessment, Sensors, Glucose control algorithm, Interface with HIS/EPR, Networking, PAN/BAN, Physiology models, Data management, Architecture, Backend middleware, Communication, Context management		
Work package:	WP8, WP6, WP4		
Rationale:	The REACTION platform should maintain and automatically update relevant clinical and non-clinical data which is the basis for further processing to achieve functional requirements (e.g. construction of a health status profile of a patient, knowledge discovery, decision support, risk prediction, etc.)		
Source/Originator:	DoW/MSG		
Fit Criterion:	Up-to-date data are available in the REACTION platform as a basis for higher level functionality		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:50 PM]

Main impact is on WP4

Comment by [Lhocine Ben Mohammadi](#) [21/Jun/11 10:03 AM]

This should not be connected with the sensor itself but rather with platform behind, delete relevance for WP3 and shift to WP6

Comment by [Franco Chiarugi](#) [21/Jun/11 5:43 PM]

Relevance for WP3 has been deleted, but main impact is on WP4

Comment by [Matts Ahlsen](#) [15/Aug/11 3:16 PM]

Possible duplicate

Comment by [Stefan Asanin](#) [24/Sep/12 3:06 PM]

With continuous RPM it assumes that data is always up-to-date. REACTION client > server with adopted Continua push model ensures this.

[REACTION-76] [Portability](#) Created: 14/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Architecture, Backend middleware		
Work package:	WP4, WP10		
Rationale:	All components should have the capability of running at least under two of the most common operating systems (e.g. Linux and Windows 7 or XP)		
Source/Originator:	Technical meetings		
Fit Criterion:	Specific test has to be done on each component		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:34 PM]

Main impact is on WP4.

Comment by [Franco Chiarugi](#) [28/Jul/10 10:21 AM]

Changed the rationale in order to address Lukas's comments

Comment by [Matts Ahlsen](#) [12/Aug/11 2:57 PM]

Windows 7 and Linux by Mono.

Comment by [Franco Chiarugi](#) [10/Apr/12 2:09 PM]

Implemented for the in-hospital prototype. It does not seem realistic to be implemented for primary care.

Comment by [Stefan Asanin](#) [24/Sep/12 3:31 PM]

Implemented for the in-hospital prototype. It is not realistic to be implemented for primary care.

[REACTION-77] [Browser Compatibility](#) Created: 14/Jun/10 Updated: 01/Nov/12 Due: 31/Oct/12 Resolved: 02/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Web user interface		
Work package:	WP10		
Rationale:	The web based interface should be perform properly in the last 2 editions of the 5 most common browsers		
Source/Originator:	Technical Meetings		
Fit Criterion:	Specific tests have to be performed		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [20/Jul/11 5:25 PM]

Being the in-hospital prototype an Android application, this requirement applies only to the primary care prototype.

Comment by [Jira Administrator](#) [20/Oct/11 12:16 PM]

RQ was marked QC Passed

Comment by [Franco Chiarugi](#) [21/Oct/11 2:25 PM]

Waiting for the finalization of the detailed specifications for primary care. The feeling is that probably this requirement will be part of specification (only for the primary care environment).

Comment by [Franco Chiarugi](#) [27/Mar/12 5:48 PM]

Since the in-hospital application is an application and not a web application, this requirement cannot be applied to this application. On the other side, it has to be decided which are the "target" browsers for the patient portal and the health professional portal. 5 most common browsers are probably too many.

Comment by Franco Chiarugi [30/Apr/12 2:34 PM]
Partially implemented
Comment by Franco Chiarugi [02/Oct/12 6:25 PM]
This requirement is mainly important for the web applications UI (used in the primary care)

[REACTION-78] Mechanistic physiology-based models of insulin and glucose kinetics Created: 14/Jun/10 Updated: 25/Sep/12 Due: 28/Feb/14					
Status:	In Progress				
Project:	REACTION requirements				
Component/s:	Patient sphere				
Affects Version/s:	Extended In-hospital prototype				
Type:	Volere Requirement	Priority:	Major		
Reporter:	Peter Beck	Assignee:	Thomas Eissing		
Resolution:	Unresolved	Votes:	0		
Sub-Tasks:	Key	Summary	Type	Status	Assignee
	REACTION-487	Physiology-based model for "in-vitro"...	Sub-task	Resolved	Thomas Eissing
	REACTION-488	Validation of the physiology-based mo...	Sub-task	In Progress	Thomas Eissing
	REACTION-489	Integration of the physiology-based m...	Sub-task	In Progress	Thomas Eissing
	REACTION-502	Validation of the physiology-based mo...	Sub-task	Open	Thomas Eissing
Requirement Type:	Functional - REACTION platform				
Sub-Component/s:	Risk assessment, Portable devices, Glucose control algorithm, Interface with HIS/EPR, Physiology models, Data management				
Work package:	WP8, WP6, WP3, WP10				
Rationale:	The REACTION platform should provide mechanistic physiology-based models to investigate risk assessment models and services.				
Source/Originator:	DoW/MSG				
Fit Criterion:	Mechanistic physiology-based models are available within the REACTION platform				
Customer Satisfaction:	Interested				
Customer Dissatisfaction:	Neutral Unhappiness				

Comment by Franco Chiarugi [07/Jul/10 12:43 PM]
Main impact is on WP6

[REACTION-79] Off-the-Shelf Devices Created: 14/Jun/10 Updated: 05/Oct/12 Due: 31/Oct/12 Resolved: 05/Oct/12					
Status:	Resolved				
Project:	REACTION requirements				
Component/s:	Medical & environmental devices				
Affects Version/s:	REACTION Platform				
Type:	Volere Requirement	Priority:	Major		
Reporter:	Franco Chiarugi	Assignee:	Stelios Louloudakis		
Resolution:	Implemented	Votes:	0		
Requirement Type:	Constraint - Off-the-Shelf Sensors & Devices				
Sub-Component/s:	Portable devices, Sensors				
Work package:	WP3, WP5				
Rationale:	Non standard communication protocols imply a significant development effort. Such development effort can be very huge and very often also not feasible if non standard protocol is non disclosed.				
Source/Originator:	Technical Meetings				
Fit Criterion:	The commercial devices not developed by the consortium have to be compliant with relevant communication standard or, only in special cases, have a full-disclosed protocol				
Customer Satisfaction:	Extremely Pleased				
Customer Dissatisfaction:	Extreme Unhappiness				

Comment by Franco Chiarugi [07/Jul/10 12:42 PM]

Main impact is on WP5

[REACTION-80] [Only one or max two categories of different mobile operating systems will be considered for the portable devices](#) Created: 14/Jun/10 Updated: 27/Sep/12 Due: 31/Dec/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Portable devices		
Work package:	WP3		
Rationale:	The large spread of existing operating systems will not make affordable a development effort on a large number of mobile operating systems. The more effective solution is to focus on one or max two common and largely diffuse operating systems.		
Source/Originator:	Technical Meetings		
Fit Criterion:	Internal test and field trials will be performed only using portable devices with one of the selected operating systems		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:51 PM]

Continua? (Thomas, IMM)

Comment by [Franco Chiarugi](#) [07/Jul/10 12:41 PM]

This issue refers to the portable device to be used in the "black box", thus to the measurement collector (BAN integration node). Several types of portable devices (PDA, SmartPhone, mobile phone, etc.) are available in the market with different operating systems. We have to focus on one or max two of them.

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 2:07 PM]

Old components relevant: Portable Devices

Comment by [Franco Chiarugi](#) [10/Apr/12 2:07 PM]

It has been implemented for the in-hospital prototype.

Comment by [Thomas Klotzbuecher](#) [27/Sep/12 3:07 PM]

Portable devices to display information to the patients or the physicians is beyond the scope of WP3. I suggest to address the requirement to WP5!

[REACTION-81] [Long-term risk calculation and health professional-oriented presentation](#) Created: 14/Jun/10 Updated: 03/Oct/12 Due: 31/May/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Vincenzo Lagani
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Data management, Risk assessment, Web user interface		
Work package:	WP6, WP8		
Rationale:	Calculate long-term risk based on patient health profile and visualize in a health professional-oriented form. The long-term risk calculator mainly will be used in the outpatient/primary care area as input for decision support		
Source/Originator:	D2.1 (p.21, p.31)/MSG		
Fit Criterion:	The REACTION platform offers a service to calculate diabetes dependent long-term risks		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:36 PM]

Main impact is on WP6
Comment by Jira Administrator [19/Oct/11 7:52 PM]
RQ was marked Incomplete
Comment by Franco Chiarugi [30/Apr/12 2:34 PM]
Partially implemented

[REACTION-82] [Contextualized and personalized feedback to patients and carers](#) Created: 14/Jun/10 Updated: 03/Oct/12 Due: 31/May/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Communication, Context management, Data management, Glucose control algorithm, Interface with HIS/EPR, Ontology/Terminology, Portable devices, Portable user interface, Risk assessment, Web user interface, Alert & alarm subsystem, Architecture, Backend middleware		
Work package:	WP4, WP6, WP8, WP10		
Rationale:	The results of risk assessments should be provided to the end-users within the REACTION platform with emphasis on usability		
Source/Originator:	DoW, D2.1 (p. 27, p. 31, p. 61)/MUG		
Fit Criterion:	The REACTION platform offers services for feedback for patients and carers (incl. positive usability testing)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:36 PM]

Main impact is on WP6

Comment by [Franco Chiarugi](#) [20/Jul/11 5:24 PM]

Usability tests have been introduced early in the life cycle of the in-hospital prototype in order to enhance the user acceptance. Similar approach should be followed for the primary care prototype.

Comment by [Franco Chiarugi](#) [03/Oct/12 2:29 PM]

Usability tests have been applied also to the primary care prototype

[REACTION-83] [Interface to clinical data from "near" real-time observations for decision support](#) Created: 14/Jun/10 Updated: 05/Oct/12 Due: 31/Oct/12 Resolved: 05/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate is incorporated by REACTION-434 Interface to Lab Information System (... Resolved		
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Alert & alarm subsystem, Architecture, Backend middleware, Communication, Context management, Data management, Glucose control algorithm, PAN/BAN, Physiology models, Portable devices, Portable user interface, Risk assessment, Sensors		
Work package:	WP5, WP4, WP3, WP6		
Rationale:	"Near" real-time data will be necessary to implement a decision support system for insulin dosing in inpatient and in primary care; the system should implement an interface to devices which measure real-time data and provide the pre-processed data for risk assessment (decision support)		
Source/Originator:	DoW, D2.1 (p.49, p.62)/MSG		
Fit Criterion:	Data will be available shortly after measurement in the REACTION database		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Helene Udsen [29/Jun/10 5:20 PM]
Check potential overlap with issue 172 and compare with Fit Criterion of issue 57 /Helene
Comment by Franco Chiarugi [07/Jul/10 12:31 PM]
Main impact is on WP5
Comment by Franco Chiarugi [07/Jul/10 12:33 PM]
#172 is specific for glucose measurement while this requirement refers to all data/measurements necessary for the insulin dosage evaluation. #57 refers to the response time of generic functions of the system, while this requirement is focused on the decision support.
Comment by Lhoucine Ben Mohammadi [21/Jun/11 10:07 AM]
It should be defined on which time scale data has to be generated, for the IMM glucose sensor it is expected that data is measured on a time scale of minutes
Comment by Franco Chiarugi [10/Apr/12 1:57 PM]
This is fully implemented for the in-hospital prototype and is currently in progress for the primary care prototype.

[REACTION-84] [Interface to patients health history information from EPR/HIS](#) Created: 14/Jun/10 Updated: 05/Feb/13 Due: 30/Jun/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Third-party system interfaces		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend depends REACTION-346 Knowledge Discovery from unstructured... In Progress		
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Risk assessment, Ontology/Terminology, Architecture, Backend middleware, Communication, Context management, Data management, Interface with HIS/EPR, Networking		
Work package:	WP8, WP6, WP4, WP10		
Rationale:	Patients health history information will be important to facilitate knowledge discovery for risk assessment; therefore the REACTION platform should provide an interface to the EPR/HIS in order to get relevant information		
Source/Originator:	DoW, D2.1 (p.61)/MSG		
Fit Criterion:	The reaction platform provides an standardised interface to EPR/HIS to get health history of patients		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 12:28 PM]
Main impact is on WP10
Comment by Franco Chiarugi [20/Jul/11 5:22 PM]
The HIS/EPR interface is already under development for the in-hospital prototype.
Comment by Franco Chiarugi [03/Oct/12 4:52 PM]
Health history is out-of-scope for the in-hospital prototype and the interface with the HIS is only related to the demographic data of the patient. Probably this requirement is not valid for the primary care since the primary care health information system (PCHIS) is a closed and not accessible system.

[REACTION-85] [Present effectiveness of medication therapies to patients and carers](#) Created: 14/Jun/10 Updated: 06/Nov/12 Resolved: 18/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Malcolm Clarke
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Context management, Ontology/Terminology, Portable user interface, Risk assessment, Web user interface, Architecture		
Work package:	WP6, WP10		

Rationale:	In order to present how successful therapy schemes have been for patient treatment, the outpatient application should implement an adequate front-end
Source/Originator:	D2.1 (p.42)/MSG
Fit Criterion:	Front-end for therapy-scheme quality presentation
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Low Unhappiness

Comment by [Franco Chiarugi](#) [07/Jul/10 12:26 PM]

Main impact is on WP10

Comment by [Jira Administrator](#) [20/Oct/11 12:16 PM]

RQ was marked QC Passed

Comment by [Franco Chiarugi](#) [21/Oct/11 2:28 PM]

Waiting for the finalization of the detailed specifications for the primary care. Probably it will be part of the specifications.

Comment by [Franco Chiarugi](#) [30/Apr/12 2:39 PM]

Partially implemented

Comment by [Malcolm Clarke](#) [18/Oct/12 7:31 PM]

There is an evaluation programme for the primary care pilot for clinician and patient. These are being used for iterative development and final evaluation

[REACTION-86] [Estimate short- and medium-term risk and identify successful therapy schemes for patient groups](#) Created: 14/Jun/10 Updated: 19/Apr/13 Due: 30/May/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Risk assessment		
Work package:	WP6, WP8		
Rationale:	For the REACTION project data mining methods and heuristic algorithms should be used in order to identify: - risk profiles for short- and medium-term risk based on stratification of population health data in large populations - successful therapy strategies for different patient groups to be used as input for decision support		
Source/Originator:	DoW/MSG		
Fit Criterion:	Health risk profiles (short- and medium-term) are available for risk profiling, and knowledge discovery within the data sets can be conducted. Based on a score for "therapy success" more successful therapies can be identified for different patient groups.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:24 PM]

Main impact is on WP6

Comment by [Franco Chiarugi](#) [30/Apr/12 2:40 PM]

Not implemented

Comment by [Jira Administrator](#) [06/Nov/12 2:38 PM]

To be reviewed after the Stockholm Integration meeting

[REACTION-87] [Define network architectural model](#) Created: 14/Jun/10 Updated: 04/Oct/12 Due: 31/Aug/11 Resolved: 10/Aug/11

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stelios Louloudakis	Assignee:	Stelios Louloudakis

Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Operational		
Sub-Component/s:	Architecture, Communication, Networking		
Work package:	WP5, WP4		
Rationale:	Handle resources and services in heterogeneous networks (define heterogeneous networks) and dynamically change performance data of the resources without restricting only to IP networks. Analysis on existing models and standards.		
Source/Originator:	DoW		
Fit Criterion:	None		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	None		
Dependencies:	None		

Comment by [Franco Chiarugi](#) [05/Jul/10 9:15 AM]

I think this issue is related to WP4 & WP5

Comment by [Franco Chiarugi](#) [07/Jul/10 12:23 PM]

Changed the involved WPs in order to address Franco's comments

Comment by [Franco Chiarugi](#) [07/Jul/10 12:24 PM]

Main impact is on WP5

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:08 AM]

This should not be connected with the sensor itself but rather with platform behind, delete relevance for WP3 and shift to WP5 (DONE)

[REACTION-88] [Define the provided input for SMS communication](#) Created: 14/Jun/10 Updated: 30/Nov/12 Due: 31/Oct/12 Resolved: 04/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	Basic Primary care prototype , REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stelios Louloudakis	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Portable devices		
Work package:	WP4, WP5		
Rationale:	Define the attributes of the provided input for the instant communication method (on SMS).		
Source/Originator:	DoW		
Fit Criterion:	None		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		
Conflicts:	None		
Dependencies:	Based on the input that will be provided from the Reaction middleware (Decision support issues)		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:22 PM]

Main impact is on WP5

Comment by [Franco Chiarugi](#) [30/Apr/12 2:40 PM]

Partially implemented

Comment by [Stelios Louloudakis](#) [04/Oct/12 2:37 PM]

The only constrain for this requirement is that the message sent through the Rule Engine should not exceed the 160 characters limit. If the xml sent by the rule engine contains more than 160 characters, the xml is rejected automatically by the REACTION SMS system.

[REACTION-89] [Network management subsets](#) Created: 14/Jun/10 Updated: 04/Oct/12 Due: 30/Apr/12 Resolved: 04/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		

Type:	Volere Requirement	Priority:	Major
Reporter:	Stelios Louloudakis	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Communication, Networking, PAN/BAN		
Work package:	WP10, WP5		
Rationale:	Define network management subsets for data traffic management between Patient's sphere and Carer's sphere communication. Integration and communication of back-end systems and EHRs with BAN & PAN components.		
Source/Originator:	DoW		
Fit Criterion:	None		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	High Unhappiness		
Conflicts:	None		
Dependencies:	Define back-end systems		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:22 PM]

Main impact is on WP5

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:27 AM]

This should not be connected with the sensor itself but rather with platform behind, communication protocol could be CONTINUA IEEE11073

Comment by [Franco Chiarugi](#) [21/Jun/11 5:57 PM]

Deleted any impact on WP3

[REACTION-90] [Identifiability: Recipients and senders of information must be identifiable, though not necessarily personally identifiable](#) Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype , Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>depends REACTION-385 Digital identities for the Reaction p... Resolved</p> <p>Incorporate</p> <p>is incorporated by REACTION-414 Communication between the Reaction Ho... Resolved</p> <p>is incorporated by REACTION-452 Communication between the Reaction De... Resolved</p> <p>is incorporated by REACTION-438 Communication between the Reaction De... Resolved</p> <p>is incorporated by REACTION-339 Communication between the Reaction De... Resolved</p> <p>is incorporated by REACTION-403 Each entity in the Reaction platform ... Resolved</p>		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Reports/measurements must be assignable to the 'right' patient file/device		
Source/Originator:	DoW/SIT		
Fit Criterion:	Recipients and senders must have unique identifiers		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [21/Sep/12 1:42 PM]

Users and Servers of the GMS are identified by digital certificates

Comment by [Matthias Enzmann](#) [25/Sep/12 10:10 AM]

Primary care uses LinkSmart's P2P with XML Digital Signatures to provide integrity protection.

[REACTION-91] [Authenticity: Processors of information should be able to determine whether the data being processed is authentic](#) Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved
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Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic In-hospital prototype , Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate incorporates REACTION-354 Data/messages exchanged between the R... Resolved incorporates REACTION-400 Data/messages exchanged between the R... Resolved incorporates REACTION-431 Data/messages exchanged between the R... Resolved is incorporated by REACTION-452 Communication between the Reaction De... Resolved		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Medical personnel should know if information relating to their patient originates from a known/trusted source, e.g., the patient's blood glucose sensor or medical personnel, in order to assess the data's quality		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a mechanism that allows to verify the authenticity of some information		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [21/Sep/12 2:25 PM]

Primary Care: Hydra (Smartlink) uses its own P2P protocol which uses XML Encryption and XML Digital Signatures to provided confidentiality and integrity/authenticity, respectively. In-Hospital: GMS client uses TLS with strong client authentication, thus the server component knows the identity of the person providing the data.

[REACTION-92] [Integrity: Information, in particular health data, must be protected from any kind of unintended changes during transport](#) Created: 14/Jun/10 Updated: 06/Nov/12 Resolved: 06/Nov/12

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic In-hospital prototype , Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate is incorporated by REACTION-452 Communication between the Reaction De... Resolved		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Any kind of undetectable changes in patient's data may give rise to wrong treatment and harm patients		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a mechanism for ensuring data integrity		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [27/Jul/10 4:54 PM]

Addressed Thomas's comments changing summary and rationale

Comment by [Matthias Enzmann](#) [21/Sep/12 2:04 PM]

Primary Care: Hydra (Smartlink) uses its own P2P protocol which uses XML Encryption and XML Digital Signatures to provided confidentiality and integrity/authenticity, respectively. In-Hospital: SSA uses TLS/SSA for transport which in turn uses a keyed MAC for integrity checking.

[REACTION-93] [Confidentiality: Sensitive information must not be readable by unauthorised persons](#) Created: 14/Jun/10 Updated: 01/Nov/12 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	REACTION Platform		

Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Issue Links:	Incorporate is incorporated by REACTION-414 Communication between the Reaction Ho... Resolved is incorporated by REACTION-452 Communication between the Reaction De... Resolved is incorporated by REACTION-354 Data/messages exchanged between the R... Resolved is incorporated by REACTION-400 Data/messages exchanged between the R... Resolved is incorporated by REACTION-431 Data/messages exchanged between the R... Resolved is incorporated by REACTION-438 Communication between the Reaction De... Resolved is incorporated by REACTION-339 Communication between the Reaction De... Resolved		
Requirement Type:	Non-functional - Security		
Sub-Component/s:	Security		
Work package:	WP4, WP7		
Rationale:	Various stakeholders exchange information over the REACTION platform which, without any safeguards, would allow third parties to learn sensitive information of patients		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a mechanism for ensuring data confidentiality		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-58 & REACTION-59		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:21 PM]

Main impact is on WP4

Comment by [Franco Chiarugi](#) [21/Jul/10 3:30 PM]

#58 & #59 are duplicates of this requirement

[REACTION-94] Availability: Patient data and other resources must be available to ensure proper treatment Created: 14/Jun/10 Updated: 18/Oct/12 Due: 31/Aug/12 Resolved: 10/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Security		
Sub-Component/s:	Security		
Work package:	WP7, WP5		
Rationale:	Non-availability of patient data will hamper further treatment and might even impair the patient's health		
Source/Originator:	DoW/SIT		
Fit Criterion:	REACTION platform should remain operational in case of failures		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [21/Jul/10 12:06 PM]

Although non-availability might become a security problem, it is not per se a security issue but one of network connectivity, IMHO. Even in DDoS attacks, which are considered a security problem, countermeasures I know of are mostly on the network layer and do not involve security mechanisms. Thus, I push this issue to WP4. Feel free to disagree ;-)

Comment by [Franco Chiarugi](#) [21/Jul/10 3:33 PM]

Better to involve WP5 which is focused on Network Management

Comment by [Stelios Louloudakis](#) [04/Oct/12 4:27 PM]

Availability of all user devices can be measured by the NMS. So the NMS will help identify the potential problem. However it cannot resolve the issue, if this is what is meant by this requirement.

In any case since automatic resolution of network errors is not realistic what could address this requirement is ensuring that the network failure is not witnessed by the users (e.g. through replication of resources) or to minimize the time of its impact (e.g. administrators are immediately notified, caching, etc.).

Comment by [Stelios Louloudakis](#) [10/Oct/12 12:20 PM]

Implemented through the CHC database

[REACTION-95] [Accountability: Stakeholders should be held accountable for relevant actions](#) Created: 14/Jun/10 Updated: 22/Oct/12 Resolved: 22/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-415	Each person MAY only perform actions ... Resolved
	depends	REACTION-403	Each entity in the Reaction platform ... Resolved
	depends	REACTION-385	Digital identities for the Reaction p... Resolved
Requirement Type:	Non-functional - Legal		
Work package:	WP7		
Rationale:	Certain actions or decisions will have an impact on the person making the decision or on the person affected by it, thus it should be clear, e.g., who made the decision, what kind of decision was made, and when was it made		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a procedure or mechanism allowing to review relevant actions of stakeholders		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [22/Oct/12 5:45 PM]

Basic logging mechanisms are implemented, though not necessarily auditable ones in a strict sense. Having stronger accountability for logs would require a significant amount of work, conceptual and implementation. Therefore, strong accountability is out of scope, at the moment.

[REACTION-96] [Visualization individual patient data to support glucose control \(decision support\)](#) Created: 14/Jun/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 18/Aug/11

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate		
	is incorporated by	REACTION-466	(Web) Service to present decision sup... Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Context management, Data management, Networking, Portable devices, Portable user interface, Risk assessment, Web user interface		
Work package:	WP6, WP10		
Rationale:	Following functions should be fulfilled by the visualization module: - different modes of visualization (chart, table, symbols, ...) - display of several parameters over time in a chart - tabular display: highlight relevant values - easy selection of relevant parameters, quick presentation of data - parameters ordered in individual patient display (- overview screen "all patient's blood glucose")		
Source/Originator:	D2.1 (p.62)/MSG; revision based on ID6-5		
Fit Criterion:	Inpatient REACTION pilot offers dynamic visualization module for decision support		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 12:19 PM]

Main impact is on WP10

Comment by [Peter Beck](#) [08/Jul/10 5:39 PM]

in close collaboration with WP6 (MSG)

[REACTION-99] [Authorisation: Stakeholders must be authorised before they are allowed to perform relevant actions](#) Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-415	Each person MAY only perform actions ... Resolved
	is depended by	REACTION-429	Before transmitting any personal data... Closed
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Certain actions are not permitted for everybody but may only be carried out by authorised personnel		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a procedure or mechanism allowing to authorise relevant actions		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-58 & REACTION-59		

Comment by [Franco Chiarugi](#) [21/Jul/10 3:35 PM]

#58 & #59 are duplicates of this requirement

[REACTION-100] [Access control: Access to sensitive information should only by given to authorised personnel](#) Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-403	Each entity in the Reaction platform ... Resolved
	is depended by	REACTION-341	Roles MUST be defined for stakeholder... Resolved
	is depended by	REACTION-343	Every person represented in the React... Resolved
	is depended by	REACTION-437	Each role MUST be assigned to a set o... Resolved
	is depended by	REACTION-415	Each person MAY only perform actions ... Resolved
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Sharing patient data is necessary in health care to treat patients but access should only be given to persons involved in the treatment		
Source/Originator:	DoW/SIT		
Fit Criterion:	Availability of a mechanism allowing to control access to sensitive data		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		
Dependencies:	REACTION-58 & REACTION-59		

Comment by [Franco Chiarugi](#) [21/Jul/10 3:36 PM]

#58 & #59 are duplicates of this requirement

[REACTION-104] [Need-to-know Basis: Stakeholders processing information should only learn what is](#)

<u>necessary to carry out their specific task</u> Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 21/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate is incorporated by REACTION-385 Digital identities for the Reaction p... Resolved		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	In an information processing chain, several stakeholders might be involved but it might not be necessary for every stakeholder to know which exact data another stakeholder has processed		
Source/Originator:	DoW/SIT		
Fit Criterion:	Process design takes into account the need-to-know principle		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [21/Sep/12 2:17 PM]

Roles and permissions for user groups had been defined which take into account the need-to-know principle as well as the principle of least privilege.

[REACTION-109] Scalability: the security must not materially impact the performance of the system

Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Performance		
Work package:	WP7		
Rationale:	the security resources have to scale well with the overall architecture		
Source/Originator:	DoW/ATOS		
Fit Criterion:	Security does not significantly impact overall latency of the system		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [21/Sep/12 1:52 PM]

The performance of the SSA/ACC components will be continuously monitored but their performance has already been deemed acceptable.

[REACTION-114] Modularity: the system has to be divided into components Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Work package:	WP7		
Rationale:	It is easier to implement, exchange, and integrate the modules.		

Source/Originator:	DoW/ATOS
Fit Criterion:	REACTION platform should be modular
Customer Satisfaction:	Uninterested
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Matthias Enzmann](#) [21/Sep/12 2:15 PM]

Primary care: the patient portal and the health professional portal are realised as web applications, the SmartLink architecture relies on web services. In-Hospital: the GMS client uses a layered architecture for the application and the transport/security layer. The GMS server provides web services, the access control component is realised separately as a server component, just like the component for checking certificate validity.

[REACTION-115] [Transparency: Security configuration should be hidden from the user as far as possible](#)

Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Work package:	WP7		
Rationale:	Users usually do not have the expertise to choose the 'right' security options.		
Source/Originator:	DoW/SIT		
Fit Criterion:	No, or as few as possible, additional user interactions for security.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [10/Apr/12 2:06 PM]

It seems to be fully implemented for the in-hospital prototype.

[REACTION-116] [Availability of security mechanisms to manage sensitive data](#) Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 25/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic In-hospital prototype , Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Work package:	WP7		
Rationale:	In REACTION, we are dealing with sensitive data, thus security must be available on all platforms.		
Source/Originator:	DoW/SIT		
Fit Criterion:	Security mechanisms are available for all target platforms of REACTION.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Helene Udsen](#) [29/Jun/10 12:54 PM]

The implications of the Title/Summary are much wider than the Rationale /Helene

Comment by [Franco Chiarugi](#) [07/Jul/10 11:41 AM]

Changed the title/summary in order to address Helene's comments

Comment by [Matthias Enzmann](#) [25/Sep/12 10:17 AM]

Security mechanisms are implemented for the GMS communication (in-hospital), patients and health professional in primary care will use browser security (HTTPS), and observations are transmitted securely by LinkSmart's P2P protocol.

[REACTION-117] Cross-platform usability: user experience should be the same on all platforms Created: 14/Jun/10 Updated: 03/Oct/12 Due: 31/Oct/12 Resolved: 03/Oct/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Web user interface		
Work package:	WP10		
Rationale:	Users should only see familiar interfaces in order to adapt to a new platform more easily.		
Source/Originator:	DoW/ATOS		
Fit Criterion:	Different platforms do not have significantly different user interfaces, i.e., REACTION should be 'platform agnostic'.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [20/Jul/10 10:18 AM]

Interface design should be handled in WP 10/11, thus, this task should be assigned to Forth or CNET

Comment by [Franco Chiarugi](#) [20/Jul/11 5:21 PM]

Specifically an Android platform has been selected for the in-hospital prototype (from this point of view it is implemented). This requirement has to be considered for the primary care prototype.

Comment by [Franco Chiarugi](#) [03/Oct/12 4:56 PM]

the in-hospital is targeted for Android (thus this requirement is automatically solved), while the patient portal is a web application multi-platform which presents the same interface on different fixed or mobile devices.

[REACTION-118] [Assurance: the architecture and its implementation must provide assurance that it delivers the security and compliance properties it promises](#) Created: 14/Jun/10 Updated: 25/Sep/12 Resolved: 25/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Legal		
Work package:	WP7		
Rationale:	If allegedly secure functions do not live up to their expected functionality, the whole platform could be compromised.		
Source/Originator:	DoW/ATOS		
Fit Criterion:	Successful review of expected security functionality.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [25/Sep/12 10:15 AM]

Test documentation has been prepared, unit tests and integration tests have been performed to comply with the requirements of the medical device directive.

[REACTION-123] [Define components and services](#) Created: 15/Jun/10 Updated: 04/Oct/12 Due: 31/Aug/11 Resolved: 10/Aug/11

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		

Type:	Volere Requirement	Priority:	Critical
Reporter:	Stelios Louloudakis	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Communication, Data management, Networking		
Work package:	WP5, WP4		
Rationale:	Define the necessary components, services and orchestration methods under a Service Oriented Architecture perspective.		
Source/Originator:	DoW,		
Fit Criterion:	none		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [05/Jul/10 9:12 AM]

I think this issue is mainly related to WP4 & WP5

Comment by [Franco Chiarugi](#) [07/Jul/10 11:36 AM]

Added WP4 in order to address Franco's comments

Comment by [Franco Chiarugi](#) [07/Jul/10 11:37 AM]

Main impact is on WP5

[REACTION-124] [Portable device should collect all the relevant vital signs measured on the patient](#)

Created: 15/Jun/10 Updated: 05/Oct/12 Due: 31/Oct/12 Resolved: 05/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, PAN/BAN, Portable devices		
Work package:	WP8, WP5, WP3		
Rationale:	A portable with adequate features/performances should collect all the relevant vital signs measured on the patient realizing the BAN		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	A commercial portable device will be selected in order to perform the internal tests and the field trials		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 1:56 PM]

This issue has something in common with issue 34. In this case the black box should contain a commercial portable device which collects all the acquired relevant vital signs (Stelios & Franco)

Comment by [Franco Chiarugi](#) [07/Jul/10 11:35 AM]

Main impact is on WP5

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:30 AM]

Relevant parameters except glucose level should be defined by the physicians, the reviewers pointed out that parameters indicating a hypo, like e.g. heart rate, could be useful

Comment by [Franco Chiarugi](#) [21/Jun/11 6:01 PM]

Inserted also WP8 with the role of defining what is relevant

[REACTION-125] [Home gateway should be easily extendable in order to receive data from environmental sensors](#)

Created: 15/Jun/10 Updated: 17/Oct/12 Due: 28/Feb/13 Resolved: 17/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major

Reporter:	Franco Chiarugi	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, PAN/BAN, Portable devices		
Work package:	WP3, WP5		
Rationale:	The home gateway should be able to receive and transmit data from environmental sensors, provided as an update of the REACTION platform		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	BAN and PAN integration will be tested on the same portable device which will collect measurements provided by consortium devices/sensors and by off-the-shelf devices used in the platform		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 1:58 PM]

The portable device could eventually be a part of the "black box" defined in issue 34 (Stelios & Franco)

Comment by [Franco Chiarugi](#) [02/Jul/10 3:47 PM]

This does not comply with the DOW, I think additional sensors other than described in the DOW can not be developed here (Thomas, IMM)

Comment by [Franco Chiarugi](#) [07/Jul/10 11:34 AM]

Main impact is on WP5

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:32 AM]

environmental measurements should be deleted, since too many sensors had to be developed or integrated as COTS

[REACTION-126] [Portable device should allow patients to complete the acquired data set with questionnaire or additional information \(status, activity, food intake\)](#) Created: 15/Jun/10 Updated: 20/Mar/13 Due: 31/Dec/13 Resolved: 20/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-424	Contextualization of measurements Resolved
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, PAN/BAN, Portable devices		
Work package:	WP3, WP5		
Rationale:	The necessity to provide a context for the acquired measurements implies that non-directly measurable data have to be collected. The possibility to collect this information using the same portable device used for the BAN/PAN integration reduces the overall cost of the acquisition system improving the sustainability of the overall solution. The portable device could eventually be a part of the "black box".		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	Verify that the additional non-directly measurable data can be collected by the patient herself with the portable device		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 1:58 PM]

The portable device could eventually be a part of the "black box" defined in issue 34 (Stelios & Franco)

Comment by [Franco Chiarugi](#) [02/Jul/10 3:46 PM]

Probably the same as [REACTION-215](#) and [REACTION-243](#) (Thomas, IMM)

Comment by [Franco Chiarugi](#) [05/Jul/10 3:38 PM]

Changed the rationale in order to address Stelios's comments

Comment by [Franco Chiarugi](#) [07/Jul/10 11:32 AM]

Main impact is on WP3 (graphical user interfaces)

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:38 AM]

It should be defined by BTS how to implement the relevant data into the physiological model

Comment by Thomas Klotzbuecher [20/Feb/12 2:04 PM]
Old components relevant: Architecture, PAN/BAN, Portable Devices
Comment by Thomas Klotzbuecher [27/Sep/12 3:04 PM]
I think portable devices for displaying information to the patient or the physicians are not within the scope of WP3. I suggest to address them to WP5 only!

[REACTION-127] Home gateway Created: 15/Jun/10 Updated: 30/Nov/12 Due: 30/Apr/13			
Status:	In progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stelios Louloudakis
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Portable devices, Communication, Architecture		
Work package:	WP3, WP5		
Rationale:	The portable device should be able to act as home and mobile gateway. When connection to the public wireless network is not available at home, the portable device should be able to use a home gateway (PC) in order to send the acquired information. The home gateway should work only as gateway and not as a data collection device. The mobile gateway function has to be performed by the portable device and not by a further hand-held device.		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	Specific tests have to be performed when public wireless network is not available at home.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [07/Jul/10 11:31 AM]
Main impact is on WP5

[REACTION-128] Portable device should allow the display of feedback to patient Created: 15/Jun/10 Updated: 20/Mar/13 Due: 31/Dec/13 Resolved: 20/Mar/13			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Portable devices, Portable user interface		
Work package:	WP3, WP5, WP10		
Rationale:	In mobile situation the only available device is the portable device and patient should be able to use it for uploading or downloading data. The possibility of using the "black box" also as output device for displaying data related to feedback to patient would help in simplifying cost and complexity of the solution.		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	The portable user interface should be used also for displaying the clinician feedback to patients, graphical representation of the data acquired in the last week/day/etc.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 2:00 PM]
In case of "black box", the possibility of using the black box also as output device for displaying data related to feedback to patient would help (Stelios & Franco)
Comment by Franco Chiarugi [05/Jul/10 3:35 PM]
Changed the rationale in order to address Stelios's comments
Comment by Franco Chiarugi [07/Jul/10 11:30 AM]
Main impact is on WP3 (graphical user interfaces)

Comment by Thomas Klotzbuecher [20/Feb/12 2:01 PM]
Old components relevant: Architecture, Portable Devices, Portable User Interface
Comment by Thomas Klotzbuecher [07/Mar/13 4:07 PM]
What data should be displayed!?

[REACTION-130] [The platform shall be easily used by elderly people with no specific technological knowledge](#) Created: 15/Jun/10 Updated: 06/Mar/13 Due: 31/Dec/12 Resolved: 05/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Look and feel		
Sub-Component/s:	Portable user interface, Web user interface		
Work package:	WP3, WP5, WP10		
Rationale:	Being the diabetes quite common in elderly people, several patients will have no specific knowledge in technology, but they should be able to easily use the platform.		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	User learning curve (especially with elderly people) should be very quick		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:45 PM]
Is probably the same as REACTION-186 (Thomas, IMM)
Comment by Franco Chiarugi [05/Jul/10 10:42 AM]
In some way it is similar to #147 but #147 is focused on generic user while this requirement is focused on elderly patients
Comment by Franco Chiarugi [07/Jul/10 11:28 AM]
Main impact is on WP10
Comment by Franco Chiarugi [20/Jul/11 5:18 PM]
Patients are not user in the in-hospital prototype. This requirement has to be taken into account for the primary care prototype.
Comment by Jira Administrator [20/Oct/11 12:14 PM]
RQ was marked QC Passed
Comment by Franco Chiarugi [21/Oct/11 2:30 PM]
Waiting for the finalization of the detailed specifications for the primary care. It has to be considered in the design of the mock-ups for the "patient portal".
Comment by Franco Chiarugi [03/Oct/12 4:58 PM]
Early usability tests have been performed with a small subset of patients. First outcomes are positive.
Comment by Franco Chiarugi [05/Feb/13 2:06 PM]
Implemented and already verified in initial usability tests

[REACTION-131] [The platform shall appear authoritative](#) Created: 15/Jun/10 Updated: 22/Oct/12 Resolved: 22/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Look and feel		
Sub-Component/s:	Architecture		
Work package:	WP9, WP7, WP6, WP5, WP4, WP3, WP10		
Rationale:	Trust of end-users is paramount		
Source/Originator:	DoW and Technical Meetings		
Fit Criterion:	After their first encounter with the product, 2/3 of representative end-users shall agree they feel they can trust		

	the platform and its services
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by [Franco Chiarugi](#) [01/Jul/10 4:36 PM]

Main impact is on WP9.

Comment by [Franco Chiarugi](#) [02/Jul/10 3:40 PM]

If data are entered into the platform by the patient (outpatient) this should be stored somewhere in the platform for security reasons?! (Thomas, IMM)

Comment by [Ann-Katrin Habbig](#) [22/Oct/12 2:08 PM]

I discussed this requirement with Franco and we came to the conclusion that it might be better to assign it to FHG-SIT, since the architectural and security choices (having in mind this requirement as well as all the others) were made in full agreement with FHG-SIT and now the "trust of the platform" from end-users should be confirmed by the initial tests in the pilot sites or by the field trials in WP8.

Comment by [Matthias Enzmann](#) [22/Oct/12 5:10 PM]

The validation of users' perspective will be performed during the field trials.

[REACTION-132] [The platform shall help the user to avoid making mistakes](#) Created: 15/Jun/10 Updated: 05/Feb/13 Due: 31/Dec/12 Resolved: 05/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Architecture, Portable user interface, Web user interface		
Work package:	WP3, WP10		
Rationale:	Platform should be useful also in order to reduce mistakes performed by end-users in their current workflows		
Source/Originator:	DoW and workshops		
Fit Criterion:	End-users will be guided through the workflows they have to perform.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [07/Jul/10 11:27 AM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 5:17 PM]

Facilitation of workflows has been taken into account in the in-hospital prototype. Similar approach should be follow also for the primary care.

Comment by [Franco Chiarugi](#) [03/Oct/12 4:59 PM]

The logical grouping of functionalities used for the patient portal was performed also in view of matching this requirement.

Comment by [Franco Chiarugi](#) [05/Feb/13 2:04 PM]

Especially in the patient portal range of acceptable values have been inserted in the user interface avoiding the introduction of wrong values

[REACTION-133] [A patient, informal or formal carers should be able to be productive within a short time \(one day of training\)](#) Created: 15/Jun/10 Updated: 06/Nov/12 Resolved: 18/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Malcolm Clarke
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Architecture		
Work package:	WP10, WP13		

Rationale:	The platform should be easy to use and learn in order to be accepted by end users
Source/Originator:	DoW and workshops
Fit Criterion:	Should be designed to be as simple to use as possible, especially for elderly
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Franco Chiarugi](#) [07/Jul/10 11:26 AM]

Main impact is on WP13

Comment by [Franco Chiarugi](#) [07/Jul/10 1:39 PM]

#64 and this requirement complement each other, but this requirement is focused on the quality of training while #64 is focused on easy and user-friendly user interface

Comment by [Jira Administrator](#) [06/Mar/12 4:49 PM]

This also applies to Health Professional sphere

Comment by [Malcolm Clarke](#) [18/Oct/12 7:30 PM]

The home gateway and devices are designed to be easy to use (minutes of training). This will be evaluated.

[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](#) Created: 15/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Performance		
Sub-Component/s:	Architecture		
Work package:	WP4, WP10		
Rationale:	Response time should be quick enough except for reasons independent from the technical design of the platform		
Source/Originator:	DoW and workshops		
Fit Criterion:	The platform when the public network is perfectly working at the max speed shall respond in less than 5 sec in 90% of functions activated by the user interface. No response shall take longer than 10 sec.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:39 PM]

Main impact is on WP4.

Comment by [Matts Ahlsen](#) [12/Aug/11 3:02 PM]

Too be tested for performance at later stage of development.

Comment by [Jira Administrator](#) [20/Oct/11 12:13 PM]

RQ was marked QC Passed

Comment by [Stefan Asanin](#) [16/Apr/12 11:14 AM]

Preferably and most accurately supported by the Network Monitor Manager.

Comment by [Stefan Asanin](#) [24/Sep/12 3:08 PM]

Implemented. Quality is secured by Network Monitor Manager.

[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.](#) Created: 15/Jun/10 Updated: 01/Nov/12 Due: 31/May/13 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin

Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Performance		
Sub-Component/s:	Architecture		
Work package:	WP4, WP10		
Rationale:	A maximum number of simultaneous users has to be fixed. These numbers are very reasonable considering the number of potential end-users at the field trial sites and also considering the initial expectations as product on the market.		
Source/Originator:	DoW and workshops		
Fit Criterion:	The platform will be tested with the max number of simultaneous users verifying that the response time for the most common operations are satisfactory		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:40 PM]

Main impact is on WP4.

Comment by [Stefan Asanin](#) [24/Sep/12 2:20 PM]

Fixed for expected number of simultaneous users. Need to be verified in pilot.

Comment by [Stefan Asanin](#) [24/Sep/12 2:20 PM]

Needs to be verified in pilot with 10-20 number of users.

[REACTION-138] [The platform shall be expected to operate within reasonable maintenance effort for all the duration of the field trials](#) Created: 15/Jun/10 Updated: 03/Oct/12 Due: 31/May/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Performance		
Sub-Component/s:	Architecture		
Work package:	WP10		
Rationale:	Problems at the field trials should be minimized		
Source/Originator:	DoW and workshops		
Fit Criterion:	Problems signalled at the field trials should be under a fixed threshold		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 3:44 PM]

remote access for remote service? (Lukas)

Comment by [Franco Chiarugi](#) [19/Jul/11 5:56 PM]

In the in-hospital prototype the usability checks and the the discussion on functionalities and user interfaces with the end user since the early beginning of the design should help in minimizing the number of problems in the field trials. Furthermore, also the first integration performed at FORTH premises should contribute to minimize the problems. A similar approach should be follow also for the primary care prototype.

[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](#) Created: 15/Jun/10 Updated: 05/Feb/13 Due: 31/Dec/12 Resolved: 05/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Operational		
Sub-Component/s:	Architecture		

Work package:	WP10
Rationale:	The local technical partners shall take care of the installation and configuration of the field trials
Source/Originator:	DoW and Technical Meetings
Fit Criterion:	Adequate installation and configuration manuals have to be provided to the local technical partners.
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Franco Chiarugi](#) [19/Jul/11 5:58 PM]

In the in-hospital prototype installation and configuration manuals have been prepared and are continuously updated by FORTH-ICS. A similar approach has to be followed also for the primare care prototypes.

Comment by [Franco Chiarugi](#) [03/Oct/12 5:08 PM]

Installation and configuration manuals have been released also for the primary care prototype. A strict collaboration with UBRUN has been created and a copy of the deployable system has been installed in UBRUN. All that should go in the direction of solving this requirement.

[REACTION-140] [The platform shall prevent incorrect data from being introduced](#) Created: 15/Jun/10 Updated: 05/Feb/13 Due: 31/Dec/12 Resolved: 05/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Security		
Sub-Component/s:	Security, Web user interface, Data management, Interface with HIS/EPR, Portable user interface		
Work package:	WP7, WP10		
Rationale:	Incorrect data might hamper a correct clinical decision		
Source/Originator:	DoW and workshops		
Fit Criterion:	Check that the user interface and specific procedures protect the end-user from the introduction of incorrect data as much as possible		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 5:03 PM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 5:15 PM]

For the in-hospital prototype the design of the user interface has taken into account this requirement. Similar approach should be use also for the primary care prototype.

Comment by [Franco Chiarugi](#) [03/Oct/12 5:10 PM]

Similar approach has been adopted also for the primary care prototyep, with type-checking in the patient (and clinician?) portal(s).

Comment by [Franco Chiarugi](#) [04/Dec/12 1:25 PM]

Type checking is fully implemented in the patient portal v1.17

[REACTION-141] [The user should have choices regarding all data collection activities concerning his personal data](#) Created: 15/Jun/10 Updated: 06/Nov/12 Resolved: 06/Nov/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Eugenio Mantovani
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Legal		
Work package:	WP9		
Rationale:	User control implies the option to make choices, even if this means the end of an interaction or transaction. Choice is also mandated by consent, which is an important ground for legitimate collection and use of personal data (see EC Directive 95/46/EC article 7 sub a.: Member States shall provide that personal data		

	may be processed only if: a) the data subject has unambiguously given his consent.) Choice is interpreted as leaving the user as much room to decide which personal data to disclose as possible. This, for instance, means that mandatory data should be limited. Instead, the user should be left the choice to leave certain fields empty. The user should have choices regarding all data collection activities concerning his personal data
Source/Originator:	DOW
Fit Criterion:	Offering the user opt-in and opt-out choices for particular uses of collected data is an element of choice. When there is a choice to provide the user with an opt-in or opt-out option, the one that limits the user's efforts is to be preferred. Questions to be asked: Does the application have mandatory data entry fields only for data necessary for providing a service (also a data minimisation requirement)? Does the application provide the users with choices with respect to the use and secondary use of their data, for instance by providing options with respect to: - whether or not to provide personal data - what personal data is to be shared - for what purpose data can be used - when and how long data may be used
Customer Satisfaction:	Interested
Customer Dissatisfaction:	Low Unhappiness
Conflicts:	n/a
Dependencies:	n/a

Comment by [Jira Administrator](#) [06/Nov/12 2:32 PM]

This has been implemented to the extent possible by the design of the system architecture

[REACTION-145] [The user must consent to the collection of personal data whenever possible](#) Created: 15/Jun/10 Updated: 17/Jan/13 Due: 07/Dec/12 Resolved: 17/Jan/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Chorleywood Health Centre
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>is depended by REACTION-429 Before transmitting any personal data... Closed</p> <p>is depended by REACTION-370 A consent MUST NOT be considered vali... Closed</p> <p>is depended by REACTION-412 It MUST be possible to revoke a conse... Closed</p>		
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Data management, Security		
Work package:	WP7, WP9		
Rationale:	<p>The user is taken to be an autonomous individual who, in principle, decides what personal data to disclose and to whom. Of course this is not an absolute right, because legal obligations such as the law, contractual obligations, but also consequences of the performance of a contract, may overrule the right for the individual to withhold consent. Consent contributes to the realisation of a number of fundamental human values founding modern (western) societies, such as individuality, autonomy, dignity and civility.</p> <p>The requirement must be updated and better specified in the light of the Proposed Data Protection Regulation COM(2012) 11 final:</p> <p>Individual consent does not provide a valid legal ground when the individual has no genuine and free choice and is subsequently not able to refuse or withdraw consent without detriment. In such cases, the valid legal basis for the processing of personal data must be provided by a legitimate interest, such as data processing performed as part of for medical treatment.</p> <p>However, in the case where the individual retains a genuine choice, e.g., when the data processing concerns a specific purpose that is different from the original one (for which consent was obtained or for which a legitimate interest provided the legal basis), consent must be obtained in a distinguishable form. The data subject should be made aware that and to what, he or she gives consent.(see next requirement) The distinguishable form, (explicit written) shall be kept by the controller as proof for the data subject's consent to the processing of their personal data for specified purposes.</p>		
Source/Originator:	DOW Deliverable D9-2 Proposed Regulation on Data Protection		
Fit Criterion:	The fact that consent is instrumental to a number of fundamental values, means that it has to be revocable when it turns out that the effects of the previously given consent are different than the user may have		

	<p>expected given the available information at the time.</p> <p>Consent requires the user to be able to:</p> <ul style="list-style-type: none"> • give informed agreement to the collection and processing of personal data • give explicit permission to the entity collecting the personal data to perform the services contracted for • give specific, unambiguous agreement to the collection and processing of sensitive data • give special consent when data will not be editable • agree to the automatic collection and processing of (personal) data (the main reasons for which this requirement has been inserted) <p>Questions to be asked:</p> <p>Does the application offer the user ways to provide explicit consent to (personal) data disclosure?</p> <p>Does the application offer the user ways to provide explicit permission to use certain data for performing the service contracted for?</p> <p>Does the application offer ways to treat sensitive personal data different from the way it treats other personal data?</p> <p>Does the application provide special warnings when data is not editable after disclosure?</p> <p>Does the application offer ways for the user to explicitly agree to the automatic collection and processing of (personal) data</p> <p>Does the application offer ways to revoke previously given consent?</p>
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Jira Administrator [20/Oct/11 12:12 PM]
RQ was marked QC Passed
Comment by Jira Administrator [05/Jun/12 3:27 PM]
Out of Scope? See R-412
Comment by Franco Chiarugi [14/Jun/12 1:01 PM]
Main impact on WP9
Comment by Jira Administrator [06/Nov/12 2:47 PM]
To be reviewed after the Stockholm Integration meeting
Comment by Chorleywood Health Centre [17/Jan/13 10:13 AM]
Written consent is being taken from each patient prior

[REACTION-146] It should be possible to configure the application to different socio-cultural settings			
Created: 15/Jun/10 Updated: 12/Mar/13 Due: 07/Dec/12 Resolved: 12/Mar/13			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Cultural and political		
Sub-Component/s:	Architecture		
Work package:	WP9		
Rationale:	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.		
Source/Originator:	DOW		
Fit Criterion:	<p>The application should cater for configuring at least:</p> <ul style="list-style-type: none"> - 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. <p>Does the application allow for changing interface language, symbol/icon sets, help files and documentation?</p> <p>Does the application allow for managing privacy settings to different social contexts?</p>		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Jira Administrator [06/Mar/12 4:56 PM]
This also applies for Health professional sphere,
Comment by Ann-Katrin Habbig [22/Oct/12 1:01 PM]
Relates to applications like the one presented by Kamila (CNET) in Mainz.

Comment by Jira Administrator [06/Nov/12 3:15 PM]
To be reviewed after the Stockholm Integration meeting
Comment by Stephan Spat [12/Mar/13 6:12 PM]
parts of the specification have been implemented: e.g. language setting. Other parts of the specification are out of scope for the in-hospital applications.

[REACTION-151] The user must be able to correct, rectify, block or erase personal data that has been disclosed - Primary care Created: 15/Jun/10 Updated: 17/Jan/13 Due: 17/Mar/13			
Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Vivek Verma
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Work package:	WP9		
Rationale:	<p>People make mistakes and novel information may render earlier decisions unfortunate. This goes for users and service providers alike. User control mandates that users can correct mistakes they, or the service providers, make with respect to their data. A step further is that users also have the possibility to reset choices they made. If users are not content with the way their data is used, they should be able to recall or change the access rights to their data.</p> <p>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.</p> <p>This is strengthened in the new proposal on a data protection framework of the EC.</p>		
Source/Originator:	DOW		
Fit Criterion:	<p>Levels of ex-post user control that can be distinguished are:</p> <ul style="list-style-type: none"> - 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 <p>Does the application show the user's rights to access, rectify, block or erase disclosed (personal) data and the procedures to execute these right?</p>		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Jira Administrator [06/Nov/12 2:59 PM]
To be reviewed and redefined in detail by the Primary Care Clinical Partner
Comment by Chorleywood Health Centre [17/Jan/13 10:08 AM]
I have extended the due date. And will be assigning this to Vivek and Brunel University

[REACTION-153] Symptoms of diabetes or hyperglycaemia Created: 16/Jun/10 Updated: 01/Nov/12 Due: 30/Jun/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Issue Links:	<p>Depend</p> <p>is depended by REACTION-433 Results of screening, symptoms and ty... Resolved</p> <p>Incorporate</p> <p>is incorporated by REACTION-346 Knowledge Discovery from unstructured... In Progress</p>		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Data management, Interface with HIS/EPR, Web user interface		
Work package:	WP4, WP10		
Rationale:	At the diabetic patient enrolment (or recruitment or registration) his symptoms or results of screening confirming he has diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision,		

	weight loss, tiredness, recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).
Source/Originator:	D2-1 and workshops
Fit Criterion:	Specific design in the user interfaces, ontologies and data management
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Franco Chiarugi](#) [06/Jul/10 4:53 PM]

Main impact on WP10

Comment by [Jira Administrator](#) [20/Oct/11 12:11 PM]

RQ was marked QC Passed

Comment by [Franco Chiarugi](#) [21/Oct/11 2:32 PM]

Waiting for the detailed specifications for the primary care environment in order to see if this is or not part of the specifications.

Comment by [Franco Chiarugi](#) [30/Apr/12 2:42 PM]

Partially implemented

Comment by [Malcolm Clarke](#) [18/Oct/12 7:29 PM]

Please define data requirements for long term risk engine and pass to Tamas to define for short term risk engine

[REACTION-155] [The System should keep an electronic paperless data record of the data relevant for Glucose Management](#) Created: 16/Jun/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 10/Apr/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Peter Beck
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Context management, Data management, Interface with HIS/EPR, Networking, Security		
Work package:	WP4		
Rationale:	Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues)		
Source/Originator:	D2.1 (p.62)/MSG		
Fit Criterion:	The inpatient pilot application stores data records/charts		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-156] [The system should provide a regular backup of data](#) Created: 16/Jun/10 Updated: 18/Dec/12 Due: 25/Oct/12 Resolved: 18/Dec/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Peter Beck
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate is incorporated by REACTION-417 Dynamic data structure for In-hospita... Resolved		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Backend middleware		
Work package:	WP4		
Rationale:	Inpatient pilot application offers data backup mechanism		

Source/Originator:	D2.1 (p.62)/MSG
Fit Criterion:	Regular backup of data
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by [Jira Administrator](#) [20/Oct/11 12:11 PM]

RQ was marked QC Passed

Comment by [Peter Beck](#) [18/Dec/12 9:32 AM]

Backup was not "programmed" into the system, it is organized by the hospital data centre where the system is hosted.

[REACTION-160] [Alerts for the annual and 6-month clinical checks](#) Created: 16/Jun/10 Updated: 13/Mar/13 Due: 29/Mar/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Risk assessment, Backend middleware, Alert & alarm subsystem		
Work package:	WP4		
Rationale:	When a patient has forgotten to perform the annual and/or the 6-month clinical checks, an alert should be sent him in order to remind him the action to be taken (content and frequency of the alert should be agreed)		
Source/Originator:	DoW and workshops		
Fit Criterion:	Verify that in case of not compliance with the established clinical checks an alert is sent to the patient with specific content and frequency		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Low Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 3:47 PM]

Clinical protocol or clinical checks? (Lukas)

Comment by [Franco Chiarugi](#) [05/Jul/10 3:15 PM]

Changed clinical protocol with clinical checks (addressing Lukas's comments)

Comment by [Franco Chiarugi](#) [06/Jul/10 4:49 PM]

Main impact is on WP5

Comment by [Jira Administrator](#) [05/Mar/12 6:07 PM]

The way the rationale is worded makes it Patient sphere, but annual/6-mo clinical checks are done by the health professionals. The reminder could be that the patient forgot to show up for his appointment. RQ should be revised based on actual needs of clinicians

Comment by [Franco Chiarugi](#) [30/Apr/12 2:42 PM]

Partially implemented

Comment by [Stelios Louloudakis](#) [04/Oct/12 2:49 PM]

This requirement has been assigned to WP4 only, since the input for the alarms is provided by the rule engine. If the rule engine provides these kinds of alarms (such as the 6-month clinical checks), the REACTION SMS service will forward them to the end users (patients).

Comment by [Stefan Asanin](#) [13/Mar/13 2:31 PM]

Check-up functionalities are left behind schedule and has here been rescheduled. Needs more input from Care plan and Service Orchestrator improvements.

[REACTION-161] [The system should remind caregivers to perform measurements.](#) Created: 16/Jun/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 10/Apr/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Peter Beck
Resolution:	Implemented	Votes:	0

Issue Links:	Incorporate is incorporated by REACTION-193 Alarm & alert generation In Progress
Requirement Type:	Functional - In-hospital pilot application
Sub-Component/s:	Alert & alarm subsystem, Architecture, Communication, Context management, Data management, Web user interface
Work package:	WP4
Rationale:	Measurements are required to allow the algorithm to function accurately and safely. A decision was taken not being too intrusive and providing only passive reminders (for the moment)
Source/Originator:	D2.1 (p.62)/MSG
Fit Criterion:	Reminder to perform measurements is available within the inpatient platform. This could be an "open tasks" view, where such reminders are displayed.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by [Franco Chiarugi](#) [01/Jul/10 3:48 PM]

This statement is similar to N-193 (Lukas)

Comment by [Franco Chiarugi](#) [06/Jul/10 3:49 PM]

#193 refers to alarm and alert in general and to the need of not being too intrusive. This requirement is just related to reminders.

Comment by [Peter Beck](#) [08/Jul/10 5:25 PM]

OK! This is a special reminder for performing measurements.

Comment by [Stephan Spat](#) [17/Aug/11 4:22 PM]

The word "active" was removed from the issue title, as a decision was made not to prompts users in an intrusive way.

[REACTION-162] [Documentation of user interfaces - in-hospital prototype](#) Created: 16/Jun/10 Updated: 10/Jan/13 Due: 31/Oct/13 Resolved: 10/Jan/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Peter Beck
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Portable devices, Portable user interface, Risk assessment, Web user interface		
Work package:	WP6, WP10		
Rationale:	Documentation for User Interface of all frontend applications.		
Source/Originator:	DoW		
Fit Criterion:	User manual for all frontend applications		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Peter Beck](#) [09/Oct/12 9:58 AM]

I assign this to Franco, as the user interface development is mainly in WP10.

Comment by [Franco Chiarugi](#) [09/Oct/12 1:56 PM]

User manual is already available for all front-end applications. Some retrofits might be necessary after the field trials.

Comment by [Peter Beck](#) [10/Jan/13 7:03 PM]

The user manual is a mandatory part of the software as a medical device and has to be ready before real-life operation of the device.

Comment by [Peter Beck](#) [10/Jan/13 7:04 PM]

User manual is ready for the software release used in the clinical feasibility study and has to be updated for each software version released to the clinical environment.

[REACTION-165] [Error Messages](#) Created: 16/Jun/10 Updated: 12/Mar/13 Due: 25/Oct/12 Resolved: 12/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Basic In-hospital prototype		

Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Stephan Spat
Resolution:	Validated	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Backend middleware		
Work package:	WP6, WP4		
Rationale:	Error messages for every component within the application have to be foreseen so that they are helpful for the end user.		
Source/Originator:	DoW/FORTH		
Fit Criterion:	Services and feedback to user.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Jira Administrator](#) [06/Mar/12 2:57 PM]

Difficult to determine from context if this is the correct component/Helene

Comment by [Stephan Spat](#) [12/Mar/13 6:09 PM]

Implementation finished and validated

[REACTION-168] [Remote Patient Monitoring \(RPM\)](#) Created: 16/Jun/10 Updated: 30/Nov/12 Due: 31/Oct/12 Resolved: 05/Oct/12

Status:	Resolved																										
Project:	REACTION requirements																										
Component/s:	Patient sphere																										
Affects Version/s:	Basic Primary care prototype																										
Type:	Volere Requirement	Priority:	Major																								
Reporter:	Franco Chiarugi	Assignee:	Stelios Louloudakis																								
Resolution:	Implemented	Votes:	0																								
Issue Links:	<table border="0"> <tr> <td>Depend</td> <td></td> <td></td> <td></td> </tr> <tr> <td>depends</td> <td>REACTION-414</td> <td>Communication between the Reaction Ho...</td> <td>Resolved</td> </tr> <tr> <td>depends</td> <td>REACTION-452</td> <td>Communication between the Reaction De...</td> <td>Resolved</td> </tr> <tr> <td>depends</td> <td>REACTION-438</td> <td>Communication between the Reaction De...</td> <td>Resolved</td> </tr> <tr> <td>depends</td> <td>REACTION-339</td> <td>Communication between the Reaction De...</td> <td>Resolved</td> </tr> <tr> <td>depends</td> <td>REACTION-415</td> <td>Each person MAY only perform actions ...</td> <td>Resolved</td> </tr> </table>			Depend				depends	REACTION-414	Communication between the Reaction Ho...	Resolved	depends	REACTION-452	Communication between the Reaction De...	Resolved	depends	REACTION-438	Communication between the Reaction De...	Resolved	depends	REACTION-339	Communication between the Reaction De...	Resolved	depends	REACTION-415	Each person MAY only perform actions ...	Resolved
Depend																											
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depends	REACTION-438	Communication between the Reaction De...	Resolved																								
depends	REACTION-339	Communication between the Reaction De...	Resolved																								
depends	REACTION-415	Each person MAY only perform actions ...	Resolved																								
Requirement Type:	Functional - Primary care pilot application																										
Sub-Component/s:	Architecture, PAN/BAN, Portable devices, Portable user interface, Sensors, Web user interface																										
Work package:	WP3, WP4, WP5, WP7, WP10																										
Rationale:	RPM has to be used in the Primary care Pilot Applications in order to improve the supervision of the patient at home. Glucose control and eventual other measurements can be collected using the RPM.																										
Source/Originator:	D2-1 and workshops																										
Fit Criterion:	RPM module has to be present in the Primary care field trials																										
Customer Satisfaction:	Extremely Pleased																										
Customer Dissatisfaction:	Extreme Unhappiness																										

Comment by [Franco Chiarugi](#) [01/Jul/10 4:47 PM]

Main impact is on WP5.

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:45 AM]

This should not be connected with the sensor itself but rather with platform behind, most relevant for WP5

Comment by [Franco Chiarugi](#) [30/Apr/12 2:43 PM]

Partially implemented

[REACTION-169] [Display and input of data should be possible at different locations simultaneously \(centrally managed data repositories\)](#) Created: 16/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 09/Mar/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended In-hospital prototype		

Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Backend middleware, Communication, Data management, Networking		
Work package:	WP10		
Rationale:	A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously (mobile access points - e.g. tablet PC at point of care versus fixed access points - e.g. screens at physicians/nurses base)		
Source/Originator:	D.2.1 (p. 62)/MSG		
Fit Criterion:	Clinicians can input relevant information via tablet PC from every place within the hospital ward.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [20/Jul/11 5:12 PM]

The back-end contains a multiuser database engine (Posgress) and the front-end (Android-based device) can access wireless the back-end

[REACTION-170] [Selection of a mobile device for In-hospital glucose control based on given requirements](#) Created: 16/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 09/Mar/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Portable devices		
Work package:	WP10		
Rationale:	The devices should be: <ul style="list-style-type: none"> - Lightweight/portable - Easy to hold / handle and ergonomic design - Spill an drip resistant (easy disinfection) - Inputs for stylus and touch operations (incl. touch keyboard) - Wireless communication - Ease of operations 		
Source/Originator:	D 2.1 (p. 62)/MSG		
Fit Criterion:	Devices with desired functionality are available within the project		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [20/Jul/11 5:09 PM]

The device for the in-hospital prototype has been selected and made available since the first-year prototype (Samsung Galaxy Tab with Android)

[REACTION-171] [Data input application for In-hospital glucose control](#) Created: 16/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 09/Mar/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Context management, Data management, Networking, Ontology/Terminology, Portable devices, Portable user interface, Web user interface		

Work package:	WP10
Rationale:	The system should ask for data entry of relevant parameters. Main parameters for documentation (once, at the enrolment) 1. type of diabetes (insulin requirement) 2. newly diagnosed diabetes 3. weight 4. classification of the patient regarding insulin sensitive/normal/resistant Parameters required regularly (for decision support) 1. glucose level (time, trend, last measurement) 2. injected insulin 3. food intake / nutrition 4. hypoglycaemic and hyperglycaemic episodes
Source/Originator:	D 2.61 (p.62/63) / MSG
Fit Criterion:	Data entry system will be available for In-hospital decision support system with devices (tablet PC)
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	High Unhappiness
Dependencies:	REACTION-254

Comment by [Franco Chiarugi](#) [01/Jul/10 3:52 PM]

this is similar to N-254 (Lukas)

Comment by [Franco Chiarugi](#) [06/Jul/10 3:43 PM]

Inserted the dependency from #254 addressing Lukas's comments

Comment by [Franco Chiarugi](#) [20/Jul/10 5:11 PM]

#254 is a duplicate of this requirement

[REACTION-172] [The system should automatically transfer measurements from the POCT devices into the platform within a few seconds](#) Created: 16/Jun/10 Updated: 05/Mar/13 Due: 31/Oct/13 Resolved: 05/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Third-party system interfaces		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Minor
Reporter:	Peter Beck	Assignee:	Peter Beck
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Duplicate is duplicated by REACTION-257 Automated transfer of measured and re... Resolved</p> <p>Incorporate is incorporated by REACTION-379 Interface for transmission of glucose... Closed</p>		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Backend middleware, Communication, Context management, Data management, Interface with HIS/EPR, Networking, PAN/BAN, Portable devices, Portable user interface		
Work package:	WP4, WP10		
Rationale:	The system should automatically transfer measurements from the POCT devices into the platform within a few seconds in order to have the data available for decision support		
Source/Originator:	D 2.61 (p.62/63)/MSG		
Fit Criterion:	POCT data is transmitted within short time to the platform		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 3:52 PM]

this statement is similar to N-225? (Lukas)

Comment by [Franco Chiarugi](#) [01/Jul/10 4:49 PM]

Main impact is on WP10.

Comment by [Peter Beck](#) [08/Jul/10 4:19 PM]

N225 describes the use of a POCT device in the first year. N172 describes the requirement for automatic transfer of POCT device data into the platform in order to have electronic decision support.

Comment by [Franco Chiarugi](#) [05/Mar/13 4:52 PM]

This requirement is implemented since the blood glucose measurements are manually inserted in the tablet PC (this is the final procedure foreseen in REACTION) and immediately transferred to the REACTION data management.

[REACTION-173] [Platform should allow ubiquitous access to end-users and sharing of information among caregivers \(multiuser access to relevant data\)](#) Created: 16/Jun/10 Updated: 19/Dec/12 Due: 31/Oct/12 Resolved: 05/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Backend middleware, Communication, Context management, Data management, Networking		
Work package:	WP4, WP5, WP10		
Rationale:	The system should allow caregivers to be independent from location and time; one or more caregivers should can use the system anywhere in the ward independently		
Source/Originator:	D 2.1 (p. 62/63) / MSG		
Fit Criterion:	Achieving location independence and multi-user support		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matts Ahlsen](#) [18/Jun/10 1:34 PM]

This requirement may fit better in WP10 and / or WP5.

Comment by [Franco Chiarugi](#) [01/Jul/10 4:51 PM]

Main impact is on WP5.

Comment by [Franco Chiarugi](#) [02/Jul/10 2:09 PM]

Probably the title could be reviewed such to explain better the requirement itself. Our suggestion is: platform should allow ubiquitous access to end-users and sharing of information among caregivers (multiuser access to relevant data) (Stelios & Franco)

Comment by [Franco Chiarugi](#) [05/Jul/10 3:10 PM]

The title (summary) has been reviewed in order to address Stelios's comments

Comment by [Peter Beck](#) [08/Jul/10 4:54 PM]

OK!

[REACTION-174] [The system must provide interfaces to HIS and implement data management and data structures for In-hospital scenario](#) Created: 16/Jun/10 Updated: 18/Dec/12 Due: 25/Oct/12 Resolved: 18/Dec/12

Status:	Resolved														
Project:	REACTION requirements														
Component/s:	Third-party system interfaces														
Affects Version/s:	Basic In-hospital prototype														
Type:	Volere Requirement	Priority:	Blocker												
Reporter:	Peter Beck	Assignee:	Peter Beck												
Resolution:	Implemented	Votes:	0												
Issue Links:	<table border="0"> <tr> <td>Incorporate</td> <td></td> <td></td> <td></td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-362</td> <td>Interface to patient demographic regi...</td> <td>Resolved</td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-363</td> <td>Interface to Hospital Information Sys...</td> <td>Resolved</td> </tr> </table>			Incorporate				is incorporated by	REACTION-362	Interface to patient demographic regi...	Resolved	is incorporated by	REACTION-363	Interface to Hospital Information Sys...	Resolved
Incorporate															
is incorporated by	REACTION-362	Interface to patient demographic regi...	Resolved												
is incorporated by	REACTION-363	Interface to Hospital Information Sys...	Resolved												
Requirement Type:	Functional - In-hospital pilot application														
Sub-Component/s:	Architecture, Backend middleware, Communication, Data management, Interface with HIS/EPR, Networking														
Work package:	WP4, WP10														
Rationale:	The platform must offer interface to HIS; moreover the system needs data structures and data management functionality for the In-hospital scenario														
Source/Originator:	D 2.61 (p. 62/63)/MSG														
Fit Criterion:	Data structures and data management functionality														
Customer Satisfaction:	Very Pleased														
Customer Dissatisfaction:	High Unhappiness														

Comment by [Franco Chiarugi](#) [06/Jul/10 3:38 PM]

HIS/EPR interface is foreseen in WP10. Thus main impact is on WP10

[REACTION-179] [Daily data review by clinicians or telehealth support team](#) Created: 16/Jun/10 Updated: 06/Nov/12 Resolved: 18/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Malcolm Clarke
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by REACTION-408 Non-pharmacological and/or pharmaco... Resolved		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Architecture, Data management, Ontology/Terminology, Web user interface		
Work package:	WP4, WP6, WP10		
Rationale:	When RPM is used, the acquired data (once contextualized) will be reviewed daily by clinicians or the telehealth support team in order to check the patient progress against individualized targets set up for the patient.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	The phase "daily check of acquired data" for patients under RPM has to be present with outcomes on non-pharmacological and/or pharmacological treatment.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:56 PM]

Main impact is on WP10.

Comment by [Jira Administrator](#) [20/Oct/11 12:09 PM]

RQ was marked QC Passed

Comment by [Franco Chiarugi](#) [21/Oct/11 2:46 PM]

Waiting for the detailed specifications for the primary care.

Comment by [Franco Chiarugi](#) [30/Apr/12 2:43 PM]

Partially implemented

Comment by [Malcolm Clarke](#) [18/Oct/12 7:27 PM]

Not sure what this means

Comment by [Malcolm Clarke](#) [18/Oct/12 7:27 PM]

This protocol is already enacted

Comment by [Malcolm Clarke](#) [06/Nov/12 11:57 AM]

The clinician portal is designed to assist in looking at patient data on daily basis and prioritises patients needing review

[REACTION-180] [Measurement of glucose should be specific and the glucose sensor should be able to monitor glucose in complex media](#) Created: 16/Jun/10 Updated: 07/Mar/13 Due: 28/Feb/13 Resolved: 07/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	If the glucose monitoring is not specific, detection could be disturbed by other components of the ISF or the blood, influencing the accuracy of the sensor. For realisation of a closed-loop-system (glucose measurement + insulin dosage) a highly accurate sensor is required.		
Source/Originator:	L. Ben Mohammadi		

Fit Criterion:	Sensor should exhibit a high accuracy even if other media are in contact with the sensor area.
Customer Satisfaction:	Interested
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Franco Chiarugi](#) [02/Jul/10 3:39 PM]

Is correlated to [REACTION-267](#) (Thomas, IMM)

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:58 PM]

Old components relevant: sensors

Comment by [Thomas Klotzbuecher](#) [07/Mar/13 4:20 PM]

Specificity of glucose sensors is in case of the I-Cath sensor achieved by by addressing the life time of the characteristic fluorescence and since the tissue is transparent of the fluorescence wavelength of 780 nm, information can be transferred from the interstitial liquid (ISF as medium) to the detector unit above the skin. In case of the IR sensor specificity is achieved by measuring difference absorption against a reference liquid (in case of microdialysis the perfusion solution), since only changes in glucose concentration are expected to cause major differences in the signal amplitude. The sensor can be operated in complex media like ISF (subcutaneous) or blood (intravenously) by applying a semipermeable membrane with 10 to 20 kDalton. The sensor operating principles are described in more detail within D3-6.

[REACTION-181] [Decision on therapy in Primary care environment](#) Created: 16/Jun/10 Updated: 19/Apr/13 Due: 30/May/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend is depended by REACTION-408 Non-pharmacological and/or pharmaco... Resolved		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Architecture, Context management, Data management, Ontology/Terminology, Web user interface		
Work package:	WP4, WP6, WP10		
Rationale:	At each review visit but also as a result of the daily check, non-pharmacological treatment (diet and lifestyle) can be adjusted and also pharmacological treatment (OAD or insulin) can be reviewed after accurate evaluation of patient kidney functions.		
Source/Originator:	D2-1 and workshops		
Fit Criterion:	Specific fields have to be foreseen in the data management, ontologies and user interfaces. Also user interfaces with an optimal display of the relevant information have to be designed.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:59 PM]

Main impact is on WP10.

Comment by [Jira Administrator](#) [20/Oct/11 12:08 PM]

RQ was marked QC Passed

Comment by [Franco Chiarugi](#) [21/Oct/11 2:48 PM]

Waiting for the detailed specifications for the primary care. If it is a real requirement, it should be considered in the mock-up of the primary care.

Comment by [Franco Chiarugi](#) [30/Apr/12 2:44 PM]

Partially implemented

Comment by [Malcolm Clarke](#) [18/Oct/12 7:26 PM]

Await evaluation with patients to develop further

Comment by [Malcolm Clarke](#) [18/Oct/12 7:37 PM]

Handled by EPR

Comment by [Malcolm Clarke](#) [06/Nov/12 11:52 AM]

This has the same issues as many requirements in trying to determine what functionality is included in the platform to provide EPR functionality and what already exists in a site to provide EPR. In UK we anticipate to use the primary care EPR as the main repository, and so information is light in the platform to reduce burden of dual entry.

Comment by [Chorleywood Health Centre](#) [08/Nov/12 5:17 PM]

This has not been implemented yet. Forms part of the discussion in Stockholm. As it mainly part of the ontology I think it should be

assigned to ALL

[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](#) Created: 16/Jun/10 Updated: 07/Mar/13 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	For AGC the accuracy should be +/-5% of the measured value in the specified range. For a closed loop sensor system (glucose measurement + insulin dosage) especially in the lower concentration range of about 3-4 mM or less a high accuracy is required to avoid mistreatments in the hyperglycaemic range.		
Source/Originator:	L. Ben Mohammadi		
Fit Criterion:	Performance of reference measurements on defined samples.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:37 PM]

Is correlated to [REACTION-267](#) (Thomas, IMM)

Comment by [Franco Chiarugi](#) [28/Jul/10 11:21 AM]

Changed the rationale in order to address Lukas's comments

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:56 PM]

Old components relevant: sensors

Comment by [Thomas Klotzbuecher](#) [07/Mar/13 3:58 PM]

Cannot be resolved until clinical trials are finished.

[REACTION-186] [The sensor platform should be robust and simple to be used, enabling the device to be operated by the patient himself](#) Created: 16/Jun/10 Updated: 27/Sep/12 Due: 07/Jan/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	Sensor platform has to be worn for several days and should not hinder the patient in his normal activities.		
Source/Originator:	L. Ben Mohammadi		
Fit Criterion:	Simplicity and reliability in patient trials is to be demonstrated.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:37 PM]

Is probably the same as #130 (Thomas, IMM)

Comment by [Franco Chiarugi](#) [06/Jul/10 2:58 PM]

#130 is referred to easy usability of the entire platform especially by elderly people

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:55 PM]

Old components relevant: sensors

Comment by [Franco Chiarugi](#) [30/Apr/12 2:45 PM]

Partially implemented

[REACTION-188] [Storage of events for context of measurements](#) Created: 16/Jun/10 Updated: 07/Mar/13 Due: 28/Feb/13 Resolved: 07/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Issue Links:	Depend is depended by REACTION-366 Storage of events for context of meas... Closed		
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Ontology/Terminology, Portable devices, Web user interface, Context management		
Work package:	WP3, WP4, WP10		
Rationale:	Significant events (e.g. nutritions, drug administrations, adverse events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context for the acquired measurements. A suitable user interface has to be provided in order to facilitate patients performing this task (any data entry can be felt as too intrusive for patients). The possibility of integrating existing commercial log-devices used by the patients has to be considered.		
Source/Originator:	Workshops		
Fit Criterion:	There should be a user-friendly interface for the registration of significant event and also a user-friendly interface for the joint display of the acquired measurements and the relevant associated events (giving a context for the measurements)		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:36 PM]

What is meant by "Events"? (Thomas, IMM)

Comment by [Franco Chiarugi](#) [06/Jul/10 2:55 PM]

Changed the rationale in order to address Thomas's comments

Comment by [Franco Chiarugi](#) [06/Jul/10 2:55 PM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [28/Jul/10 11:23 AM]

Changed the rationale in order to address Lukas's comments

Comment by [Franco Chiarugi](#) [20/Jul/11 2:57 PM]

Nutritions and drug administrations are already available in the in-hospital prototype. Management of adverse events has not been implemented yet. For the primary care the previous experience performed in the in-hospital might be useful (at least in the design phase).

Comment by [Franco Chiarugi](#) [04/Dec/12 1:22 PM]

Nutrition and drug intake information are also present in the patient portal being by themselves context information and being also stored with context information

[REACTION-189] [Other implications for type I diabetic patients](#) Created: 17/Jun/10 Updated: 30/Nov/12 Due: 31/Oct/12 Resolved: 03/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Vincenzo Lagani
Resolution:	Implemented	Votes:	0
Issue Links:	Depend is depended by REACTION-442 Management of complications Part of specification		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Architecture, Communication, Web user interface		
Work package:	WP10, WP6		

Rationale:	Type I diabetic patients may have significant risk of developing complications (neuropathy, nephropathy, neurobehavioral complications, retinopathy)
Source/Originator:	D2.1 and workshops
Fit Criterion:	In the care program, management of diabetes (through insulin) should be accompanied by the capability of evaluating the risk of long-term complications
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by Helene Udsen [28/Jun/10 4:36 PM]
1) This is relevant for all diabetes patients, not just Type 1. 2) Check potential overlap with issue 195 /Helene
Comment by Franco Chiarugi [01/Jul/10 1:54 PM]
Complications in this issue and in issue 195 should be the same (Helene)
Comment by Franco Chiarugi [05/Jul/10 3:00 PM]
Changed the rationale in order to address Helene's comments. Now complications are the same as in #195.
Comment by Franco Chiarugi [06/Jul/10 2:53 PM]
Main impact is on WP10
Comment by Peter Beck [09/Jul/10 9:24 AM]
Here I would like to refer to the e-mail from of Peter Beck from 1st of July: "Is REACTION a TELEMONITORING project, or should it become a DISEASE MANAGEMENT project?"
Comment by Franco Chiarugi [09/Jul/10 12:00 PM]
The view is that telemonitoring should help in better disease management. At this moment we should proceed with this view.
Comment by Jira Administrator [20/Oct/11 12:06 PM]
RQ was marked QC Passed
Comment by Franco Chiarugi [21/Oct/11 5:10 PM]
In contrast with the DoW. Only reduction of risk of complications is required in the DoW. As it is it will not be part of specifications. We should replace the word managements with monitoring of risk (of complications).
Comment by Franco Chiarugi [30/Apr/12 2:46 PM]
Partially implemented

[REACTION-190] [In the Primary care environment the medications are usually self-administered by the patient himself or by informal carers \(rarely\)](#) Created: 17/Jun/10 Updated: 01/Nov/12 Due: 31/Oct/12 Resolved: 04/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Constraint - Implementation Environment		
Sub-Component/s:	Architecture, Communication, Web user interface		
Work package:	WP10		
Rationale:	Usual practice for diabetic patient outside of secondary or tertiary care is self-administration of medications		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the overall solutions no doctor or nurse resources shall be scheduled or dedicated to the medication administration at patient home		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Jira Administrator [20/Oct/11 12:05 PM]
RQ was marked QC Passed
Comment by Franco Chiarugi [21/Oct/11 5:12 PM]
Waiting for the detailed specifications of primary care.

[REACTION-193] [Alarm & alert generation](#) Created: 17/Jun/10 Updated: 11/Oct/12 Due: 29/Mar/13

Status:	In Progress
Project:	REACTION requirements

Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Issue Links:	Incorporate incorporates REACTION-161 The system should remind caregivers t... Resolved		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Alert & alarm subsytem, Risk assessment		
Work package:	WP5, WP6		
Rationale:	The alerts and alarms should not be generated too often in such a way the system will be considered too intrusive for the patient himself. However serious and especially life-threatening situations have to be promptly signalled. ROC analysis might be used in order to tune the alarm and alert system.		
Source/Originator:	Workshops		
Fit Criterion:	Some serious or life-threatening situations can be simulated in the integration environment and the production of adequate alarms can be verified.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 3:57 PM]

Very important point. Evaluation using ROC-analysis (Lukas)

Comment by [Franco Chiarugi](#) [06/Jul/10 2:51 PM]

Changed the rationale in order to address Lukas's comments. Main impact is on WP6

Comment by [Franco Chiarugi](#) [30/Apr/12 2:46 PM]

Partially implemented

Comment by [Peter Beck](#) [02/Oct/12 3:17 PM]

We are not going to implement something on alarms and alerts for patients outside the hospital. I assign that to you, Stefan.

Comment by [Stefan Asanin](#) [11/Oct/12 5:15 PM]

Part of the newly discussed "dynamic thresholds", etc. at the deployment meeting at Brunel.

[REACTION-197] [Care spaces in the primary care environment](#) Created: 17/Jun/10 Updated: 25/Feb/13 Resolved: 23/Oct/12

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Chorleywood Health Centre
Resolution:	Validated	Votes:	0
Issue Links:	Depend depends REACTION-343 Every person represented in the React... Resolved is depended by REACTION-436 Care space in outpatient environment Closed		
Requirement Type:	Functional - Primary care pilot application		
Work package:	WP4, WP5, WP7, WP8, WP10		
Rationale:	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members. The patients have to be provided with their own self management tasks in an ongoing relationship with the other members of the team. Only people registered in the patient care space can access the patient data (clinical and demographic).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Each member of the care space will have specific roles and tasks in the patient's care.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [01/Jul/10 5:00 PM]

The rational talks about roles and care spaces which have to be defined in order to develop some kind of interaction model between the roles. However, the fit criterion implies that it is sufficient to have some kind of access control mechanisms in place, which seems to be

less than the rational asks for.
Comment by Franco Chiarugi [01/Jul/10 5:01 PM]
Main impact is on WP7.
Comment by Franco Chiarugi [06/Jul/10 2:45 PM]
Changed the rationale and the fit criterion in order to address Matthias's comments
Comment by Jira Administrator [20/Oct/11 12:03 PM]
RQ was marked QC Passed
Comment by Franco Chiarugi [30/Apr/12 2:47 PM]
Partially implemented
Comment by Matthias Enzmann [08/Oct/12 3:30 PM]
In primary care, roles in terms of role-based-access-control (RBAC) will not be used. Users of the patient portal will all be given the same permissions w.r.t. their own data. At the moment it is unclear whether health professionals (HP) accessing the HP platform will have different permissions with respect to the management of patient data. I am re-assigning this requirement to CHC since the implementation of roles, if any, will be done by UBRUN/CHC - Franco would have been a candidate for the patient portal part but I understand that roles will not be taken into account there.

[REACTION-202] [Set up remote patient monitoring scheme](#) Created: 17/Jun/10 Updated: 01/Nov/12 Due: 26/Feb/13 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-411	Monitoring scheme Closed
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Ontology/Terminology, PAN/BAN, Portable devices, Sensors, Web user interface, Architecture, Data management		
Work package:	WP4, WP5, WP10		
Rationale:	At the first visit (but it could happen also at the next visits) the patient is assigned to a remote patient monitoring scheme (parameters to be monitored, frequency, etc.)		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	An enrolled patient can be assigned to a configurable RPM scheme		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 2:33 PM]
Main impact on WP4
Comment by Jira Administrator [20/Oct/11 12:00 PM]
RQ was marked QC Passed
Comment by Stefan Asanin [28/Feb/12 1:09 PM]
Possible a duplicate
Comment by Stefan Asanin [16/Apr/12 10:32 AM]
Part of what is to be developed within Service Orchestrator.
Comment by Franco Chiarugi [30/Apr/12 2:48 PM]
Partially implemented
Comment by Stefan Asanin [11/Oct/12 4:28 PM]
Requirements for "configurable RPM scheme" needs to be provided.

[REACTION-204] [Wireless interfacing of other devices than ePatch](#) Created: 17/Jun/10 Updated: 18/Dec/12 Due: 20/Jun/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Critical

Reporter:	Jens Branebjerg	Assignee:	Peter Rosengren
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	PAN/BAN, Sensors		
Work package:	WP3		
Rationale:	The ePatch is the preferred device and technology used to attached and connect sensors to the body. However, it should be possible that data from commercially available sensors not connected to the ePatch can be read by the REACTION platform.		
Source/Originator:	DELTA		
Fit Criterion:	Hardware fabricated.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Dependencies:	BAN/PAN		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:35 PM]

Is this really a requirement? Sounds more like a definition (Thomas, IMM)

Comment by [Franco Chiarugi](#) [28/Jul/10 9:36 AM]

Changed the rationale in order to address Lukas's comments

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:49 AM]

e-patch properties should be specified

Comment by [Jira Administrator](#) [06/Mar/12 11:14 AM]

Original Reporter was Rasmus Groenbek Haahr

Comment by [Jira Administrator](#) [01/Nov/12 2:28 PM]

The Summary does not fit the Rationale which is about anything BUT the ePatch. And maybe component is Data management?

[REACTION-205] [Docking station for the ePatch](#) Created: 17/Jun/10 Updated: 01/Nov/12 Due: 12/Dec/12

Status:	In progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Minor
Reporter:	Jens Branebjerg	Assignee:	Jens Branebjerg
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	Charging of the reusable sensor in the ePatch		
Source/Originator:	DELTA		
Fit Criterion:	Hardware fabricated.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		
Dependencies:	ePatch		

Comment by [Franco Chiarugi](#) [28/Jul/10 10:14 AM]

This requirements refers to the recharging of reusable sensors and not to the portable device

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:50 AM]

Properties of the e-patch docking station should be specified

Comment by [Jira Administrator](#) [06/Mar/12 11:46 AM]

Original Reporter was Rasmus Groenbek Haahr

[REACTION-206] [ePatch reusable sensor](#) Created: 17/Jun/10 Updated: 01/Nov/12 Due: 12/Dec/12

Status:	In progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major

Reporter:	Jens Branebjerg	Assignee:	Jens Branebjerg
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	The ePatch reusable sensor contains the optical and electrical sensor components, electronics, radio, antenna, and battery. Eventually the ePatch might be consisting of two components, one reusable, containing the optics and electronics, and one disposable, containing the optical cell and waste for the dialysis.		
Source/Originator:	DELTA		
Fit Criterion:	Hardware fabricated.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Dependencies:	ePatch		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:34 PM]

The ePatch might be consisting of two components, one reusable containing the optics and electronics and one disposable, containing the optical cell and waste for the dialysis (Thomas, IMM)

Comment by [Franco Chiarugi](#) [06/Jul/10 2:28 PM]

Changed the rationale in order to address Thomas's comments

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 10:51 AM]

Properties of the reusable e-patch sensors should be specified

Comment by [Jira Administrator](#) [06/Mar/12 11:45 AM]

Original Reporter was Rasmus Groenbek Haahr

[REACTION-207] [ePatch communication](#) Created: 17/Jun/10 Updated: 07/Mar/13 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Jens Branebjerg	Assignee:	Jens Branebjerg
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Communication, PAN/BAN, Sensors		
Work package:	WP5, WP3		
Rationale:	The reusable sensor in the ePatch communicates wirelessly at 2.4 GHz using the Continua Alliance ZigBee standard and/or Bluetooth.		
Source/Originator:	DELTA		
Fit Criterion:	The ePatch sensor can wirelessly transfer data to other parts of the REACTION platform (BAN integration node or portable device of the "black box").		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 2:26 PM]

Main impact is on WP3 (communication protocol implemented on the ePatch side)

Comment by [Franco Chiarugi](#) [27/Jul/10 2:26 PM]

Addressed Thomas's comments changing the rationale

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:53 PM]

Old components relevant: Communication, PAN/BAN, sensors

Comment by [Jira Administrator](#) [06/Mar/12 11:57 AM]

Original Reporter was Rasmus Groenbek Haahr

Comment by [Thomas Klotzbuecher](#) [26/Sep/12 5:26 PM]

As far as I know, the ePatch platform of DELTA is already able to communicate with the REACTION platform. If confirmed by Jens Branebjerg, this requirement can be closed.

Comment by [Thomas Klotzbuecher](#) [07/Mar/13 3:49 PM]

Requirement should be resolved by M36 within D3-9. Assignee changed to Jens Branebjerg.

[REACTION-208] ePatch adhesive base Created: 17/Jun/10 Updated: 01/Nov/12 Due: 12/Dec/12			
Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Jens Branebjerg	Assignee:	Jens Branebjerg
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	The adhesive base forms the contact between the ePatch sensor and the skin surface of a human. Sensors measuring physiological data should be specified. First sensor is a bioelectronic sensor for ECG. Second sensor is an optical sensor for oxygen saturation and NIR spectroscopy.		
Source/Originator:	DELTA		
Fit Criterion:	ePatch can stick to the skin and sensor can measure physiologic data.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:33 PM]
Specify sensors for which this is relevant (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 2:23 PM]
Changed the rationale in order to address Thomas's comments
Comment by Lhoucine Ben Mohammadi [21/Jun/11 10:54 AM]
Properties of the adhesive base should be specified
Comment by Jira Administrator [06/Mar/12 11:44 AM]
Original Reporter was Rasmus Groenbek Haahr

[REACTION-209] ePatch adhesive base has unique physical properties Created: 17/Jun/10 Updated: 01/Nov/12 Due: 12/Dec/12			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Jens Branebjerg	Assignee:	Jens Branebjerg
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	The ePatch adhesive base contains 3 gel electrodes with impedance matched to the skin. The gel or part of the gel is optical transparent in the visible and NIR range of the electromagnetic spectrum.		
Source/Originator:	DELTA		
Fit Criterion:	ePatch can stick to the skin and optical or NIR sensor (if required) can measure physiologic data.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:32 PM]
The optical sensor of IMM will be connected to the patient via a microdialysis needle. Therefore, a measurement through the adhesive is not required (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 2:20 PM]
Changed the fit criterion in order to address Thomas's comments.
Comment by Lhoucine Ben Mohammadi [21/Jun/11 10:57 AM]
Adhesive base should be further specified, see also comment on REACTION-208
Comment by Jira Administrator [06/Mar/12 11:42 AM]
Original Reporter was Rasmus Groenbek Haahr

[REACTION-210] ePatch adhesive base has unique adhesive properties Created: 17/Jun/10 Updated: 18/Dec/12 Due: 03/Jun/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Jens Branebjerg	Assignee:	Jens Branebjerg
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	The ePatch adhesive base contains at least two type of adhesive materials: 1) One with good skin adhesive properties 2) An adhesive gel or similar with electrical and optical properties matched to electrical and optical sensors.		
Source/Originator:	DELTA		
Fit Criterion:	Adhesive can stick to skin and sensors can measure.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Jira Administrator](#) [06/Mar/12 11:38 AM]

Original Reporter was Rasmus Groenbek Haahr

Comment by [Jira Administrator](#) [18/Dec/12 11:09 AM]

To be reviewed by due date

[REACTION-214] [Activity parameters must be measured \(e.g. pulse frequency, body temperature\) by sensors](#) Created: 18/Jun/10 Updated: 07/Mar/13 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Jens Branebjerg
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Glucose control algorithm, Portable devices, Sensors		
Work package:	WP8, WP3		
Rationale:	For input to the AGC algorithm to make prediction of glucose levels activity parameters are required. Which ones are still tbd but heart rate and body temperature should be included.		
Source/Originator:	T. Klotzbuecher		
Fit Criterion:	Activity parameter sensors must be integrated into the REACTION e-patch.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:29 PM]

Is correlated to [REACTION-265](#), since activity parameters are part of the clinical parameters (Thomas, IMM)

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 11:00 AM]

Specify exactly (physicians!) which activity parameters are going to be measured, see also comment on [REACTION-124](#), potential candidates could be those related to hypo events, like e.g. heart rate

Comment by [Franco Chiarugi](#) [21/Jun/11 6:18 PM]

Added WP8 in order to clearly specify the necessary activity measurements. However, main impact is on WP3.

Comment by [Jira Administrator](#) [19/Oct/11 7:34 PM]

RQ was marked Incomplete

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:50 PM]

Old components relevant: sensors, glucose control algorithm, portable devices

Comment by [Thomas Klotzbuecher](#) [27/Sep/12 9:19 AM]

Since temperature nor pulse frequency are not necessarily related to physical activity, it should be discussed whether this requirement makes sense?! In principle the activity could be measured by accelerometers, as where integrated into the SOLINAIS sensor platform. However, currently we have no partner in the project who could take care of that.

Comment by [Thomas Klotzbuecher](#) [07/Mar/13 3:47 PM]

Current parameters other than glucose concentration are ECG and respiration. Requirement should be resolved with D3-9, due M36. Assignee changed to Jens Branebjerg.

[REACTION-217] [Acquired values in the alarm range](#) Created: 18/Jun/10 Updated: 01/Nov/12 Due: 28/Feb/13 Resolved: 16/Apr/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Web user interface, Risk assessment, Architecture, Backend middleware, Data management, Ontology/Terminology, Alert & alarm subsystem		
Work package:	WP4, WP5, WP6, WP10		
Rationale:	When the acquired values are in the alarm range, an alarm has to be sent to the clinicians in charge (call centre). If the alarm is confirmed by them, then either the patient has to be sent to the hospital in case of serious episode or the treatment and the RPM schema have to be adequately changed		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Check the overall procedure in case of acquired measurements in the alarm range.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 2:11 PM]

Main impact is on WP4 (alarm & alert handling)

Comment by [Jira Administrator](#) [20/Oct/11 11:57 AM]

RQ was marked QC Passed

Comment by [Stefan Asanin](#) [16/Apr/12 11:10 AM]

Implemented by the Rule Engine but to be extended with more advanced computing.

Comment by [Stefan Asanin](#) [11/Oct/12 4:03 PM]

Needs a new version of requirement addressing latest discussions on rules, thresholds, timed/manual alarm settings/ranges. Also the rationale needs to be rewritten to be a) realistic, b) fitting primary care workflow, and c) provide conceptual input for subtask 4.5.1.

[REACTION-219] [Safe Glycaemic Control \(SGC\)](#) Created: 18/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Data management, Glucose control algorithm, Ontology/Terminology, Physiology models, Risk assessment, Web user interface		
Work package:	WP4, WP6, WP10		
Rationale:	Safe Glycaemic Control is the goal of the Inpatient environment and has to be part of the electronic decision support system (eDSS) in the Inpatient environment. Safe Glycaemic Control is preferred to Tight Glycaemic Control (TGC) which might cause a significant number of hypoglycaemic episodes.		
Source/Originator:	D2.1 and workshops; revision based on ID6-5		
Fit Criterion:	Thresholds for the blood sugar level are higher than in TGC (but safer) and they can be adapted (personalized) to each patient based on his medical history and actual state. In the first iteration step all patients will use the same threshold.		
Customer Satisfaction:	Extremely Pleased		

Customer Dissatisfaction:	Extreme Unhappiness
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Comment by Franco Chiarugi [06/Jul/10 2:07 PM]
Main impact is on WP4
Comment by Peter Beck [09/Jul/10 10:25 AM]
This should be part of the electronic decision support system (eDSS) in the inpatient area.
Comment by Franco Chiarugi [09/Jul/10 11:51 AM]
Changed the rationale addressing Peter's comments
Comment by Franco Chiarugi [20/Jul/11 2:50 PM]
Thresholds have been implemented as lower and upper ranges of glucose level. They can be personalized for each patient.

[REACTION-220] Healthcare professionals perform the safe glycaemic control in In-hospital environment (not self-management) Created: 18/Jun/10 Updated: 18/Dec/12 Due: 31/Aug/11 Resolved: 10/Aug/11			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-402	Measurements of blood glucose and ins... Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Backend middleware, Data management, Glucose control algorithm, Ontology/Terminology, Web user interface		
Work package:	WP5, WP4, WP10		
Rationale:	In In-hospital environment, the blood glucose level measurements are in most cases performed by nurses and the treatment is performed by clinicians and/or nurses		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:02 PM]
Type 1: most of them do their measurements themselves; Type 2: most measurements are done by the nurses (Lukas)
Comment by Franco Chiarugi [06/Jul/10 2:06 PM]
Changed the rationale in order to address Lukas's comments. Considering the main issue is the storage of measurements, this issue impacts mainly on WP5

[REACTION-223] Basic workflow for insulin treatment in In-hospital environment Created: 18/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12			
Status:	Closed		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-441	Basic workflow in In-hospital environ... Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Ontology/Terminology, Web user interface, Glucose control algorithm		
Work package:	WP8, WP6, WP4, WP10		
Rationale:	The basic workflow is based on measurement of blood glucose, evaluation of the necessary insulin (bolus or basal) based also on additional parameters and insulin administration		

Source/Originator:	D2.1 and workshops
Fit Criterion:	The basic workflow should be easily accessible in the REACTION In-hospital application
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by [Franco Chiarugi](#) [06/Jul/10 2:00 PM]

Main impact is on WP10 (but with significant efforts in WP4 and WP6)

Comment by [Peter Beck](#) [09/Jul/10 9:14 AM]

Without WP8 (MUG) this requirement cannot be fulfilled. Therefore I would suggest to add WP8! Further I would suggest that the main work on developing a electronic decision support for glucose administration (that's what this requirement is about?) should be done in the ward by MUG and MSG in WP6/WP8. WP10 would be responsible for implementation into the inpatient REACTION pilot application.

Comment by [Franco Chiarugi](#) [09/Jul/10 11:49 AM]

Added WP8 as suggested by Peter

Comment by [Franco Chiarugi](#) [20/Jul/11 2:46 PM]

Basic workflow has been implemented since the first-year prototype

[REACTION-224] [Basic workflow is repeated 4 times a day in In-hospital environment](#) Created: 18/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Issue Links:	Depend is depended by REACTION-441 Basic workflow in In-hospital environ... Resolved		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Web user interface		
Work package:	WP4, WP10		
Rationale:	The first workflow is in the morning a little before breakfast time (administration of bolus insulin), the second is at midday before lunch time (administration of bolus insulin), the third is in the evening before dinner time (administration of bolus insulin), and finally the fourth is at bedtime (administration of basal insulin and correction of boluses, if necessary).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	These 4 loops should be easily identified in the In-hospital application		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 1:58 PM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 2:45 PM]

The basic workflow has been implemented in the first-year prototype and can be manually repeated as many times as needed.

[REACTION-225] [PoC device for blood glucose measurement will be used by the in-hospital glucose management system](#) Created: 18/Jun/10 Updated: 05/Mar/13 Due: 25/Oct/12 Resolved: 05/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Extended In-hospital prototype , Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Interface with HIS/EPR, Sensors, Communication		
Work package:	WP3, WP10		
Rationale:	The first-year prototype has to be ready quite early and at that time no sufficient development will be made		

	for the consortium sensors. Furthermore, before their regular use in hospital ward consortium sensors have to obtain special approval. Thus, in the Inpatient environment the devices currently used will continue to be used also in the first-year prototype.
Source/Originator:	Inpatient workshop
Fit Criterion:	a) The blood glucose measurement in the first-year prototype will be performed in the same way in which it is currently performed. b) The acquired measurements will be manually inserted using the front-end in the tablet PC and stored in the REACTION data management.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by [Franco Chiarugi](#) [06/Jul/10 1:58 PM]

Main impact is on WP10 (integration with HIS is part of WP10)

Comment by [Franco Chiarugi](#) [20/Jul/11 2:43 PM]

The Roche AccuCheck glucose measuring device (PoC device) has been selected for the first-year prototype. The interface for the data retrieval from LIS is still under development.

Comment by [Franco Chiarugi](#) [05/Mar/13 4:43 PM]

The required time for the automatic acquisition and retrieval is not compatible with the needs for an immediate treatment. Thus the final procedure in REACTION is the manual insertion of the blood glucose value using the tablet PC.

[REACTION-226] [Electronic fever/sugar chart should be modelled in the data management system](#)

Created: 18/Jun/10 Updated: 01/Nov/12 Due: 31/Oct/12 Resolved: 04/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-377	Electronic fever/sugar chart Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Ontology/Terminology, Web user interface, Backend middleware		
Work package:	WP4, WP10		
Rationale:	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the design of the data management and of the user interface the electronic fever/sugar chart has to be present.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 1:54 PM]

Main impact on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 2:42 PM]

The fever/sugar chart has been electronically implemented as simply sugar (glucose) chart in the first prototype. The addition of further information (temperature and/or other vital signs) is planned for the prototype at year 3

Comment by [Peter Beck](#) [02/Oct/12 2:48 PM]

This requirement has to be discussed.

Currently I think it is more likely that we build interfaces to existing patient records / "electronic fever chart" systems to feed the glucose management data into them instead of duplicating our own electronic fever chart.

Aim of the glucose management system is to provide the algorithm and the workflow support in hospital wards. Creating a full electronic fever chart is out of scope.

Comment by [Franco Chiarugi](#) [04/Oct/12 2:30 PM]

Following Peter's comments for fever/sugar chart we should mean only the glucose chart which has been already implemented. The other vital signs are out-of-scope, since they are not strictly related to the glucose management and will be a duplication of the electronic fever chart already existing in the hospital ward.

For this reason this requirement can be resolved as implemented.

[REACTION-227] Initialization of the fever/sugar chart Created: 18/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-417	Dynamic data structure for In-hospita... Resolved
	is depended by	REACTION-377	Electronic fever/sugar chart Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Data management, Web user interface		
Work package:	WP4, WP10		
Rationale:	Immediately after the patient enrolment, the relevant information about medical history, general health status, actual status, etc. has to be registered in the fever/sugar chart		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The initialization of the fever/sugar chart is a pre-requisite for the daily management of the diabetic patient		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [06/Jul/10 1:54 PM]
Main impact is on WP4
Comment by Matts Ahlsen [15/Aug/11 11:37 AM]
One could even add some of the latest data from HIS in order to smoothen out the inpatient-outpatient transition.
Comment by Jira Administrator [20/Oct/11 11:54 AM]
RQ was marked QC Passed
Comment by Stefan Asanin [16/Apr/12 11:09 AM]
This requirement is possibly a duplicate but also indicates that whatever chart is used it is merely parameters that are to be extracted from the data management layer. We talk about "initialization" here and it is probably what it is all about.
Comment by Stefan Asanin [24/Sep/12 2:56 PM]
Implemented in in-hospital prototype.

[REACTION-228] Blood glucose measurements have to be contextualized (e.g. before/after meal) Created: 18/Jun/10 Updated: 01/Nov/12 Due: 29/Oct/12 Resolved: 10/Apr/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-424	Contextualization of measurements Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Context management, Data management		
Work package:	WP4		
Rationale:	The availability of the blood glucose measurements shall be accompanied also by the context of the measurements		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Measurements before any usage have to be contextualized		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-229] Decision on therapy in In-hospital environment Created: 18/Jun/10 Updated: 01/Nov/12 Due: 29/Oct/12 Resolved: 10/Apr/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend is depended by REACTION-375 Therapy scheme in In-hospital environ... Resolved		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Web user interface, Data management, Architecture		
Work package:	WP4, WP10		
Rationale:	Decision on therapy has to be performed immediately after performing any measurements based also on patient's medical history and associated parameters. It might imply changes in the therapy scheme.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Decision on therapy shall impact on dosage of insulin and/or OAD and also on the decision that no specific treatment is necessary or the administration of carbohydrates is necessary (hypoglycaemic episode).		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 1:52 PM]

Main impact on WP4

[REACTION-230] Therapy adjustment in In-hospital environment Created: 18/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12			
Status:	Closed		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Issue Links:	Depend is depended by REACTION-465 Clinical evaluation report Resolved		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Web user interface		
Work package:	WP4, WP10		
Rationale:	Supervision of glycaemia and according treatment is performed once a day. Adaptation of therapy or changes of medications have to be evaluated also consulting the physician on duty.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Every day an evaluation report has to be stored and available in the In-hospital application		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 1:51 PM]

Main impact on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 2:34 PM]

This functionality is the therapy adjustment which has been implemented in the in-hospital prototype

[REACTION-231] End of process for the diabetic patient in the In-hospital environment Created: 18/Jun/10 Updated: 01/Nov/12 Due: 15/Aug/12 Resolved: 10/Apr/12	
Status:	Resolved
Project:	REACTION requirements
Component/s:	Data Management

Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Ontology/Terminology, Web user interface		
Work package:	WP4, WP10		
Rationale:	The workflows in the In-hospital glycaemic control management ends with the patient discharge from the department. However, there should be a transition of care (from secondary to primary or tertiary care) which should be considered in the discharge management.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	At the patient discharge from the department, the workflow related to the patient has to be terminated		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 1:50 PM]

Main impact is on WP4

Comment by [Franco Chiarugi](#) [28/Jul/10 11:26 AM]

Changed the rationale in order to address Lukas's comments

Comment by [Matts Ahlsen](#) [15/Aug/11 11:22 AM]

Focus will be given on the hand out of outpatient tools and appliances for the REACTION system and transition herein.

[REACTION-232] [Continua Manager emulation](#) Created: 18/Jun/10 Updated: 13/Mar/13 Due: 14/Mar/13

Status:	In progress		
Project:	REACTION requirements		
Component/s:	Application development kit (ADK)		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Data management		
Work package:	WP4		
Rationale:	The integration of Continua devices requires a Continua Manager component as part of the architecture. In the absence of such a manager, the system should provide an emulation of the corresponding functionality.		
Source/Originator:	CNet WP4 architecture design meeting		
Fit Criterion:	A Continua Manager stub exists allowing simulated access to a Continua device.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Matts Ahlsen](#) [15/Aug/11 11:26 AM]

First version of the Continua Manager exists and is to be refined to fit a more portable solution. It deals with Continua devices by a compartmentalised approach where technical subprocesses are made concrete for possible explicit solution development and refinement.

Comment by [Stefan Asanin](#) [28/Feb/12 12:11 PM]

Continua Manager Emulator exists as a Web application. It needs to be modified to allow communication to other components Web Service endpoints (i.e. interfaces) when such are developed. Do not close yet as it is part of iterative process.

Comment by [Stefan Asanin](#) [13/Mar/13 2:37 PM]

Final stage of development and test. Has undergone improvement.

[REACTION-234] [Determination of health status in In-hospital environment](#) Created: 20/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major

Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Data management, Ontology/Terminology, Web user interface		
Work package:	WP4, WP10		
Rationale:	At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or adapted to the status of the patient. In the second case a dose-finding procedure for the individual patient will be started associated with education in nutrition and therapy. Type of diabetes has to be registered.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	After patient enrolment, type of diabetes and (pharmacological and non-pharmacological) therapy have to be inserted.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 1:48 PM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 2:33 PM]

This feature has been implemented since the first-year prototype

[REACTION-235] [Therapy scheme in In-hospital environment registered immediately after the patient enrolment](#) Created: 20/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Issue Links:	Depend is depended by REACTION-375 Therapy scheme in In-hospital environ... Resolved		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture, Data management, Web user interface		
Work package:	WP4, WP10		
Rationale:	The therapy scheme is continued for patients with known diabetes and defined and started for patients with newly diagnosed diabetes. It used includes: used drugs (OAD, insulin), timing and mixing of drugs, type and dosage of OAD and/or insulin. It must take into account the actual health status, nutrition, insulin resistance. Eventual additional data might be added during the course of the project.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The therapy scheme has to be registered immediately after the patient enrolment and regularly (daily at the ward round) reviewed.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [06/Jul/10 1:47 PM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 2:32 PM]

This feature has been already implemented in the first prototype

[REACTION-236] [Blood glucose measurements in In-hospital environment](#) Created: 20/Jun/10 Updated: 20/Dec/12 Due: 29/Mar/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Third-party system interfaces		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0

Requirement Type:	Functional - In-hospital pilot application
Sub-Component/s:	Interface with HIS/EPR, Portable user interface, Sensors
Work package:	WP3, WP5
Rationale:	PoC devices are currently used and will be used in In-hospital environment. The procedure is reliable and has been used since several years. Substitution of the used PoC devices with other devices (consortium sensors) in the daily practice can be done only after passing through a very severe procedure. This might not be foreseen (for the daily practice) in this project.
Source/Originator:	Inpatient workshop
Fit Criterion:	There should be in the platform an alternative way for acquiring blood glucose measurements from other commercially available glucose sensors using a procedure which should be quite simple and user friendly.
Customer Satisfaction:	Interested
Customer Dissatisfaction:	Low Unhappiness

Comment by Helene Udsen [28/Jun/10 12:42 PM]
Check for potential overlap with issue 225 /Helene
Comment by Franco Chiarugi [02/Jul/10 3:23 PM]
Comment: as an alternative the finger prick method was discussed, to be performed by the patient himself or a clinician and subsequent entering the data into the REACTION-platform, so this requirement might be connected to REACTION-215 and -243 (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 1:44 PM]
This requirement is beyond the first-year prototype (in the first-year prototype the currently used sensors will continue to be used). For the next prototypes suitable sensors with the necessary approvals have to be provided, otherwise PoC devices will necessarily continue to be used.
Comment by Franco Chiarugi [06/Jul/10 1:46 PM]
Main impact is on WP3
Comment by Franco Chiarugi [28/Jul/10 9:40 AM]
Changed the fit criterion in order to address Lukas's comments
Comment by Lhoucine Ben Mohammadi [21/Jun/11 11:05 AM]
Not sure whether this is a requirement, maybe it should be specified that COTS POC devices must be tolerated by the REACTION platform or values could be entered manually, if desired
Comment by Thomas Klotzbuecher [20/Feb/12 1:46 PM]
Old components relevant: sensors, portable user interfaces, interfaces with HIS/EPR
Comment by Peter Beck [02/Oct/12 11:50 AM]
Hi Thomas, could you please clarify what that means. Should blood glucose be measured in the hospital with commercial POCT devices or with consortium sensors or both?
Comment by Thomas Klotzbuecher [20/Dec/12 3:22 PM]
Hi Peter, I think blood glucose should be measurable with both commercial sensors and consortium sensors. But Franco should specify, he was creating this requirement. However, to let consortium sensors communicating with the platform, someone has to specify how, with what kind of protocol etc. and what kind of hardware is required (WP3 does only give the sensors).

[REACTION-237] [Annotation of blood glucose values, especially in In-hospital environment](#) Created: 20/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate is incorporated by REACTION-463 Context management for clinical (lab)... Resolved		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Interface with HIS/EPR, Ontology/Terminology, Sensors, Context management, Data management		
Work package:	WP3, WP4, WP10		
Rationale:	In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. From the HIS using HL7 interface the values can be imported in the platform.		

Source/Originator:	D2.1 and workshops
Fit Criterion:	The blood glucose values have to be annotated specifying if collected with PoC devices or by phlebotomist. In fact the values can be different considering that different procedures and reagents are used for the two measurements.
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by Franco Chiarugi [06/Jul/10 1:39 PM]	
Main impact on WP4 (context and annotations)	
Comment by Lhoucine Ben Mohammadi [21/Jun/11 11:07 AM]	
Possibly related to REACTION-128	
Comment by Matts Ahlsen [15/Aug/11 11:30 AM]	
HL7 messages show origin of measurement so this should not be any problem to fix in REACTION.	
Comment by Jira Administrator [20/Oct/11 11:53 AM]	
RQ was marked QC Passed	
Comment by Stefan Asanin [16/Apr/12 10:57 AM]	
To be handled by Context WS/Manager	
Comment by Stefan Asanin [24/Sep/12 2:59 PM]	
Implemented by in-hospital prototype.	

[REACTION-238] Update and entering of drug administration (OAD and/or insulin) data Created: 20/Jun/10 Updated: 01/Nov/12 Due: 10/Apr/12 Resolved: 10/Apr/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>is depended by REACTION-428 Drug administration data (OAD and/or ... Resolved</p> <p>Incorporate</p> <p>is incorporated by REACTION-463 Context management for clinical (lab)... Resolved</p>		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Web user interface		
Work package:	WP4, WP10		
Rationale:	Drug administration (time, type, dosage and other relevant information) has to be immediately annotated by the administering nurse.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	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.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 2:40 PM]	
Main impact on WP4	
Comment by Jira Administrator [20/Oct/11 11:53 AM]	
RQ was marked QC Passed	

[REACTION-241] Management of hypoglycaemic episodes in In-hospital environment Created: 21/Jun/10 Updated: 04/Oct/12 Due: 31/Dec/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi

Resolution:	Unresolved	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-369	Storage of hyperglycaemic or hypoglyc... Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Alert & alarm subsystem, Data management, Glucose control algorithm, Ontology/Terminology, Risk assessment, Web user interface		
Work package:	WP8, WP6, WP4, WP10		
Rationale:	The symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions...) have to be verified with a blood glucose measurement (under a certain threshold). In case of episode the reasons for hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	A specific procedure has to be present for the management of hypoglycaemic episodes. This procedure shall allow also the recording of the significant parameters and actions.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [05/Jul/10 2:35 PM]

Main impact on WP10

Comment by [Peter Beck](#) [09/Jul/10 9:08 AM]

The details for this requirement (especially which parameters are relevant) have to be identified together with WP8 (clinicians), because they influence the organizational work at the ward.

Comment by [Franco Chiarugi](#) [09/Jul/10 11:47 AM]

Added WP8 in order to address Peter's comments

Comment by [Franco Chiarugi](#) [20/Jul/11 2:18 PM]

The episode management has to be properly included in the in-hospital prototypes. It is necessary to check if that has been done.

Comment by [Peter Beck](#) [02/Oct/12 3:06 PM]

This issue has to be discussed, it may be out of scope.

There are diverse reasons for hypoglycaemia, documentation can always be entered as a comment, but we do not enforce more than that.

It is not relevant to document "therapy" or measures taken. It is more important to take care of a proper follow-up. Therefore, currently hypoglycaemia triggers a control measurement which the user is prompted to schedule within a defined time period (50 min.-2 hours after the event)

I assign this for now to the extended in-hospital prototype, but we may decide that we do not need more documentation on hypos.

[REACTION-245] [Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation](#) Created: 21/Jun/10 Updated: 05/Oct/12 Due: 31/Dec/13 Resolved: 05/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Trivial
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-450	Fever and infections shall be registered Closed
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Glucose control algorithm, Ontology/Terminology, Risk assessment, Web user interface, Context management, Data management		
Work package:	WP4, WP6, WP10		
Rationale:	Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of ketotic acid in the urine are performed to increase the insulin dose to the current needs. Similar checks can be also and more effectively performed with blood gas analysis.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Fever and infections shall be registered in the fever chart and have an impact in the insulin dosage calculation.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:06 PM]
Blood gas analysis is more appropriate than keton bodies in urine (Lukas)
Comment by Franco Chiarugi [05/Jul/10 2:31 PM]
Changed the rationale in order to address Lukas's comment
Comment by Franco Chiarugi [05/Jul/10 2:32 PM]
Main impact is on WP10 (user interface)
Comment by Franco Chiarugi [20/Jul/11 12:48 PM]
No specific work has been done on this issue that is not relevant in the first prototype. The main question is to verify if this issue is still relevant for the in-hospital prototype or if it has become out-of-scope.
Comment by Franco Chiarugi [30/Nov/11 1:30 PM]
REACTION-450 is a duplicate of this requirement
Comment by Franco Chiarugi [10/Apr/12 1:37 PM]
Probably out of scope, but to be checked during the 3rd year.
Comment by Franco Chiarugi [05/Oct/12 1:10 PM]
Fever and infections affect insulin resistance. To keep documentation overhead low, fever and infections are not directly documented in the glucose management application because they are already documented elsewhere in the patient documentation. The system provides an option for "insulin resistance" in general, where the clinical personnel can enter a value according to their estimation considering all facts that contribute to insulin resistance. This requirement has been implemented through the "insulin resistance" option.

[REACTION-246] Multi-user availability and display of the fever chart Created: 21/Jun/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-377	Electronic fever/sugar chart Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Context management, Data management, Web user interface		
Work package:	WP4, WP10		
Rationale:	The fever/sugar chart shall be considered as a central document and collects all the information about the patient stay in the hospital ward (blood glucose level, information about the actual status of the patients, drug administration, nutrition, relevant events, etc.). Other eventual parameters could be considered during the overall life cycle of the development.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Clinical decision is often taken based on this document which has to be available (multi-user) and continuously updated.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [05/Jul/10 2:27 PM]
Main impact on WP4
Comment by Franco Chiarugi [10/Apr/12 1:35 PM]
The fever chart does not seem to be necessary while the sugar chart is. This issue should be solved during the 3rd year.
Comment by Stefan Asanin [24/Sep/12 3:30 PM]
implemented by in-hospital prototype.

[REACTION-247] Mobile access point in wards of In-hospital environment Created: 21/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12	
Status:	Closed
Project:	REACTION requirements
Component/s:	Patient sphere

Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Networking, Web user interface, Architecture, Backend middleware, Communication, Data management		
Work package:	WP4, WP10		
Rationale:	Nurses/clinicians have to use a mobile device during their duties around the wards (patient beds). The mobile device (e.g. tablet PC) will be wireless connected to the backend middleware providing all the necessary information for the optimal patient management and clinical decision and will allow, at the same time, the recording of treatments, relevant information/events and actions.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	User interfaces have to be targeted on mobile devices like tablet PCs. One specific type of mobile device for the hospital ward will be selected based on the following requirements: lightweight/portable, easy to hold/handle, ergonomic design, spill and drip resistant (easy disinfection), input for stylus and touch operation, user friendly user interface, wireless communication, ease of operation.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matts Ahlsen](#) [01/Jul/10 1:45 PM]

WP4: not specifically a WP4 requirement. More likely WP10 only.

Comment by [Franco Chiarugi](#) [05/Jul/10 2:27 PM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 12:45 PM]

The selected device is the Samsung Galaxy tablet PC with Android and a prototype has already been released based on this mobile device

[REACTION-250] [Different contextualization of the patient clinical information](#) Created: 21/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Web user interface		
Work package:	WP4, WP10		
Rationale:	Different modes of visualisation with different relevant parameters for decision support shall be foreseen. The relevant data have to be displayed contextualized. The relevant values have to be highlighted.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The possibility of configure the display of the patient clinical data (mainly the sugar chart) has to be present.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [05/Jul/10 2:25 PM]

Main impact is on WP10

Comment by [Franco Chiarugi](#) [20/Jul/11 11:58 AM]

The possibility of showing the glucose levels with insulin administrations and food intakes for a period of time has been implemented. Presentation can be graphical or tabular and the window of time can be adjusted.

[REACTION-251] [Creation of electronic decision support rules shall be supported](#) Created: 21/Jun/10 Updated: 01/Nov/12 Due: 15/Aug/12 Resolved: 10/Apr/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		

Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Glucose control algorithm, Risk assessment		
Work package:	WP4		
Rationale:	An electronic decision support system with standardised instructions and decisions (e.g. evidence based medicine, support identification of "patients at risk") shall be present. There have to be "guidelines" on how to titrate insulin. An active alarm system would remind the staff to perform measurements/injections.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Suggestions on treatments shall be available in order to facilitate the clinical decision. An available protocol from literature (e.g. RABBIT II trial) should be implemented and improved. Alerts for next insulin administration should be provided together with a support for calculation of insulin amount depending on known (acquired or estimated/evaluated) parameters.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Matts Ahlsen](#) [15/Aug/11 11:44 AM]

GlucoMan Sys eDSS. Needs to be extended as a global DSS in REACTION.

[REACTION-253] [Data entry shall be facilitated as much as possible](#) Created: 21/Jun/10 Updated: 11/Mar/13 Due: 30/Nov/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture		
Work package:	WP8, WP4, WP3, WP10		
Rationale:	Data entry in any information system is an additional task for patients and formal/informal carers. This additional workload has not to be burdensome in order to facilitate the adoption of the platform in the clinical sites.		
Source/Originator:	Workshops		
Fit Criterion:	Specific evaluation (e.g. using questionnaire) shall be made on this issue asking end-users how much additional work they have to do and how much this additional work (if any) is useful.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Matts Ahlsen](#) [01/Jul/10 12:00 PM]

WP4: not a specific WP4 requirement, more likely WP10 or 8

Comment by [Franco Chiarugi](#) [02/Jul/10 3:22 PM]

Requirement? (Thomas, IMM)

Comment by [Franco Chiarugi](#) [05/Jul/10 2:23 PM]

Main impact is on WP8 (verification of easy data entry is a task of WP8)

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 11:09 AM]

This should not be connected with the sensor itself but rather with platform behind, delete for WP3 and shift to WP8

Comment by [Jira Administrator](#) [12/Nov/12 5:04 PM]

As this is unresolved it must be Extended version only. If it is indeed In-hospital I think Rationale should list only formal carers, not patients or informal carers.

[REACTION-255] [Management of missing data](#) Created: 21/Jun/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 27/Jul/11

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		

Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Minor
Reporter:	Franco Chiarugi	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Context management, Data management		
Work package:	WP10, WP6		
Rationale:	Mandatory fields have to be filled otherwise the user cannot go on the workflow of the inpatient prototype. Guessing for default values is not safe enough for a medical device.		
Source/Originator:	D2.1 and workshops; revision based on ID6-5		
Fit Criterion:	Mandatory fields have to be filled in a safe and traceable manner!		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Matts Ahlsen](#) [01/Jul/10 11:53 AM]

WP4: Suggest this requirement to be attributed to WP10 only.

Comment by [Franco Chiarugi](#) [05/Jul/10 1:47 PM]

Probably parameter estimation is a task of WP6. WP10 cannot make an estimation of the missing value but simply ask WP6 for the "best value" to assign to the field. I propose to change WP4 with WP6 but main impact will be on WP6.

Comment by [Peter Beck](#) [09/Jul/10 9:00 AM]

I depends very much on the parameters whether parameter estimation is suitable or not. For critical medical parameters like blood glucose or lab values I would not suggest to offer automatic default values as input parameters by the system (e.g. for decision support). A better way would be to show past values and the user has to choose the appropriate one.

Comment by [Franco Chiarugi](#) [09/Jul/10 11:42 AM]

Changed the fit criterion in order to address Peter's comments

[REACTION-258] [Automated transfer of patient related data from the hospital information system](#) Created: 21/Jun/10 Updated: 19/Dec/12 Due: 31/Oct/12 Resolved: 19/Dec/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Third-party system interfaces		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-362	Interface to patient demographic regi... Resolved
	is depended by	REACTION-363	Interface to Hospital Information Sys... Resolved
	is depended by	REACTION-336	HIS interfaces for patient demographi... Resolved
	is depended by	REACTION-361	Baseline and clinical history handled... Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Interface with HIS/EPR, Ontology/Terminology, Web user interface		
Work package:	WP4, WP10		
Rationale:	At the diabetic patient enrolment, the significant data (it has to be clearly specified) through an HL7 interface can be automatically transferred from the HIS to the platform (when a HIS/EPR is present in the clinical site). This procedure reduces transcription errors and save doctors/nurses time for manual data entry. This procedure must be flexible enough to interface different HIS/EPR HL7-based including the one used at the clinical site.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The relevant data can be retrieved and transferred from HIS and displayed in an user interface for their verification and use.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:10 PM]

This has to be adapted to the current status in the hospital (Lukas)

Comment by [Franco Chiarugi](#) [05/Jul/10 1:04 PM]

Changed the rationale trying to address Lukas comments
Comment by Franco Chiarugi [06/Jul/10 3:11 PM]
Main impact is on WP10
Comment by Franco Chiarugi [20/Jul/11 11:54 AM]
The patient management has been mostly implemented. However, the HL7 interface is still under development.
Comment by Franco Chiarugi [19/Dec/12 10:42 AM]
Implemented and running in the field trials for the in-hospital

[REACTION-261] [The platform shall not generate additional workload for the clinical staff](#) Created: 21/Jun/10 Updated: 11/Mar/13 Due: 30/Nov/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Architecture		
Work package:	WP8, WP4, WP10		
Rationale:	Additional workflow shall be avoided or allowed only when the advantages produced by this workflow overcome the disadvantages		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the field trials evaluation additional workflow shall be assessed by questionnaire or quantitative measurements and its advantages/disadvantages properly evaluated		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Matts Ahlsen [01/Jul/10 11:32 AM]
Requirement not directly related to WP4. Suggest to assign to WP8 only.
Comment by Franco Chiarugi [05/Jul/10 12:47 PM]
Probably main impact is on WP8 (but proper design is necessary in WP4 & WP10, proper definition of the evaluation plan in WP2 and performing of the evaluation in WP8)

[REACTION-262] [Improve productivity and efficiency, reducing cost](#) Created: 21/Jun/10 Updated: 14/Jan/13 Due: 01/Sep/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Performance		
Sub-Component/s:	Architecture		
Work package:	WP8, WP4, WP10		
Rationale:	The platform shall improve productivity and efficiency and at the same time shall reduce the cost of the diabetic patient workflow and management		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Qualitative or quantitative measurements of productivity, efficiency and cost shall be foreseen in the field trials in order to make a proper comparison between the performances before the introduction of the REACTION platform and after the introduction of the REACTION platform. Assessment in field trial will be based on questionnaire for evaluating productivity and efficiency and on cost-benefit analysis estimating the different performances before the introduction of the REACTION platform and after the introduction of the REACTION platform. Usability tests will be performed early in the life cycle in order to adjust specifications of the system. Questionnaires will be part of the first clinical trial to assess usability.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Matts Ahlsen [01/Jul/10 11:30 AM]
This requirement is not directly attributed to WP4. Propose to assign is to WP8 only. Fit crit: initial assessment procedures should be indicated
Comment by Franco Chiarugi [05/Jul/10 12:41 PM]
Modified the fit criterion trying to address Matts's comment. Probably main impact is on WP8 (but proper design is necessary in WP4 & WP10, proper definition of the evaluation plan in WP2 and performing of the evaluation in WP8)

[REACTION-263] [Improve documentation quality and streamlined access to information](#) Created: 21/Jun/10 Updated: 06/Nov/12 Resolved: 19/Jun/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Chorleywood Health Centre
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Architecture		
Work package:	WP8		
Rationale:	The registration of all measurements, additional information, decision on treatments, drug administration will improve the quality of documentation. The reduction of the number of missing information and an efficient access to all information related to the patient will improve the quality of care.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The platform shall allow the registration of all relevant information and its contextualized retrieval. In the questionnaires used in the evaluation procedures specific questions should be included in order to verify the user satisfaction about the improvement in the documentation and in the streamlined access to information.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Matts Ahlsen [23/Jun/10 4:14 PM]
WP4: The fit criterion must be detailed in order to be measurable. The requirement can be broken down into multiple ones in order to achieve this.
Comment by Franco Chiarugi [05/Jul/10 12:36 PM]
Changed the fit criterion trying to address Matts's comment. In the questionnaire associated to the evaluation plan, end-users will be asked to evaluate the improvement in documentation and streamlined access to information
Comment by Jira Administrator [20/Oct/11 11:40 AM]
RQ was marked QC Passed

[REACTION-264] [Increase accuracy and reduce errors](#) Created: 21/Jun/10 Updated: 01/Nov/12 Due: 31/Mar/13

Status:	In progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Performance		
Sub-Component/s:	Architecture		
Work package:	WP4		
Rationale:	The registration of all relevant data (vital sign and environmental measurements, nutrition and lifestyle, drugs/insulin administration, adverse events) shall allow a reduction in the errors committed in the current workflows and an improvement in the accuracy of the diabetic patient management		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Qualitative and quantitative criteria shall be present in the field trial evaluations in order to measure the reduction of errors compared to the existing workflows before the installation of the REACTION platform and a quality improvement in the clinical decision.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Matts Ahlsen [22/Jun/10 3:45 PM]
Need refinement: specify the "relevant data" as far as possible. Also the fit criterion should be quantified.
Comment by Franco Chiarugi [05/Jul/10 12:28 PM]
Matts's comment has been addressed in the reviewed version of this requirement
Comment by Matts Ahlsen [15/Aug/11 11:20 AM]
With reservation on "all relevant data".

[REACTION-265] The clinical parameters to be measured must be specified Created: 22/Jun/10 Updated: 21/Dec/12 Due: 19/Nov/12 Resolved: 21/Dec/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Physiology models, Sensors		
Work package:	WP3		
Rationale:	For sensor development the type of clinical parameter must be specified to adapt sensor properties to the specific parameter.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Clinical parameters given by the clinicians, but also parameters that are necessary for running the physiological model		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:20 PM]
For this requirement the physicians in the project should specify what they would like to have and also Bayer should say what say need for their algorithms (Thomas, IMM)
Comment by Lhoucine Ben Mohammadi [21/Jun/11 11:12 AM]
Should be specified by the physicians and is connected to REACTION-124 and REACTION-214
Comment by Thomas Klotzbuecher [20/Feb/12 1:42 PM]
Old componenets relevant: sensors, physiology models
Comment by Thomas Klotzbuecher [27/Sep/12 9:00 AM]
For the different applications within REACTION already additional parameters to be measured other than glucose, have been specified. These are for clinical application: none, for primary care: blood pressure(device is not developed within REACTION), weight(device is not developed withinREACTION), heart rate (DELTA ECG ePatch?) and for closed loop: activity (DELTA ECG ePatch?). If partners agree on that, the requirement could be considered closed.
Comment by Thomas Klotzbuecher [21/Dec/12 9:17 AM]
For the different applications within REACTION the following additional parameters to be measured other than glucose, have been specified: 1) for clinical application: none, 2) for primary care: blood pressure(device is not developed within REACTION), weight(device is not developed withinREACTION), heart rate (DELTA ECG ePatch) and for closed loop: activity (DELTA ECG+Respiration ePatch).

[REACTION-266] Type of sensor/signal should be specified Created: 22/Jun/10 Updated: 20/Dec/12 Due: 19/Nov/12 Resolved: 20/Dec/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	Type of sensor/signal, whether chemical, electrical, optical, etc. is important for integration in e-patch and sensor platform and for the possibility to build an online sensor.		

Source/Originator:	Lukas Schaupp
Fit Criterion:	Type of sensor specified by the sensor manufacturers.
Customer Satisfaction:	Uninterested
Customer Dissatisfaction:	Very Low Unhappiness

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:39 PM]

Old components relevant: Sensors

Comment by [Thomas Klotzbuecher](#) [20/Dec/12 5:08 PM]

With the IR CGM sensor the optical transmission in the near infrared region of the spectrum (1400-1600 nm) of a sample liquid (perfusate via microdialysis) containing the glucose is measured and compared to the optical transmission in the same spectral region of a reference liquid (pure perfusate). The optical signals are transferred into electrical signals via photo-detectors and afterwards amplified and differentiated. Changes of glucose concentration results in a change of difference signal, the relation of which is linear in the concentration range of 0-5000 mg/dL. Interference with concentration changes of other substances in the sample liquid (like e.g. Lactate) is possible.

With the fluorescence spectroscopy based sensor, a fluorescence (phosphorescence) of the glucose molecules is excited via illumination of the ISF through the skin in the visible range of the spectrum (635 nm) and the fluorescence signal in the nearinfrared spectrum (860 nm) is monitored as a function of time. To correct for oxygen fluorescence (617 nm excitation) present in the background, it is measured also at a second wavelength (768 nm). The modulated optical signals are converted into electrical signals by photo-detectors. The signal phase shift is correlated with the glucose concentration. Since the fluorescence maxima and life times are very characteristic for glucose, the method is more specific compared to the IR transmission spectroscopy.

[REACTION-267] [Accuracy/precision of sensors should be specified](#) Created: 22/Jun/10 Updated: 07/Mar/13 Due: 30/Apr/13

Status:	In progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP8, WP3		
Rationale:	For all types of sensors the accuracy/precision has to be known. In some sensors a high accuracy can be required, as, for example, for online monitoring of glucose where a high precision is required, especially in the hypoglycaemic regime.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	The accuracy/precision should be specified by the sensor manufacturers.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:20 PM]

Is correlated to [REACTION-180](#) (interference, specificity) and [REACTION-183](#) (accuracy in the lower concentration range) (Thomas, IMM)

Comment by [Franco Chiarugi](#) [05/Jul/10 12:26 PM]

This is a generic requirement which addresses all sensors used in the REACTION platform while #180 & #183 refer to the blood glucose sensors

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 11:13 AM]

It should be specified by the physicians which accuracy is required for which application (closed loop, primary care, inpatient)

Comment by [Franco Chiarugi](#) [21/Jun/11 6:24 PM]

Add WP8 in order to have clinicians deciding the accuracy required in the various clinical environments. Main impact is on WP3.

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:33 PM]

Old components relevant: Sensors

Comment by [Thomas Klotzbuecher](#) [07/Mar/13 3:44 PM]

Cannot be resolved until clinical trials are finished.

[REACTION-268] [Response time and drift of the sensors should be specified](#) Created: 22/Jun/10 Updated: 07/Mar/13 Due: 30/Apr/13

Status:	In Progress
Project:	REACTION requirements

Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	Response time of the sensor is important for online monitoring and it may not be too long, drift could influence the accuracy and could require regular calibrations.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Response time and drift should be specified by the sensor manufacturers.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:19 PM]

Is correlated with [REACTION-267](#) since drift could influence the accuracy (Thomas, IMM)

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:32 PM]

Old components relevant: Sensors

Comment by [Thomas Klotzbuecher](#) [07/Mar/13 3:41 PM]

Cannot be resolved until clinical trials are finished.

[REACTION-269] [Working range of sensors should be specified \(linearity and detection limit\)](#) Created: 22/Jun/10 Updated: 07/Mar/13 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	The working range of the sensors should cover the required ranges as defined by the clinicians and ideally should be linear, the detection limit should be well below the minimal relevant measured variable.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Working range of the different sensors should be specified by the sensor manufacturers.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by [Lhoucine Ben Mohammadi](#) [21/Jun/11 11:14 AM]

Concrete values should be given

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 1:12 PM]

Old components relevant: Sensors

Comment by [Thomas Klotzbuecher](#) [07/Mar/13 1:55 PM]

Can not be completed before clinical trials are finished.

[REACTION-270] [Operating temperature of sensors should be specified and kept on equal level for the IR GM sensor reference and measuring channel](#) Created: 22/Jun/10 Updated: 20/Feb/13 Due: 07/Jan/13 Resolved: 20/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major

Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	The temperature might influence the result of the measurement and its accuracy.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Either sensor manufacturers should specify the operating temperature of the sensors or the device should be able to adjust the measurement based on the temperature value (in this case a temperature sensor has to be integrated in the device)		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:18 PM]

Is correlated to [REACTION-29](#) although less specific (Thomas, IMM)

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 11:54 AM]

Old components relevant: Sensors

Comment by [Thomas Klotzbuecher](#) [20/Feb/13 9:20 AM]

The operating temperature for the Joanneum Fluorescence Spectroscopy sensor is specified to 25°C-37°C. The operating temperature for the IMM infrared transmission spectroscopy sensor is specified to -10°C-50°C. Since the IMM sensor is not applied within the body, a larger temperature interval is tolerable. The operating temperature of the body interface (microdialysis catheter) may differ from these values, following the specifications of the corresponding suppliers.

[REACTION-271] [The calibration of the sensors should be specified \(strategy, intervals, reference, algorithms\)](#) Created: 22/Jun/10 Updated: 28/Jan/13 Due: 07/Jan/13 Resolved: 28/Jan/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	The sensor must be calibrated before usage and might be re-calibrated after a certain time, also might the calibration required to be individual for a single patient.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Calibration routines of the sensors should be specified by the sensor manufacturers.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Very Low Unhappiness		

Comment by [Franco Chiarugi](#) [02/Jul/10 3:18 PM]

Calibration is correlated to [REACTION-268](#), since drift could require regular calibrations! (Thomas, IMM)

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 11:45 AM]

Old components relevant: Sensors

Comment by [Thomas Klotzbuecher](#) [28/Jan/13 11:25 AM]

The sensor calibration, for both the IMM IR CGM and the JOA Fluorescence Spectroscopy CGM has been specified and documented in the deliverable ID3-9.

[REACTION-272] [The body interface of the sensors should be specified](#) Created: 22/Jun/10 Updated: 20/Dec/12 Due: 19/Nov/12 Resolved: 20/Dec/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher

Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3, WP8		
Rationale:	The body interface of the sensors determines whether it is invasive or non-invasive, it probably influences the accuracy and operating time of the sensors.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	The body interface should be specified by the sensor manufacturers.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [01/Jul/10 4:13 PM]
It impacts also in WP8 (Lukas)
Comment by Franco Chiarugi [02/Jul/10 3:16 PM]
Is connected to REACTION-267 (Thomas, IMM)
Comment by Franco Chiarugi [06/Jul/10 3:07 PM]
Main impact is on WP3
Comment by Thomas Klotzbuecher [20/Feb/12 11:42 AM]
Old components relevant: Sensors
Comment by Thomas Klotzbuecher [20/Dec/12 3:40 PM]
For the IMM IR CGM sensor the body interface will be a CMA 64 IView catheter from Microdialysis AB (Sweden) for intravascular application or a CMA 60 IView catheter from the same company for subcutaneous application, both connected to the chip-based IR sensor of IMM. Alternatively for intravascular application also a catheter Microeye PME 11 from Probe Scientific (England) can be used. The body interfaces are medically approved.
For the JOA fluorescence spectroscopy sensor the body interface is a medically approved insulin cannulae made of PTFE (Polytetrafluorethylene) of 0.5-0.9 mm tubing diameter which will be applied subcutaneously under an angle of 20-45°.

[REACTION-273] [The sensor safety should follow the device directive 93/42/EEC and subsequent amending directives like the directive 2007/47/EC](#) Created: 22/Jun/10 Updated: 20/Dec/12 Due: 19/Nov/12 Resolved: 20/Dec/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Security, Sensors		
Work package:	WP3		
Rationale:	The safety directive is essential for sensors being operated on patients. The off-the-shelf sensors/devices and the consortium-designed sensors/devices must comply with the device directives in force. In addition document history files among other quality assurance documents must be available to be submitted to the local authorities when conducting clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Sensors should be designed in a way that the directive 93/42/EEC is fulfilled.		
Customer Satisfaction:	Uninterested		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Helene Udsen [28/Jun/10 11:49 AM]
Issue 273 and 281 are the same or overlap /Helene
Comment by Franco Chiarugi [01/Jul/10 4:14 PM]
is the same as N281 (Lukas)
Comment by Franco Chiarugi [02/Jul/10 3:15 PM]
is the same as REACTION-281 (Thomas, IMM)
Comment by Franco Chiarugi [05/Jul/10 12:00 PM]
Impact only on WP3. The off-the-shelf sensors/devices and the consortium-designed sensors/devices must comply with the device directives in force.
Comment by Franco Chiarugi [28/Jul/10 10:16 AM]

Changed the rationale in order to address Lukas's comments
Comment by Thomas Klotzbuecher [20/Feb/12 11:27 AM]
Old components relevant: Sensors, Security
Comment by Thomas Klotzbuecher [20/Dec/12 4:26 PM]
For the sensor application within REACTION only medically approved body interfaces are applied (see also REACTION-272). In case of the IMM IR CGM sensor a risk analysis has been performed, following the MDD 93/42/EEC (RiskAnalysis_v2.docx), indicating that only minor risks exist when connecting the sensor with the medically approved catheters. In case of the fluorescence spectroscopy based sensor similar risk analysis has been performed, followed by a biocompatibility testing.

[REACTION-274] [The cost of the sensor should be specified](#) Created: 22/Jun/10 Updated: 20/Feb/13 Due: 07/Jan/13 Resolved: 20/Feb/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Sensors		
Work package:	WP3		
Rationale:	The cost of the sensor determines its later potential for a certain application (outpatient or inpatient use) and is influenced by its production effort.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	The cost of the sensor should be specified by the sensor manufacturers and be as low as possible. The cost of the sensor should be specified and the cost should not exceed tbd EUR for inpatient application, tbd EUR for primary care, tbd EUR for AGC.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [02/Jul/10 3:15 PM]
Costs are difficult to estimate unless not a real supplier is known. E.g. if IMM produces the sensors they might be much more expensive (Thomas, IMM)
Comment by Franco Chiarugi [05/Aug/11 11:46 AM]
Costs are under evaluation and should be definitely estimated at latest during the PB meeting in September 2011
Comment by Thomas Klotzbuecher [20/Feb/12 11:15 AM]
Old components relevant: Sensors
Comment by Thomas Klotzbuecher [20/Feb/13 10:11 AM]
The cost of the CGM sensors are difficult to specify at the current status, since during the development phase the cost per sensor unit are much higher compared to a later production phase. However, rough estimations are given for both sensor types (fluorescence and IR spectroscopy) with the assumption that about 1 Mio. pieces per year are manufactured: a) Fluorescence spectroscopy based sensor: 100 EUR for the reader device + 20 EUR for the sensor unit (functionalised catheter), sensor unit has to be replaced for each patient b) IR spectroscopy based sensor with microdialysis: 100 EUR for the sensor device + 10 EUR for the chip + 20 EUR for the microdialysis catheter, chip and catheter have to be replaced for each patient

[REACTION-275] [Clinical trials, formal application](#) Created: 22/Jun/10 Updated: 11/Mar/13 Due: 30/Nov/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Documentation		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Risk assessment		
Work package:	WP8		
Rationale:	A formal application is required for clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Formal application must be made before clinical trials.		

Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

[REACTION-276] [Clinical trials, patient's information sheet including informed consent](#) Created: 22/Jun/10 Updated: 11/Mar/13 Due: 30/Nov/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Documentation		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Risk assessment		
Work package:	WP8		
Rationale:	Patient's information sheet including informed consent is needed for clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Patient's information sheet including informed consent must be given before clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-277] [Clinical trials study protocol](#) Created: 22/Jun/10 Updated: 11/Mar/13 Due: 30/Nov/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Documentation		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Risk assessment		
Work package:	WP8		
Rationale:	A study protocol must be written during clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Study protocol must be available after clinical trials. The protocol should fulfil EN ISO 14155-1 and EN ISO 14155-2		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-278] [Clinical trials case report form](#) Created: 22/Jun/10 Updated: 11/Mar/13 Due: 30/Nov/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Documentation		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Risk assessment		
Work package:	WP8		
Rationale:	For clinical trials a case report form has to be generated.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Case report form was generated for clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer	High Unhappiness		

Dissatisfaction:	
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[REACTION-279] [Clinical trials investigators brochure](#) Created: 22/Jun/10 Updated: 11/Mar/13 Due: 30/Nov/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Risk assessment		
Work package:	WP3, WP8		
Rationale:	It is important to create an investigators brochure (sensor development) for clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Investigators brochure present for clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:16 PM]

It impacts also in WP3 (Lukas)

Comment by [Franco Chiarugi](#) [05/Jul/10 12:07 PM]

Main impact on WP8

[REACTION-280] [Device manual for clinical trials](#) Created: 22/Jun/10 Updated: 21/Dec/12 Due: 19/Nov/12 Resolved: 21/Dec/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Sensors		
Work package:	WP3, WP8		
Rationale:	For clinical trials a sensor device manual must be available.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Manual available for clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:16 PM]

It impacts also in WP3 (Lukas)

Comment by [Franco Chiarugi](#) [05/Jul/10 12:04 PM]

Main impact is on WP3.

Comment by [Thomas Klotzbuecher](#) [20/Feb/12 11:11 AM]

Old components to be addressed to this requirement: Sensors

Comment by [Thomas Klotzbuecher](#) [21/Dec/12 9:04 AM]

Device manual has been generated for clinical trials at MUG, see document "Betriebsanleitung_IR_CGM_Sensor_v6.doc".

[REACTION-281] [Clinical trials CE- certification OR certification that the medical device fulfils the MDD 93/42/EEC and subsequent amending directives like the directive 2007/47/EC](#) Created: 22/Jun/10 Updated: 14/Jan/13 Due: 01/Sep/13

Status:	In Progress		
Project:	REACTION requirements		

Component/s:	Medical & environmental devices		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Sensors		
Work package:	WP8		
Rationale:	For clinical trials applied sensors, devices or software (as medical device) must fulfil the medical device directive (MDD). The clinical sites have to check the requirements (also on sensors/devices/software which will be used) for starting the clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Sensors/devices/software (as medical device) applied in clinical trials fulfil the MDD.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Franco Chiarugi](#) [01/Jul/10 4:16 PM]

It impacts also in WP3 (Lukas)

Comment by [Franco Chiarugi](#) [02/Jul/10 3:13 PM]

Is the same as [REACTION-273](#) (Thomas, IMM)

Comment by [Franco Chiarugi](#) [05/Jul/10 11:58 AM]

Main impact is on WP8. The clinical sites have to check the requirements for starting the clinical trials.

[REACTION-282] [Insurance for clinical trials must be made](#) Created: 22/Jun/10 Updated: 10/Jan/13 Due: 01/Sep/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Documentation		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Risk assessment		
Work package:	WP8		
Rationale:	Insurance is required for clinical trials otherwise it can not be performed.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Insurance made before clinical trials.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-283] [Qualification of the investigator for clinical trials](#) Created: 22/Jun/10 Updated: 28/Sep/12 Due: 01/Sep/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Lhoucine Ben Mohammadi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Sub-Component/s:	Risk assessment		
Work package:	WP8		
Rationale:	Qualification of investigator must be given for clinical trials.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Qualification of investigator given in advance of clinical trials.		

Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

[REACTION-284] Clinical data to be stored in the In-hospital environment Created: 05/Jul/10 Updated: 01/Nov/12 Due: 31/Mar/12 Resolved: 01/Nov/12			
Status:	Closed		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Validated	Votes:	0
Issue Links:	Depend is depended by REACTION-446 Clinical data to be stored in the Inp... Closed		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Context management, Data management		
Work package:	WP4		
Rationale:	<p>The data management shall be design in order to allow the storage of the clinical data to be registered at the patient enrolment and other clinical parameters which have to be acquired more frequently.</p> <p>The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, comorbidities, therapy scheme.</p> <p>Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, estimation of insulin sensitivity and resistance.</p> <p>The possibility of adding further parameters should be foreseen in the design.</p>		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The data management shall allow the insertion and the update of all the listed clinical parameters.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Dependencies:	REACTION-254		

Comment by Franco Chiarugi [28/Jul/10 10:49 AM]
Changed the rationale in order to address Lukas's comments
Comment by Franco Chiarugi [20/Jul/11 11:52 AM]
The data model of the in-hospital prototype has been completed. Some parameters have not been considered relevant and will not be part of the implementation.

[REACTION-285] User interface for the clinical data stored in the In-hospital environment Created: 05/Jul/10 Updated: 01/Nov/12 Due: 31/May/12 Resolved: 09/Mar/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Web user interface		
Work package:	WP10		
Rationale:	<p>The user interface shall allow the insertion, modification and visualization of the clinical data registered at the patient enrolment and of the clinical data acquired more frequently.</p> <p>The main data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight, therapy scheme, estimation of insulin resistance.</p> <p>Other parameters have to be acquired more frequently: glucose level, injected insulin, food intake/nutrition, hypoglycaemia and hyperglycaemia.</p> <p>The possibility of adding further parameters at the enrolment or during daily acquisitions should be foreseen in the design.</p>		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	There shall be a user interface which allows the insertion and the update of all the listed parameters.		

Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness
Dependencies:	REACTION-254

Comment by [Franco Chiarugi](#) [28/Jul/10 10:50 AM]

Changed the rationale in order to address Lukas's comments

Comment by [Franco Chiarugi](#) [20/Jul/11 11:48 AM]

All parts have been implemented but task manager and insulin administration. Interface is not Web based but Android application based (according to the detailed specification of the in-hospital prototype)

[REACTION-321] [Risk analysis](#) Created: 06/Jun/11 Updated: 11/Mar/13 Due: 30/Nov/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Operational		
Sub-Component/s:	Glucose control algorithm		
Work package:	WP6, WP8		
Rationale:	Risk Analysis has to be started in the very early stage of the development. The identified risks have to be identified and assessed.		
Source/Originator:	Lessons learned Y1		
Fit Criterion:	All risks must be in an acceptable range according to the assessment criteria.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [24/Aug/11 2:23 PM]

Main impact is on WP8

[REACTION-323] [Providing a complete audit trail for each user's data and action taken on the system](#)

Created: 15/Aug/11 Updated: 18/Dec/12 Due: 04/Feb/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Malcolm Clarke
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Data management		
Work package:	WP7		
Rationale:	There must be a complete audit trail of all actions taken in the system by any user. No user shall have the permission to permanently delete data from the system. This refers to the system logging and all actions taken by different users. The system shall also provide traceability of each action to the user taken those actions.		
Source/Originator:	Chorleywood Health Centre workshop.		
Fit Criterion:	The system shall foresee the possibility of traceability for each action which has been taken in the system by the user.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Jira Administrator](#) [18/Apr/12 2:01 PM]

Tentatively changed from WP2 to WP7

Comment by [Franco Chiarugi](#) [30/Apr/12 2:51 PM]

Fully implemented for the in-hospital
Comment by Malcolm Clarke [06/Nov/12 11:46 AM]
Needs detailed requirements to be defined for each aspect. Eg what is exact definition of access (view, search) and what level of logging of access.
Comment by Malcolm Clarke [18/Dec/12 6:38 PM]
Still acquiring requirements

[REACTION-325] The possibility to manage user accounts by user name and password and secure log in and log out Created: 15/Aug/11 Updated: 06/Nov/12 Resolved: 23/Oct/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Chorleywood Health Centre
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Data management, Security, Web user interface		
Work package:	WP8		
Rationale:	Administrator of the system shall have full ability to reset user name and password of users, Add , Delete and Edit user accounts. The users shall be added to the system by their name and their role (user type) and also the ability to suspend and reactivate the user's account.		
Source/Originator:	CHC workshop		
Fit Criterion:	The system shall differ between active and suspended user accounts. Active users shall be displayed both with colour indicator and as a list function.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Jira Administrator [18/Apr/12 1:55 PM]
Changed to WP8 because it is assigned to CHC. This could be wrong, but it is surely not WP2. The Fit Criterion only covers a fraction of the Rationale
Comment by Franco Chiarugi [30/Apr/12 2:52 PM]
Not implemented
Comment by Chorleywood Health Centre [23/Oct/12 2:03 PM]
The clinician can manage user accounts. and mark patients as active or non active

[REACTION-326] The registration of the enrolled patient on to the system shall be accured manually by the Care giver at the Primary Care Created: 15/Aug/11 Updated: 23/Oct/12 Due: 01/Oct/12 Resolved: 23/Oct/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Vivek Verma
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Web user interface		
Work package:	WP10		
Rationale:	The clinician shall be able to monitor the patient's input data .The patient's account will be managed by the patient's care giver. In addition the clinician shall have the ability to add, delete, edit, search a patient by a list of patients. This list shall be sorted by ; Active , Non active, Last name or Disease Category		
Source/Originator:	CHC, ID2-6-2		
Fit Criterion:	NON		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Jira Administrator [03/Nov/11 4:00 PM]
This requirement appears to be inconsistent and incomplete. The meaning of the Summary is unclear to me and appears not to match

the Rationale. And why no Fit Criterion?
Comment by Jira Administrator [18/Apr/12 1:46 PM]
a) I am not sure what is intended with this requirement b) there is no Fit Criterion c) I am however sure there is no way this can be WP2. Please update
Comment by Franco Chiarugi [30/Apr/12 3:02 PM]
Partially implemented
Comment by Chorleywood Health Centre [23/Oct/12 1:44 PM]
Implemented in Clinical Portal

[REACTION-330] Patient access to a library of diseases with questionnaires which help the patient to better manage his lifestyle and disease Created: 16/Aug/11 Updated: 04/Dec/12 Due: 31/Mar/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Chorleywood Health Centre
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Context management, Portable user interface, Web user interface		
Work package:	WP8		
Rationale:	An educational library with helpful content about patient's lifestyle shall be created. This library shall contain information about diet, activity, medication and advice to the patient in response to patient's lifestyle, etc.		
Source/Originator:	CHC workshop		
Fit Criterion:	It should be evaluated by focus group and the test plan.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [30/Apr/12 3:04 PM]
Partially implemented
Comment by Franco Chiarugi [04/Dec/12 1:15 PM]
We think this requirement has been implemented in v1.2 of the patient portal with the material sent by CHC to FORTH and inserted in the patient portal.

[REACTION-331] The patient portal's screen shall be easy to read and use Created: 16/Aug/11 Updated: 04/Dec/12 Due: 30/Jun/13 Resolved: 04/Dec/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Portable devices		
Work package:	WP8		
Rationale:	The interface screen used by patients shall be easily customised, e.g., different font sizes, with clear instructions to the patient. It is recommended the use of large fonts, use of colours with strong contrast, possible use of audio messages and implementation of other commonly used accessibility options (utilization of full screen size on small as well as large screens), for the interface used by patients.		
Source/Originator:	CHC workshop		
Fit Criterion:	The user friendliness and useability of the interface shall be evaluated with a focus group and the test plan.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Franco Chiarugi [30/Apr/12 3:06 PM]
Partially implemented (very advanced stage)

Comment by [Chorleywood Health Centre](#) [23/Oct/12 1:15 PM]

is a patient portal issue

[REACTION-334] [Devices should be able to operate anywhere in the home](#) Created: 18/Aug/11 Updated: 01/Nov/12 Due: 01/Nov/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Malcolm Clarke	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Architecture, PAN/BAN, Sensors		
Work package:	WP4		
Rationale:	To make a system that is ubiquitous and fits patient lifestyle		
Source/Originator:	Malcolm Clarke		
Fit Criterion:	Device specification		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [21/Oct/11 5:22 PM]

Waiting for the finalization of the detailed specifications for primary care.

Comment by [Franco Chiarugi](#) [30/Apr/12 3:07 PM]

Partially implemented

Comment by [Stefan Asanin](#) [24/Sep/12 3:25 PM]

Implemented. Different communication protocols provide different range.

[REACTION-336] [HIS interfaces for patient demographic data - Patient enrolment \(or recruitment\)](#) Created: 23/Jul/10 Updated: 12/Mar/13 Due: 25/Oct/12 Resolved: 12/Mar/13

Status:	Resolved																						
Project:	REACTION requirements																						
Component/s:	Third-party system interfaces																						
Affects Version/s:	Basic In-hospital prototype																						
Type:	Volere Requirement	Priority:	Major																				
Reporter:	Franco Chiarugi	Assignee:	Stephan Spat																				
Resolution:	Validated	Votes:	0																				
Issue Links:	<table border="0"> <tr> <td colspan="4">Depend</td> </tr> <tr> <td>depends</td> <td>REACTION-258</td> <td>Automated transfer of patient related...</td> <td>Resolved</td> </tr> <tr> <td>depends</td> <td>REACTION-152</td> <td>Patient recruitment (or enrolment)</td> <td>Closed</td> </tr> <tr> <td colspan="4">Incorporate</td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-363</td> <td>Interface to Hospital Information Sys...</td> <td>Resolved</td> </tr> </table>			Depend				depends	REACTION-258	Automated transfer of patient related...	Resolved	depends	REACTION-152	Patient recruitment (or enrolment)	Closed	Incorporate				is incorporated by	REACTION-363	Interface to Hospital Information Sys...	Resolved
Depend																							
depends	REACTION-258	Automated transfer of patient related...	Resolved																				
depends	REACTION-152	Patient recruitment (or enrolment)	Closed																				
Incorporate																							
is incorporated by	REACTION-363	Interface to Hospital Information Sys...	Resolved																				
Requirement Type:	Functional - REACTION platform																						
Sub-Component/s:	Architecture, Backend middleware, Interface with HIS/EPR																						
Work package:	WP4																						
Rationale:	When an interoperable HIS or EPR is present in the managing organization, the patient data at the patient enrolment should be obtained from the HIS or EPR through interoperable user interfaces.																						
Source/Originator:	DoW and workshops																						
Fit Criterion:	When an interoperable HIS/EPR is present, a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created, his/her data have to be taken from the HIS/EPR.																						
Customer Satisfaction:	Extremely Pleased																						
Customer Dissatisfaction:	Neutral Unhappiness																						

Comment by [Franco Chiarugi](#) [30/Nov/11 1:51 PM]

Work is under development for the in-hospital prototype, while detailed requirements has not been delivered yet for the primary care

[REACTION-337] Health status model Created: 23/Jul/10 Updated: 19/Apr/13 Due: 30/May/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Backend middleware, Glucose control algorithm		
Work package:	WP6		
Rationale:	The health status model serves as a generic prototype for Personal Health Status Profiles, i.e. defines its data content. This helps to define personal models (profiles), which permit the personalised disease management.		
Source/Originator:	2nd Technical meeting		
Fit Criterion:	A health status model is present.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Stephan Spat [13/Aug/10 9:53 AM]
main requirement subtype: data representation (semantics)
Comment by Tamas Toth [16/Aug/10 8:43 AM]
In my opinion it is not a full duplicate of #45, although they are closely related. This issue (the "model") is intended to be the general "prototype" which describes e.g. what data is needed in the health status profile. Issue #45 (the "personal profile") is the "instance" of this model, i.e. filled with actual data of a certain patient. If you think this distinction is not needed at this level, this issue may be deleted.
Comment by Stephan Spat [16/Aug/10 8:51 AM]
You are right. Duplicate-link deleted.
Comment by Franco Chiarugi [30/Apr/12 3:07 PM]
Partially implemented
Comment by Peter Beck [09/Oct/12 9:52 AM]
I assign this to you, that's related to the the personal health status profile in REACTION-392
Comment by Jira Administrator [06/Nov/12 2:14 PM]
To be reviewed after the Stockholm Integration meeting

[REACTION-338] All data entered must be checked for format, consistency and validity Created: 22/Jul/10 Updated: 04/Dec/12 Due: 30/Jun/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend		
	depends	REACTION-44	Protection against unintended user ac... In Progress
Requirement Type:	Non-functional - Security		
Sub-Component/s:	Architecture, Backend middleware, Portable user interface, Security, Web user interface		
Work package:	WP4		
Rationale:	Unintended user actions should not harm data integrity and the overall functioning of the platform. In case of doubt, the user must be warned and asked how to proceed. The user must be able to correct mistakes easily.		
Source/Originator:	DoW		
Fit Criterion:	The functional test should include specific tests in order to verify such circumstances.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Franco Chiarugi [24/Oct/11 10:25 AM]

The work is already in progress for the in-hospital prototype. Similar approach should be followed in the design of the front-end (and UI) for the primary care.

Comment by [Franco Chiarugi](#) [21/Feb/12 3:43 PM]

Data format has to be checked at any point where the data input may happen, including the health professional portal

Comment by [Franco Chiarugi](#) [04/Dec/12 1:18 PM]

Implemented in the patient portal 1.17

[REACTION-339] [Communication between the Reaction Device Hosting Server and the patient's/GP's web browser MUST be authentic \(entity authentication\), with integrity, and confidential.](#) Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 25/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>is depended by REACTION-168 Remote Patient Monitoring (RPM) Resolved</p> <p>Incorporate</p> <p>incorporates REACTION-93 Confidentiality: Sensitive informatio... In Progress</p> <p>incorporates REACTION-90 Identifiability: Recipients and sende... Resolved</p>		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	It must be assumed that data transmission from the Reaction Device Hosting Server to the patient's/GP's web browser and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.		
Source/Originator:	FHG SIT		
Fit Criterion:	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [21/Jul/10 12:41 PM]

Note that this covers the communication channel but not necessarily the data transmitted over this channel.

Comment by [Matthias Enzmann](#) [25/Sep/12 10:22 AM]

Patients and health professionals (clients) in primary care are authenticating to the system using passwords and the server authenticates to clients using a digital certificate. Integrity and confidentiality are provided by the underlying TLS/SSL protocol run between client and server.

[REACTION-340] [Storage of insulin administration](#) Created: 23/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>depends REACTION-187 Storage of administered insulin Closed</p>		
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Portable user interface, Backend middleware, Data management, Ontology/Terminology, Architecture		
Work package:	WP4		
Rationale:	Insulin administrated to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).		
Source/Originator:	DoW and workshops		
Fit Criterion:	Specific fields have to be foreseen in data management, ontologies and user interfaces (also portable).		

Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by [Matts Ahlsen](#) [15/Aug/11 2:56 PM]

Possible duplicate.

Comment by [Stefan Asanin](#) [24/Sep/12 3:02 PM]

Implemented in in-hospital prototype. Not valid for out-patient scenario as it presupposes that it is always subcutaneous (i.e. closed loop).

[REACTION-341] [Roles MUST be defined for stakeholders of the Reaction platform, e.g., doctor, nurse, patient, informal carer, administrative personnel etc.](#) Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend depends REACTION-100 Access control: Access to sensitive i... Resolved		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Each person in the Reaction platform has the right to perform a certain set of actions. In order to simplify the administration of these rights, each person is assigned to a role and roles are assigned to permissible actions. The advantage of this approach is that it is easier to manage the rights of a role than managing individual rights for each person.		
Source/Originator:	FHG SIT		
Fit Criterion:	Roles are defined for every actor from the Reaction use cases.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [10/Apr/12 2:04 PM]

Implemented for the in-hospital prototype

Comment by [Matthias Enzmann](#) [21/Sep/12 2:09 PM]

Roles definitions can be found in, e.g., D7.4.

[REACTION-342] [Low-level data fusion](#) Created: 29/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Backend middleware, Context management, PAN/BAN		
Work package:	WP4		
Rationale:	The REACTION platform should support low-level data fusion in order to interpret measurements occurring in PAN. The Data Fusion needs to take place close to the patient/user.		
Source/Originator:	Prototype architecture, E-Mail discussion between Peter R. and Stephan S. (2010-07-14) and Stephan S. and Stefan A. (2010-07-15)		
Fit Criterion:	Low-level data fusion will be available for the REACTION platform (middleware).		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 10:14 AM]

main requirement subtype: data representation (semantics)

Comment by [Matts Ahlsen](#) [15/Aug/11 4:14 PM]

More specific model in progress 15th Aug 2011.

[REACTION-343] [Every person represented in the Reaction platform MUST be assigned to one or more roles.](#) Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 25/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-100	Access control: Access to sensitive i... Resolved
	is depended by	REACTION-197	Care spaces in the primary care envir... Closed
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	In order to interact with the Reaction platform, persons need certain rights. As rights are associated with roles, persons MUST have at least one role to interact with the Reaction platform.		
Source/Originator:	FHG SIT		
Fit Criterion:	Each person is assigned to at least one role.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [10/Apr/12 2:03 PM]

This requirement has been implemented for the in-hospital prototype.

Comment by [Matthias Enzmann](#) [25/Sep/12 10:01 AM]

Roles can be assigned to identities in the GMS database, permissions for roles are set in the access control policy - persons without a role, but with an identity, are at most given access to non-critical data, if any. However, this is only the default and can be changed at any time in the policy.

[REACTION-344] [Display of acquired measurements \(values, time, context \(if available\)\)](#) Created: 23/Jul/10 Updated: 04/Oct/12 Due: 31/Oct/12 Resolved: 04/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Look and feel		
Sub-Component/s:	Context management, Data management, Portable user interface		
Work package:	WP4		
Rationale:	Provide immediate and consistent (if possible also contextualized) information to the patient.		
Source/Originator:	FORTH-ICS & FORTHNET internal focus group		
Fit Criterion:	The user interface on the mobile device shall have this functionality.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 10:10 AM]

main requirement subtype: data representation (semantics)

Comment by [Franco Chiarugi](#) [24/Oct/11 10:27 AM]

Already implemented for the in-hospital prototype (for the manual mode). Similar approach (if required in the detailed specs) should be followed for the primary care prototype.

[REACTION-345] [Two-way communication between REACTION server and client](#) Created: 29/Jul/10 Updated: 01/Nov/12 Due: 01/Nov/12 Resolved: 01/Nov/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Interface with HIS/EPR		
Work package:	WP4		
Rationale:	<p>There is a need for two-way communication between server and client e.g.for remote configuration of the end-user application running in the AHD. The data fusion engine also needs to be configured based on which values the clinician wants to observe. There is also a need for 2-way communication from the point of view of error handling. If the observed values suddenly appear out-of-range it might be necessary to check with the client if this is an error state. Other devices/sensors, e.g.the Continua-devices, might also require different types of communication.</p> <p>It might be necessary to reverse a patient's consent that had to be given 'remotely', e.g. at the doctor's surgery, because the hosting client at the patient's home is simply a 'box' with no display or input capabilities. In this restricted 'boxed case', it would be hard to change the patient's privacy settings, once they are initially configured, if we were unable to push data back to the box.</p>		
Source/Originator:	E-mail Discussion Matthias Enzmann and Peter Rosengreen (2010-07-23) and Stefan A. and Matthias E. (2010-07-22).		
Fit Criterion:	Two way communication between Client and Server will be available for the REACTION platform in order to perform: e.g. data fusion configuration, error-handling, data security (consent management).		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-346] [Knowledge Discovery from unstructured clinical text information](#) Created: 23/Jul/10 Updated: 19/Apr/13 Due: 30/May/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Third-party system interfaces		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Issue Links:	<p>Depend</p> <p>is depended by REACTION-84 Interface to patients health history ... In Progress</p> <p>Incorporate</p> <p>incorporates REACTION-153 Symptoms of diabetes or hyperglycaemia In Progress</p> <p>incorporates REACTION-74 Formalization of pre-existing clinica... Part of specification</p>		
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Interface with HIS/EPR		
Work package:	WP4, WP6		
Rationale:	EPRs often contain unstructured text information. In order to use this information for decision support or diabetes management the information has be pre-processed. NLP-technologies to find relevant information for REACTION applications from these data bases (annotation of text information: anamnesis information, co-morbidities, medical history, ...) can be a useful tool.		
Source/Originator:	Stephan Spat		
Fit Criterion:	REACTION provides a knowledge discovery module to process unstructured information and store this information in the data storage for further processing.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Stephan Spat](#) [23/Jul/10 11:42 AM]

Main impact is on WP6.

Comment by [Stephan Spat](#) [13/Aug/10 9:55 AM]

main requirement subtype: data representation (semantics)

Comment by [Tamas Toth](#) [23/May/12 12:01 PM]

It will be realized as a semantic search module, using the ontology-capsules technology.
Comment by Jira Administrator [06/Nov/12 12:39 PM]
To be reviewed after the Stockholm Integration meeting

[REACTION-347] Continuous blood glucose monitoring Created: 23/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Operational		
Sub-Component/s:	Alert & alarm subsystem, Glucose control algorithm, PAN/BAN		
Work package:	WP4		
Rationale:	Using the acquired values, the mobile device must be able to analyze the glycaemic variability and to generate alarms or alerts (hypo or hyper), based on configurable thresholds.		
Source/Originator:	FORTH-ICS & FORTHNET internal focus group		
Fit Criterion:	This functionality can be tested using the device simulator and simulated sequences of values-		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Matts Ahlsen [15/Aug/11 3:50 PM]
Title "continuous" needs to be rephrased as it might be hard to implement it.
Comment by Jira Administrator [19/Oct/11 9:04 PM]
RQ was marked Incomplete
Comment by Stefan Asanin [24/Sep/12 3:28 PM]
Data management aspects of continuous monitoring has been implemented.

[REACTION-348] High-level data fusion Created: 29/Jul/10 Updated: 13/Mar/13 Due: 28/Feb/13 Resolved: 13/Mar/13			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware		
Work package:	WP4		
Rationale:	Besides low-level data fusion on the client side a high-level data fusion should be available for the REACTION platform. The high-level data-fusion should provide the integration of external gathered information to the REACTION platform data structure and the fusion of REACTION-internal processed data.		
Source/Originator:	E-Mail discussion between Stephan S. and Peter R. (2010-07-14), prototype architecture.		
Fit Criterion:	High-level data fusion functionality will be available for the REACTION hosting server.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Stephan Spat [13/Aug/10 10:15 AM]
main requirement subtype: data representation (semantics)
Comment by Matts Ahlsen [15/Aug/11 4:14 PM]
More specific model in progress 15th Aug 2011.
Comment by Stefan Asanin [13/Mar/13 2:42 PM]
The DataFusionEngine allows fusion of both internal as external data. However, the DFE needs more parameters to be tested in larger scale although such anticipated support.

[REACTION-349] Patient questionnaires (lifestyle, physio-psychological condition, checking medication compliance, adherence to clinical pathways, education, self management) Created: 23/Jul/10 Updated: 01/Nov/12 Due: 31/Oct/12 Resolved: 04/Oct/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	PAN/BAN, Portable user interface		
Work package:	WP4		
Rationale:	Questionnaire for patients in order to collect qualitative (or quantitative but not directly measurable) information related to the parameters to be monitored has to be available. They are part of the monitoring (using a frequency set) administered by the responsible clinician.		
Source/Originator:	FORTH-ICS & FORTHNET internal focus group		
Fit Criterion:	The mobile device shall have user interfaces allowing completion of these questionnaires.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [24/Oct/11 10:31 AM]

This requirement applies only to the primary care prototype. Before taking any actions it is necessary to wait for the finalization of the detailed specs.

Comment by [Franco Chiarugi](#) [04/Oct/12 2:55 PM]

All questionnaires have been implemented in the patient portal

[REACTION-351] Telemonitoring data should be visualized to patients and professionals in a flexible and performant way Created: 18/Aug/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 16/Apr/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Stefan Asanin
Resolution:	Validated	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Context management, Data management, Portable user interface, Web user interface		
Work package:	WP4		
Rationale:	GPs and nurses as well as patients and their carers use the telemonitoring data to get an impression of the patient status. So telemonitoring data needs to be visualized in a flexible way (aggregation level, combination of parameters ...) Data has to be handled in a way that this visualization can be generated on-demand with good performance.		
Source/Originator:	Peter Beck		
Fit Criterion:	Data can be visualized flexibly and with good performance to professionals		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [19/Aug/10 11:24 AM]

main requirement subtype: data semantics

Comment by [Stefan Asanin](#) [16/Apr/12 10:55 AM]

Part of Clinical as well as Patient Applications/Portals.

[REACTION-352] Scalable / easy to use solution for REACTION software in GP surgery Created: 18/Aug/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		

Component/s:	Third-party system interfaces		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Maintainability and portability		
Sub-Component/s:	Architecture, Data management, Interface with HIS/EPR		
Work package:	WP4		
Rationale:	<p>The REACTION software which is executed in the GP surgery has to be usable for practices in different setting with different EPR systems.</p> <p>It should provide a user interface for disease management as well as Web Services which can be implemented by EPR manufacturers to easily integrate REACTION features into their products.</p>		
Source/Originator:	Peter Beck		
Fit Criterion:	REACTION software is easy to run beside an EHR application or EHR manufacturer is satisfied with ease of integration of REACTION		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		
Dependencies:	RDMM-130		

Comment by [Stefan Asanin](#) [16/Apr/12 10:55 AM]

Preferably supported by the Clinical Application.

Comment by [Stefan Asanin](#) [24/Sep/12 2:37 PM]

Implemented by External Adapter service layer which hold Web Services that in turn needs to be customized in order to be implemented by EPR manufacturers. As we have none (EPRs) at the moment this cannot be fully implemented.

[REACTION-354] [Data/messages exchanged between the Reaction Host Client and the Reaction Device Hosting Server MUST be authentic \(message authentication\), with integrity, and confidential.](#) Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved										
Project:	REACTION requirements										
Component/s:	Security and safety management										
Affects Version/s:	Basic Primary care prototype										
Type:	Volere Requirement	Priority:	Major								
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann								
Resolution:	Implemented	Votes:	0								
Issue Links:	<p>Incorporate</p> <table border="0"> <tr> <td>incorporates</td> <td>REACTION-93</td> <td>Confidentiality: Sensitive informatio...</td> <td>In Progress</td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-91</td> <td>Authenticity: Processors of informati...</td> <td>Resolved</td> </tr> </table>			incorporates	REACTION-93	Confidentiality: Sensitive informatio...	In Progress	is incorporated by	REACTION-91	Authenticity: Processors of informati...	Resolved
incorporates	REACTION-93	Confidentiality: Sensitive informatio...	In Progress								
is incorporated by	REACTION-91	Authenticity: Processors of informati...	Resolved								
Requirement Type:	Non-functional - Security										
Work package:	WP7										
Rationale:	The security of messages transferred between the Reaction Host Client and the Reaction Device Hosting Server must be ensured even _after_ the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.										
Source/Originator:	FHG SIT										
Fit Criterion:	Availability of mechanisms to provide data authenticity, integrity, and confidentiality										
Customer Satisfaction:	Extremely Pleased										
Customer Dissatisfaction:	Extreme Unhappiness										

Comment by [Matthias Enzmann](#) [21/Jul/10 12:30 PM]

Note that this covers the data/messages but not necessarily the entities involved in the communication.

Comment by [Matthias Enzmann](#) [21/Sep/12 2:22 PM]

Hydra (Smartlink) uses its own P2P protocol which uses XML Encryption and XML Digital Signatures to provided confidentiality and integrity/authenticity, respectively.

[REACTION-356] [Manual data insertion](#) Created: 23/Jul/10 Updated: 04/Oct/12 Due: 30/Apr/12 Resolved: 10/Apr/12

Status:	Resolved
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Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	PAN/BAN, Portable user interface		
Work package:	WP4		
Rationale:	In case of no connectivity with the sensor or medical device or use of a non-interoperable medical device, the mobile device should offer the possibility of manual insertion of measurement data .		
Source/Originator:	FORTH-ICS & FORTHNET internal focus group		
Fit Criterion:	Check that measurements can be inserted manually using the mobile device .		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [24/Oct/11 10:33 AM]

Already implemented for the in-hospital prototype. If required by the detailed specs (it should), a similar approach should be followed also for the primary care prototype.

[REACTION-358] [Network manager for hosting client](#) Created: 29/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Networking		
Work package:	WP4		
Rationale:	<p>TODO (Peter Rosengren) incl. security mechanism ("the Network Manager would be configured to encrypt the data")</p> <p>"The LinkSmart Network Manager has two roles, it takes care of the P2P between different nodes. It also keeps a list of LinkSmart Identifiers for different devices/services and there local endpoints. In this way it "virtualizes" devices, services, and applications behind identifiers."</p>		
Source/Originator:	Technical meeting Crete, E-Mail discussion Stephan S. and Peter R. (2010-07-14), prototype architecture, E-Mail discussion between Matthias E. and Ste[ph,f]jan and Peter R. (2010-07-20).		
Fit Criterion:	TODO (Peter Rosengren)		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-362] [Interface to patient demographic register](#) Created: 20/Jul/10 Updated: 12/Mar/13 Due: 25/Oct/12 Resolved: 12/Mar/13

Status:	Resolved																		
Project:	REACTION requirements																		
Component/s:	Third-party system interfaces																		
Affects Version/s:	Basic In-hospital prototype																		
Type:	Volere Requirement	Priority:	Major																
Reporter:	Stephan Spat	Assignee:	Stephan Spat																
Resolution:	Validated	Votes:	0																
Issue Links:	<table border="0"> <tr> <td>Depend</td> <td></td> <td></td> <td></td> </tr> <tr> <td>depends</td> <td>REACTION-258</td> <td>Automated transfer of patient related...</td> <td>Resolved</td> </tr> <tr> <td>Incorporate</td> <td></td> <td></td> <td></td> </tr> <tr> <td>incorporates</td> <td>REACTION-174</td> <td>The system must provide interfaces to...</td> <td>Resolved</td> </tr> </table>			Depend				depends	REACTION-258	Automated transfer of patient related...	Resolved	Incorporate				incorporates	REACTION-174	The system must provide interfaces to...	Resolved
Depend																			
depends	REACTION-258	Automated transfer of patient related...	Resolved																
Incorporate																			
incorporates	REACTION-174	The system must provide interfaces to...	Resolved																
Requirement Type:	Functional - In-hospital pilot application																		

Sub-Component/s:	Architecture, Data management, Interface with HIS/EPR
Work package:	WP4
Rationale:	In order to import demographic data from the patient demographic register has to be imported from the HIS. A standardized interface e.g. HL7 has to be used for data interchange. Required data fields are: - unique PID - name - age (data of birth) - sex - address
Source/Originator:	D2.5, inpatient prototype architecture
Fit Criterion:	Standardized interface (HL7) to patient demographic register is available for the In-hospital pilot application
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by [Stephan Spat](#) [12/Mar/13 6:07 PM]

Implementation finished. HL7 interface already validated in system and clinical tests.

[REACTION-363] [Interface to Hospital Information System for clinical data import/export](#) Created: 22/Jul/10 Updated: 12/Mar/13 Due: 25/Oct/12 Resolved: 12/Mar/13

Status:	Resolved																										
Project:	REACTION requirements																										
Component/s:	Third-party system interfaces																										
Affects Version/s:	Basic In-hospital prototype																										
Type:	Volere Requirement	Priority:	Major																								
Reporter:	Stephan Spat	Assignee:	Stephan Spat																								
Resolution:	Validated	Votes:	0																								
Issue Links:	<table border="0"> <tr> <td>Depend</td> <td></td> <td></td> <td></td> </tr> <tr> <td>depends</td> <td>REACTION-258</td> <td>Automated transfer of patient related...</td> <td>Resolved</td> </tr> <tr> <td>Incorporate</td> <td></td> <td></td> <td></td> </tr> <tr> <td>incorporates</td> <td>REACTION-174</td> <td>The system must provide interfaces to...</td> <td>Resolved</td> </tr> <tr> <td>incorporates</td> <td>REACTION-336</td> <td>HIS interfaces for patient demographi...</td> <td>Resolved</td> </tr> <tr> <td>incorporates</td> <td>REACTION-13</td> <td>To update EPRs with collected data</td> <td>Closed</td> </tr> </table>			Depend				depends	REACTION-258	Automated transfer of patient related...	Resolved	Incorporate				incorporates	REACTION-174	The system must provide interfaces to...	Resolved	incorporates	REACTION-336	HIS interfaces for patient demographi...	Resolved	incorporates	REACTION-13	To update EPRs with collected data	Closed
Depend																											
depends	REACTION-258	Automated transfer of patient related...	Resolved																								
Incorporate																											
incorporates	REACTION-174	The system must provide interfaces to...	Resolved																								
incorporates	REACTION-336	HIS interfaces for patient demographi...	Resolved																								
incorporates	REACTION-13	To update EPRs with collected data	Closed																								
Requirement Type:	Functional - In-hospital pilot application																										
Sub-Component/s:	Architecture, Interface with HIS/EPR																										
Work package:	WP4, WP10																										
Rationale:	In order to exchange clinical data between In-hospital pilot application and Hospital information System (HIS) an interface based on HL7 has to be provided.																										
Source/Originator:	D2.1, D2.5, prototype architecture																										
Fit Criterion:	Standardized Interface (HL7) to HIS / EPR to exchange clinical data.																										
Customer Satisfaction:	Extremely Pleased																										
Customer Dissatisfaction:	Extreme Unhappiness																										

Comment by [Stephan Spat](#) [22/Jul/10 2:15 PM]

Main impact is on WP4.

Comment by [Peter Beck](#) [02/Oct/12 12:11 PM]

There are individual requirements for
- demographich data
- laboratory data / glucose
- what other other clinical data are to be exchanged??

Comment by [Stephan Spat](#) [12/Mar/13 6:06 PM]

Finished for R1.4.1. Update will be performed for R2.0.

[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.](#) Created: 23/Jul/10 Updated: 13/Mar/13 Due: 31/Jan/13 Resolved: 13/Mar/13

Status:	Resolved
Project:	REACTION requirements

Component/s:	Internal communication		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Stelios Louloudakis	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Communication, PAN/BAN		
Work package:	WP4		
Rationale:	In the event that the hosting client is not connected through a broadband connection, the patient will be able to upload data using GPRS / 3G data networks. In this case we need to examine possible limitations.		
Source/Originator:	DoW		
Fit Criterion:	Functional test uploading data over slow mobile networks.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 10:06 AM]

main requirement subtype: Data interface

Comment by [Franco Chiarugi](#) [30/Apr/12 3:08 PM]

Partially implemented

Comment by [Stefan Asanin](#) [13/Mar/13 2:18 PM]

Implemented in the multi-protocol gateway as well as for the patient portal.

[REACTION-367] [Insertion of baseline physiological measurements at the first visit](#) Created: 26/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend depends REACTION-201 Record baseline physiological measure... Closed		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Web user interface, Data management, Glucose control algorithm		
Work package:	WP4		
Rationale:	At the first visit, baseline physiological measurements (the exact set has to be clearly defined) have to be inserted in the platform.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrollment).		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Franco Chiarugi](#) [30/Apr/12 3:08 PM]

Partially implemented

Comment by [Stefan Asanin](#) [24/Sep/12 2:25 PM]

Implemented. When clinician assigns devices it can be said that the baseline physiological measurements at the first visit are inserted.

[REACTION-371] [Use of activity patterns for context annotations](#) Created: 23/Jul/10 Updated: 13/Mar/13 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Critical

Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Context management, PAN/BAN		
Work package:	WP4		
Rationale:	Context has to be expressed synthetically in some way. A possible and common option is through activity patterns (to be specified for the two environments).		
Source/Originator:	FORTH-ICS & FORTHNET internal focus group		
Fit Criterion:	Collect measurements about physical activity, environmental data, additional information and evaluate the activity patterns verifying their correctness.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matts Ahlsen](#) [15/Aug/11 2:23 PM]

Needs further clarification on why just two environments and not a general one.

Comment by [Stefan Asanin](#) [18/Sep/12 11:06 AM]

Work initiated by ALL's structure of semantic lexicon and the implementation of the module for querying the semantic lexicon is also started.

Comment by [Stefan Asanin](#) [13/Mar/13 2:44 PM]

Needs more input from ALL algorithms and software. The Reaction database already has simple tables for this so using these or extending them to include new parameter requirements should be ok.

[REACTION-372] [Context of observations](#) Created: 29/Jul/10 Updated: 23/Jan/13 Due: 31/Dec/12 Resolved: 23/Jan/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Context management		
Work package:	WP4		
Rationale:	The middleware of the REACTION platform should support context management for observed values.		
Source/Originator:	Technical Meeting in Crete, Presentation of Peter Rosengren, E-mail discussion between Stephan S. and Peter R.		
Fit Criterion:	The REACTION platform supports context management on the client side.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 10:14 AM]

main requirement type: data representation (semantics)

Comment by [Stefan Asanin](#) [24/Sep/12 2:21 PM]

Initial work done with IEEE specializations as foundation for observed values.

Comment by [Stefan Asanin](#) [23/Jan/13 4:28 PM]

As observation context is not seen to be any deepened this requirement is seen as implemented by IEEE specializations and representation.

[REACTION-374] [Annual clinical checks](#) Created: 23/Jul/10 Updated: 13/Mar/13 Due: 29/Mar/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0

Issue Links:	Depend depends REACTION-157 Annual clinical checks Closed
Requirement Type:	Functional - Primary care pilot application
Sub-Component/s:	Backend middleware, Glucose control algorithm, Web user interface
Work package:	WP4
Rationale:	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).
Source/Originator:	D2.1 (pag. 44) and workshops
Fit Criterion:	Specific fields have to be present in ontologies and data management.
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by Stephan Spat [13/Aug/10 9:57 AM]
main requirement subtype: Data structure
Comment by Franco Chiarugi [30/Apr/12 3:08 PM]
Not implemented
Comment by Stefan Asanin [24/Sep/12 3:11 PM]
Partially implemented by the Service Orchestrator. It just needs to be configured for this purpose.
Comment by Stefan Asanin [24/Sep/12 3:13 PM]
Partially implemented by the Service Orchestrator. It just needs to be configured for this purpose.
Comment by Stefan Asanin [11/Oct/12 3:38 PM]
See REACTION-444

[REACTION-375] Therapy scheme in In-hospital environment Created: 26/Jul/10 Updated: 01/Nov/12 Due: 31/Aug/12 Resolved: 12/Mar/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends REACTION-229	Decision on therapy in In-hospital en...	Resolved
	depends REACTION-235	Therapy scheme in In-hospital environ...	Closed
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Portable user interface		
Work package:	WP4		
Rationale:	Decision on therapy has to be performed immediately after performing any measurements based also on patient history and associated parameters. It might imply changes in the therapy scheme.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The pharmaceutical and non-pharmaceutical treatment (or therapy scheme) has to be stored in the data management and can be modified during any clinical evaluation of the patient. It has to be initialized immediately after the patient enrolment.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matts Ahlsen [15/Aug/11 3:57 PM]
GlucoMan Sys.

[REACTION-376] Integrity check for the stored data Created: 22/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12	
Status:	Resolved
Project:	REACTION requirements
Component/s:	Security and safety management

Affects Version/s:	REACTION Platform														
Type:	Volere Requirement	Priority:	Critical												
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin												
Resolution:	Implemented	Votes:	0												
Issue Links:	<table border="0"> <tr> <td>Depend</td> <td></td> <td></td> <td></td> </tr> <tr> <td>depends</td> <td>REACTION-43</td> <td>Protection against data loss System m...</td> <td>Resolved</td> </tr> <tr> <td>depends</td> <td>REACTION-39</td> <td>Platform Integrity (integrity checks ...</td> <td>Closed</td> </tr> </table>			Depend				depends	REACTION-43	Protection against data loss System m...	Resolved	depends	REACTION-39	Platform Integrity (integrity checks ...	Closed
Depend															
depends	REACTION-43	Protection against data loss System m...	Resolved												
depends	REACTION-39	Platform Integrity (integrity checks ...	Closed												
Requirement Type:	Non-functional - Security														
Sub-Component/s:	Architecture, Security														
Work package:	WP4														
Rationale:	To guarantee the integrity of the stored data in the case of an unwanted happening.														
Source/Originator:	DoW														
Fit Criterion:	Use of adequate methods like e.g. Hash keys or redundancy codes for the data stored.														
Customer Satisfaction:	Very Pleased														
Customer Dissatisfaction:	Neutral Unhappiness														

Comment by [Stephan Spat](#) [13/Aug/10 9:41 AM]

main requirement subtype: Data storage

Comment by [Stefan Asanin](#) [24/Sep/12 2:44 PM]

Already handled by MS SQL REACTION DB.

[REACTION-380] [Set of alerts and reminders](#) Created: 23/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Alert & alarm subsystem		
Work package:	WP4		
Rationale:	A set of possible alerts and reminders. These can be thought as "prototypes". Action rules can define when and how they must be sent with which parameters.		
Source/Originator:	DoW		
Fit Criterion:	Alerts and reminders can be defined and stored.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 9:47 AM]

main requirement subtype: Data storage

Comment by [Stefan Asanin](#) [24/Sep/12 2:16 PM]

Partially implemented. Need to include reminders.

Comment by [Stefan Asanin](#) [24/Sep/12 3:35 PM]

Implemented in Alarms Handling GUI and Rule Engine.

[REACTION-381] [Definition of a common ontology to refer to data, metadata, interfaces and models](#) Created: 22/Jul/10 Updated: 13/Mar/13 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Minor
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0

Issue Links:	Depend depends REACTION-27 Seamless integration Closed
Requirement Type:	Functional - REACTION platform
Sub-Component/s:	Architecture, Backend middleware, Ontology/Terminology
Work package:	WP4
Rationale:	A common ontology facilitates components integration and maintain a common language among the technical people and stakeholders.
Source/Originator:	DoW & Technical meeting in London
Fit Criterion:	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
Customer Satisfaction:	Interested
Customer Dissatisfaction:	Low Unhappiness

Comment by [Matts Ahlsen](#) [15/Aug/11 4:34 PM]

"Common ontology"? REACTION might be too wide to grasp a common type.

Comment by [Jira Administrator](#) [19/Oct/11 9:07 PM]

RQ was marked Incomplete

Comment by [Stefan Asanin](#) [16/Apr/12 11:07 AM]

Preferably supported by the ALL's ontology capsules approach and/or IEEE 11073 and IHE-PCD01.

Comment by [Stefan Asanin](#) [13/Mar/13 12:28 PM]

Waiting for ALL approach. Otherwise, the requirement will be implemented by what exists, i.e. IEEE11073.

[REACTION-382] [Privacy enhancing technology](#) Created: 23/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Security		
Work package:	WP4, WP7		
Rationale:	Protect the privacy of users personally identifiable information (PII) and further more personal data.		
Source/Originator:	FORTH-ICS & FORTHNET internal focus group		
Fit Criterion:	It must not be possible for any third party to determine the relation between a measurement and the measured patient's real world identity.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Matthias Enzmann](#) [10/Apr/12 4:40 PM]

Streamlined fit criterion.

Comment by [Matthias Enzmann](#) [10/Apr/12 4:41 PM]

Applies only to the primary care scenario.

In this scenario, the patient is pseudonymised through the measurement device's serial number, i.e., instead of directly identifying the patient by name, the serial number is used as an identifier which is resolved through a database entry at the GP's network.

Comment by [Franco Chiarugi](#) [13/Jun/12 5:13 PM]

Main impact in WP7

Comment by [Matthias Enzmann](#) [21/Sep/12 2:28 PM]

The patient is pseudonymised through the measurement device's serial number, i.e., instead of directly identifying the patient by name, the serial number is used as an identifier which is resolved through a database entry at the GP's network. In addition, the data in transit is encrypted using XML Encryption (see Hydra's P2P protocol).

[REACTION-383] [Self-management and lifestyle support](#) Created: 23/Jul/10 Updated: 01/Nov/12 Due: 30/Jun/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		

Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Context management, Data management, Portable user interface, Web user interface		
Work package:	WP4		
Rationale:	Support of the patients' self-management by lifestyle (diet, exercise etc.) advices, therapy advices, health status assessment.		
Source/Originator:	DoW		
Fit Criterion:	Self-management is supported.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Stephan Spat [29/Jul/10 11:52 AM]
I would suggest moving the requirement to WP4.
Comment by Franco Chiarugi [29/Jul/10 12:21 PM]
OK
Comment by Stephan Spat [13/Aug/10 10:10 AM]
main requirement subtype: other
Comment by Franco Chiarugi [24/Oct/11 10:35 AM]
Waiting for the finalization of the primary care detailed specs.
Comment by Franco Chiarugi [30/Apr/12 3:10 PM]
Partially implemented
Comment by Franco Chiarugi [04/Oct/12 2:58 PM]
Almost implemented, except the health status assessment, which should be a results of the risk assessment subsystem.

[REACTION-385] Digital identities for the Reaction platform MUST only be issued or revoked by trusted (third) parties, e.g., a certification authority (CA). Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>depends REACTION-103 Data reduction and data economy: Pers... Resolved</p> <p>is depended by REACTION-90 Identifiability: Recipients and sende... Resolved</p> <p>is depended by REACTION-95 Accountability: Stakeholders should b... Resolved</p> <p>is depended by REACTION-152 Patient recruitment (or enrolment) Closed</p> <p>is depended by REACTION-259 Automated patient identification Closed</p> <p>Incorporate</p> <p>incorporates REACTION-104 Need-to-know Basis: Stakeholders proc... Resolved</p> <p>incorporates REACTION-196 End of process for the diabetic patie... Closed</p>		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Without a trusted party (TP), anyone could produce its own digital identity and someone relying on such an identity would have to trust that the claimed identity is genuine. By incorporating a TP, relying parties trust that the TP ensures that its issued digital identities are genuine. This makes life easier for relying parties as they only have to establish a single trust relationship (with the TP) as opposed to having a multitude of trust relationships with others. The same goes for parties that had been excluded from the Reaction platform, as each relying party would have to determine by itself if another party is still part of the Reaction platform or not. In case of a trusted party, the relying part could simply query the TP if some identity is still valid or had been revoked, e.g., because its owner left the platform.		
Source/Originator:	FHG SIT		
Fit Criterion:	Availability of a party which is trusted to orderly issue and revoke digital identities.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-387] [Information related to informed consent stored in the platform](#) Created: 23/Jul/10 Updated: 13/Mar/13 Due: 31/May/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend		
	depends	REACTION-198	Information related to informed conse... Closed
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Data management, Security, Web user interface		
Work package:	WP4		
Rationale:	An ethical approved declaration of informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION platform.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the signed paper This procedure shall be completed before any other operation can be performed.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matts Ahlsen](#) [15/Aug/11 2:20 PM]

Scan, convert to pdf and upload to patient medical biography in REACTION.

Comment by [Jira Administrator](#) [19/Oct/11 9:26 PM]

RQ was marked QC Passed

Comment by [Stefan Asanin](#) [16/Apr/12 10:49 AM]

On server side a function for storing patient related pdf files should be supported.

Comment by [Stefan Asanin](#) [24/Sep/12 3:23 PM]

Column needs to be added to the REACTION DB and table [PatientNote].

[REACTION-388] [Insulin sensitivity and insulin resistance](#) Created: 26/Jul/10 Updated: 18/Dec/12 Due: 25/Oct/12 Resolved: 18/Dec/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Peter Beck
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-233	Insulin sensitivity and insulin resis... Closed
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Web user interface		
Work package:	WP4		
Rationale:	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be directly measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.). Glucose control algorithm and physiology models should use these two parameters.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	The data management has to allow for the insertion and subsequent modifications of these values by clinicians.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-391] [Data fields for the In-hospital glucose control prototype \(eDSS\)](#). Created: 23/Jul/10

Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 02/Mar/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>depends REACTION-233 Insulin sensitivity and insulin resis... Closed</p> <p>is depended by REACTION-432 Special examinations/treatments to be... Resolved</p> <p>Incorporate</p> <p>incorporates REACTION-426 Comorbidities have to be registered In Progress</p> <p>incorporates REACTION-402 Measurements of blood glucose and ins... Resolved</p> <p>incorporates REACTION-456 Nutrition information has to be store... Resolved</p> <p>incorporates REACTION-450 Fever and infections shall be registered Closed</p>		
Requirement Type:	Constraint		
Sub-Component/s:	Context management, Data management, Glucose control algorithm		
Work package:	WP4, WP6		
Rationale:	<p>Following data fields should be provided:</p> <ul style="list-style-type: none"> - administrative data (patient name, address, PID, ward, hospital bed, physician(s) in charge, nurse(s) in charge) - demographic data (age, sex, date of birth) - medical history (type of diabetes, medication, comorbidities, former complications, pre-existing conditions) - anamnesis data (fever, infections, diarrhea, vomiting, hypo- hyperglycemia) - lab data (glucose level, HBA1c, ...) - external input (food intake, insulin sensitivity, ...) - context data (time of glucose measurement, what device, ...) 		
Source/Originator:	Stephan Spat		
Fit Criterion:	Required data fields will be provided by data structure.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Stephan Spat](#) [23/Jul/10 8:53 AM]

Main impact is on WP4.

Comment by [Stephan Spat](#) [18/Aug/10 10:36 AM]

Main requirement subtype: data source

[REACTION-392] Personal Health Status Profiles Created: 23/Jul/10 Updated: 19/Apr/13 Due: 30/May/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Issue Links:	<p>Incorporate</p> <p>incorporates REACTION-468 Provide regular update of data model ... Resolved</p>		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Backend middleware, Data management, Glucose control algorithm, Risk assessment		
Work package:	WP6		
Rationale:	Personal Health Status Profile for each patient must be generated, stored and regularly updated. It serves as an input for risk assessment and disease management.		
Source/Originator:	DoW		

Fit Criterion:	Personal Health Status Profiles can be generated.
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by Stephan Spat [13/Aug/10 9:52 AM]
main requirement subtype: Data structure
Comment by Franco Chiarugi [30/Apr/12 3:10 PM]
Partially implemented
Comment by Peter Beck [09/Oct/12 9:51 AM]
I assign this to ALL, your presentation at the project board meeting was very much about the personal health profile etc.
Comment by Jira Administrator [06/Nov/12 12:30 PM]
To be reviewed after Stockholm Integration meeting

[REACTION-395] [A REACTION application needs to be executed in the patient surgery independent from the EPR](#) Created: 18/Aug/10 Updated: 01/Nov/12 Due: 16/Apr/12 Resolved: 16/Apr/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Third-party system interfaces		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Stefan Asanin
Resolution:	Validated	Votes:	0
Requirement Type:	Constraint - End-User Workplace Environment		
Sub-Component/s:	Architecture, Interface with HIS/EPR		
Work package:	WP4		
Rationale:	<p>As it is not possible to influence/ modify many EPR systems, REACTION features inside the GP surgery have to be provided by a dedicated and independent application.</p> <p>This application communicates with</p> <ul style="list-style-type: none"> - the REACTION platform over the Internet. - other systems in the surgery (EPR, lab, etc.) <p>This application can be server-based and always on, for a prototype also an application client could be used.</p>		
Source/Originator:	Peter Beck		
Fit Criterion:	An easy to run possibility to run and access REACTION features inside the GP surgery is available.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	High Unhappiness		

Comment by Stefan Asanin [16/Apr/12 10:51 AM]
Part of the Clinical Application developed by Brunel.

[REACTION-397] [The patient shall be registered to the sytem manually and all patient monitored data will be followed.](#) Created: 15/Aug/11 Updated: 06/Nov/12 Resolved: 06/Nov/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matts Ahlsen	Assignee:	Chorleywood Health Centre
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Data management, Portable user interface, Web user interface		
Work package:	WP2		
Rationale:	The patient shall be registered by her/his care giver and having ability to send data to the caregiver due to evaluate.		
Source/Originator:	Chorlywood Primary Care,Workshop.		
Fit Criterion:	No fit Criterion identified.		
Customer Satisfaction:	Pleased		
Customer	Neutral Unhappiness		

Dissatisfaction:	
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Comment by [Franco Chiarugi](#) [30/Nov/11 1:54 PM]

Duplicate of #326

[REACTION-399] [Ongoing management](#) Created: 23/Jul/10 Updated: 19/Apr/13 Due: 30/May/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend depends REACTION-178 Ongoing management Closed		
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Data management, Ontology/Terminology, Portable user interface, Web user interface		
Work package:	WP4		
Rationale:	Ongoing management follows investigative stage. This stage is used to: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Specific fields have to be present in ontologies and data management		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [30/Apr/12 3:11 PM]

Not implemented

Comment by [Chorleywood Health Centre](#) [02/Oct/12 1:46 PM]

WP4 should provide a list of fields that are required to be in the ontologies and data management.

Comment by [Malcolm Clarke](#) [18/Oct/12 7:09 PM]

Please identify fields for ontology and for use in RISK engine

[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.](#) Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate incorporates REACTION-93 Confidentiality: Sensitive informatio... In Progress is incorporated by REACTION-91 Authenticity: Processors of informati... Resolved		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	The security of messages transferred between the Reaction Device Hosting Server and the EPR/EHR System must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.		
Source/Originator:	FHG SIT		
Fit Criterion:	Availability of mechanisms to provide data authenticity, integrity, and confidentiality		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [21/Jul/10 12:36 PM]
Note that this covers the data/messages but not necessarily the entities involved in the communication.
Comment by Matthias Enzmann [21/Sep/12 2:19 PM]
The communication between the Reaction Device Hosting Server and the GP EPR takes place in a trusted domain, i.e., within the GP's local area network. Hence, it can be assumed that authenticity, integrity, and confidentiality are given.

[REACTION-401] [Device specialization - A list of devices to be provided](#) Created: 23/Jul/10 Updated: 06/Nov/12 Due: 31/Oct/12 Resolved: 18/Oct/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Critical
Reporter:	Franco Chiarugi	Assignee:	Malcolm Clarke
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Operational		
Sub-Component/s:	Communication, Sensors		
Work package:	WP4		
Rationale:	Based on the necessary information to be monitored from the patient, a complete list of IEEE 11073 device specialization has to be completed. Measurements which cannot be collected using IEEE 11073 device specialization are also to be mentioned in this list. The complexity of the IEEE 20601 manager also depends on the number of device specializations to be managed.		
Source/Originator:	FORTH-ICS & FORTHNET internal focus group		
Fit Criterion:	For each device the supported standard has to be specified (or the company documentation).		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Malcolm Clarke [18/Oct/12 7:07 PM]
Such a list has been included in many deliverables. The list is based on the "patient journey", noting the many co-morbidities and complications that can be present. Therefore we can propose an expected list, but deploying to real patients and taking feedback from the clinicians, will identify which devices we will ultimately require. We may also add devices as opportunity to work with manufacturers arises.
We currently define: Glucose, BPM, weight, SpO2, medication dispenser, motion sensor, bed sensor, chair sensor. We have these devices available as ZigBee.
Comment by Malcolm Clarke [18/Oct/12 7:08 PM]
A full set of the devices is built and undergoing testing at Brunel

[REACTION-402] [Measurements of blood glucose and insulin injections in In-hospital environment](#) Created: 26/Jul/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 02/Mar/12

Status:	Resolved																						
Project:	REACTION requirements																						
Component/s:	Health professional sphere																						
Affects Version/s:	Basic In-hospital prototype																						
Type:	Volere Requirement	Priority:	Major																				
Reporter:	Franco Chiarugi	Assignee:	Stephan Spat																				
Resolution:	Implemented	Votes:	0																				
Issue Links:	<table border="0"> <tr> <td>Depend</td> <td></td> <td></td> <td></td> </tr> <tr> <td>depends</td> <td>REACTION-220</td> <td>Healthcare professionals perform the ...</td> <td>Resolved</td> </tr> <tr> <td>Incorporate</td> <td></td> <td></td> <td></td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-417</td> <td>Dynamic data structure for In-hospita...</td> <td>Resolved</td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-391</td> <td>Data fields for the In-hospital gluco...</td> <td>Resolved</td> </tr> </table>			Depend				depends	REACTION-220	Healthcare professionals perform the ...	Resolved	Incorporate				is incorporated by	REACTION-417	Dynamic data structure for In-hospita...	Resolved	is incorporated by	REACTION-391	Data fields for the In-hospital gluco...	Resolved
Depend																							
depends	REACTION-220	Healthcare professionals perform the ...	Resolved																				
Incorporate																							
is incorporated by	REACTION-417	Dynamic data structure for In-hospita...	Resolved																				
is incorporated by	REACTION-391	Data fields for the In-hospital gluco...	Resolved																				
Requirement Type:	Functional - In-hospital pilot application																						
Sub-Component/s:	Architecture, Portable user interface																						
Work package:	WP4																						
Rationale:	In In-hospital environment, the blood glucose level measurements are, in most cases, performed by nurses with treatment performed by clinicians and/or nurses.																						
Source/Originator:	D2.1 and workshops																						

Fit Criterion:	Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

[REACTION-403] [Each entity in the Reaction platform MUST be representable by a digital identity.](#) Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype , Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>is depended by REACTION-63 Security and privacy related to patie... Resolved</p> <p>is depended by REACTION-95 Accountability: Stakeholders should b... Resolved</p> <p>is depended by REACTION-100 Access control: Access to sensitive i... Resolved</p> <p>is depended by REACTION-259 Automated patient identification Closed</p> <p>Incorporate</p> <p>incorporates REACTION-90 Identifiability: Recipients and sende... Resolved</p>		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	In the Reaction platform, entities must be uniquely identifiable and recognisable in order to allow repeated communication, referrals, accountability of actions, exclusion of ill-behaving entities, etc.		
Source/Originator:	FHG SIT		
Fit Criterion:	Availability of a digital identity mechanism.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matthias Enzmann](#) [21/Sep/12 1:44 PM]

Users and Servers of the GMS are represented by digital certificates which are a instances of digital identities

[REACTION-404] [Service Orchestration Manager](#) Created: 29/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Backend middleware		
Work package:	WP4		
Rationale:	It should be possible to express execution of a set of services in combinations and sequences		
Source/Originator:	DoW, Technical Meeting Crete.		
Fit Criterion:	Service orchestrations can be defined and stored		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Jira Administrator](#) [19/Oct/11 6:52 PM]

This is the same as (?) RDMM-116, previous Resolution Part of Specification. But this requirement is INCOMPLETE (no Rationale, Fit Criterion) /Helene

Comment by [Stefan Asanin](#) [16/Apr/12 10:39 AM]

Initiated work
Comment by Franco Chiarugi [10/Jul/12 12:53 PM]
Updated with the title, rationale and fit criterion specified by Peter Rosengren
Comment by Stefan Asanin [24/Sep/12 2:15 PM]
Demonstrated at review.

[REACTION-408] Non-pharmacological and/or pharmacological treatment Created: 23/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends REACTION-179	Daily data review by clinicians or te...	Resolved
	depends REACTION-181	Decision on therapy in Primary care e...	Part of specification
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Data management, Ontology/Terminology, Portable user interface, Web user interface		
Work package:	WP4		
Rationale:	Non-pharmacological (diet, lifestyle, education) and pharmacological (OAD, insulin and interfering drugs) treatments have to be assigned to each patient and can be modified at each check.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	In the ontologies and data management there should be the possibility of registering the different types of treatment for each patient and of modifying them at each check.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [23/Jul/10 1:30 PM]
The links with REACTION-179 and REACTION-181 are valid for the outpatient environment but this requirement is valid also for the inpatient environment
Comment by Stephan Spat [13/Aug/10 9:59 AM]
main requirement subtype: Data structure
Comment by Stefan Asanin [24/Sep/12 3:14 PM]
Tables for these are already implemented in the REACTION DB.

[REACTION-409] Risk assessment models and rules Created: 23/Jul/10 Updated: 19/Mar/13 Due: 30/Apr/13			
Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Backend middleware, Glucose control algorithm, Risk assessment		
Work package:	WP6		
Rationale:	Models and rules must be defined to determine personal risks.		
Source/Originator:	DoW		
Fit Criterion:	Models and rules for risk assessment are present.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Stephan Spat [13/Aug/10 9:51 AM]
main requirement subtype: data representation (semantics)

Comment by Chorleywood Health Centre [08/Nov/12 11:04 AM]
I would propose that this has not been implemented as models and rules have not yet been defined above a very basic level. It could be that this is closed and a new requirement for the extended primary care version is opened?
Comment by Jira Administrator [19/Dec/12 2:27 PM]
Due date is an interim date whereby models need to be defined and checked with CHC

[REACTION-413] Connection with external services like MS HealthVault Created: 29/Jul/10 Updated: 01/Nov/12 Due: 30/Apr/12 Resolved: 16/Apr/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Third-party system interfaces		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Duplicate		
	is duplicated by	REACTION-350	Connection with other external services Closed
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Interface with HIS/EPR		
Work package:	WP4		
Rationale:	External interfaces to services of MS HealthVault should be taken into account in the REACTION platform.		
Source/Originator:	Technical Meeting in Crete, E-Mail discussion between Ste[ph,fl]an and Peter R. (2010-07-21)		
Fit Criterion:	Interfaces to MS HealthVault will be available.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-414] Communication between the Reaction Hosting Client and the Reaction Device Hosting Server MUST be authentic (entity authentication), with integrity, and confidential. Created: 20/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	is depended by	REACTION-168	Remote Patient Monitoring (RPM) Resolved
	Incorporate		
	incorporates	REACTION-93	Confidentiality: Sensitive informatio... In Progress
	incorporates	REACTION-90	Identifiability: Recipients and sende... Resolved
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	It must be assumed that data transmission from the Reaction Hosting Client to the Reaction Device Hosting Server and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.		
Source/Originator:	FHG SIT		
Fit Criterion:	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Matthias Enzmann [20/Jul/10 5:52 PM]
Note that this covers the communication channel but not necessarily the data transmitted over this channel.
Comment by Matthias Enzmann [21/Sep/12 1:49 PM]
Hydra (Smartlink) uses its own P2P protocol which uses XML Encryption and XML Digital Signatures to provided confidentiality and integrity/authenticity, respectively.

[REACTION-415] Each person MAY only perform actions permitted by her role. Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-99	Authorisation: Stakeholders must be a... Resolved
	depends	REACTION-100	Access control: Access to sensitive i... Resolved
	is depended by	REACTION-168	Remote Patient Monitoring (RPM) Resolved
	is depended by	REACTION-95	Accountability: Stakeholders should b... Resolved
	is depended by	REACTION-63	Security and privacy related to patie... Resolved
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Before a requested action is performed, a control mechanism has to check whether the requested action is part of the requester's set of permissible actions according to its role.		
Source/Originator:	FHG SIT		
Fit Criterion:	Availability of a control mechanism which decides whether a requested action may be granted or denied according to the requester's role.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-416] Patient education Created: 23/Jul/10 Updated: 23/Oct/12 Due: 31/Mar/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Chorleywood Health Centre
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Data management		
Work package:	WP8		
Rationale:	Continuous education of the patient adjusted to his/her needs.		
Source/Originator:	DoW		
Fit Criterion:	Educational material is available.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by Stephan Spat [29/Jul/10 11:54 AM]
I would suggest to move the requirement to WP8.
Comment by Stephan Spat [13/Aug/10 10:10 AM]
main requirement subtype: Data source
Comment by Franco Chiarugi [30/Apr/12 3:12 PM]
Partially implemented
Comment by Chorleywood Health Centre [23/Oct/12 1:50 PM]
Is part of the extended primary care requirements

[REACTION-419] Set of event rules Created: 23/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12	
Status:	Resolved
Project:	REACTION requirements
Component/s:	Service orchestration

Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Alert & alarm subsystem, Backend middleware, Glucose control algorithm, Risk assessment		
Work package:	WP4		
Rationale:	Event rules define the criterions of different events. Events are detected based on these rules. Personalization is possible through the use of individual thresholds and other parameters.		
Source/Originator:	DoW (T4.5.1)		
Fit Criterion:	Event rules can be defined and stored.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 9:45 AM]

main requirement subtype: data representation (semantics)

Comment by [Stefan Asanin](#) [24/Sep/12 2:12 PM]

Rule Engine demonstrated at review.

[REACTION-421] [Models and rules for insulin dose prediction \(In-hospital\)](#) Created: 23/Jul/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 02/Mar/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate		
	incorporates	REACTION-72	Provide decision support for insulin ... Resolved
	incorporates	REACTION-432	Special examinations/treatments to be... Resolved
	incorporates	REACTION-369	Storage of hyperglycaemic or hypoglyc... Resolved
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Glucose control algorithm, Physiology models		
Work package:	WP6		
Rationale:	Calculation rules and/or algorithm must be stored for insulin dosing support based on clinical protocols.		
Source/Originator:	DoW		
Fit Criterion:	Necessary models and rules are defined and stored.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [23/Jul/10 11:33 AM]

Maybe we should split decision support for inpatient and primary care (outpatient) into 2 requirements?!

Inpatient: eDSS system for physicians based on clinical routine protocols

Primary care: glucose prediction based on the mechanistic model for mainly type 1 patients

Comment by [Tamas Toth](#) [23/Jul/10 11:48 AM]

OK, I have split it!

Comment by [Stephan Spat](#) [13/Aug/10 9:47 AM]

main requirement subtype: data representation (semantics)

[REACTION-423] [Sensor quality parameters](#) Created: 30/Aug/10 Updated: 13/Mar/13 Due: 28/Feb/13 Resolved: 13/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major

Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Operational		
Sub-Component/s:	Context management, Data management, PAN/BAN, Sensors		
Work package:	WP4		
Rationale:	The REACTION data management model should consider data storage for sensor quality parameters from devices reports like for example mis-calibration, or low battery. The parameters should be used for QoS.		
Source/Originator:	Jepser Thestrup		
Fit Criterion:	Data fields for sensor quality parameters are available in the data management model.		
Customer Satisfaction:	Interested		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Stefan Asanin](#) [19/Dec/12 10:48 AM]

Parts of this requirement are implemented (e.g. storage of measurement not being sent). However, this requirement needs to be clarified as sensors on the market today do not extensively provide information on battery status and mis-calibration.

Comment by [Stefan Asanin](#) [13/Mar/13 12:32 PM]

No arguments to have this requirement in progress anymore. It is implemented by the means of my previous comments. Medical devices do not express battery status etc. in the extent that it justifies such development on the client side (I have even published a workshop article on this matter).

[REACTION-425] [Set of action rules](#) Created: 23/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Tamas Toth	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Alert & alarm subsystem, Backend middleware, Glucose control algorithm, Risk assessment		
Work package:	WP4		
Rationale:	Action rules define what should be done if an event occurs, e.g. who should be notified and how.		
Source/Originator:	DoW (T4.5.1)		
Fit Criterion:	Action rules can be defined and stored.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 9:46 AM]

main requirement subtype: data representation (semantics)

Comment by [Stefan Asanin](#) [18/Sep/12 11:09 AM]

Started by ATOS Alarm Handling component and the Rule Engine as well as the SMS service.

[REACTION-426] [Comorbidities have to be registered](#) Created: 23/Jul/10 Updated: 12/Feb/13 Due: 31/Dec/12

Status:	In Progress																		
Project:	REACTION requirements																		
Component/s:	Health professional sphere																		
Affects Version/s:	REACTION Platform																		
Type:	Volere Requirement	Priority:	Major																
Reporter:	Franco Chiarugi	Assignee:	Malcolm Clarke																
Resolution:	Unresolved	Votes:	0																
Issue Links:	<table border="0"> <tr> <td>Depend</td> <td></td> <td></td> <td></td> </tr> <tr> <td>depends</td> <td>REACTION-154</td> <td>Comorbidities have to be registered</td> <td>Closed</td> </tr> <tr> <td>Incorporate</td> <td></td> <td></td> <td></td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-391</td> <td>Data fields for the In-hospital gluco...</td> <td>Resolved</td> </tr> </table>			Depend				depends	REACTION-154	Comorbidities have to be registered	Closed	Incorporate				is incorporated by	REACTION-391	Data fields for the In-hospital gluco...	Resolved
Depend																			
depends	REACTION-154	Comorbidities have to be registered	Closed																
Incorporate																			
is incorporated by	REACTION-391	Data fields for the In-hospital gluco...	Resolved																
Requirement Type:	Functional - REACTION platform																		
Sub-Component/s:	Architecture, Backend middleware, Data management, Ontology/Terminology																		

Work package:	WP4
Rationale:	Co-morbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient.
Source/Originator:	D2.1 and workshops
Fit Criterion:	In the design of data management and ontologies the possibility of registering the co-morbidities with a basic set of attributes has to be guaranteed. Co--morbidities with their attributes have to be registered at the patient enrolment and at each subsequent visit or evaluation when new co-morbidities take place.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by Stephan Spat [13/Aug/10 9:57 AM]
main requirement subtype: data structure
Comment by Matts Ahlsen [15/Aug/11 2:49 PM]
Needs standard on approach of disease description.
Comment by Stefan Asanin [24/Sep/12 2:53 PM]
Column in REACTION db initially available by "Notes" in PatientNote. Needs to be investigated if it needs a separate column.

[REACTION-428] Drug administration data (OAD and/or insulin) Created: 26/Jul/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 02/Mar/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-238	Update and entering of drug administr... Resolved
	depends	REACTION-240	Intravenous insulin Closed
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Portable user interface		
Work package:	WP4		
Rationale:	Drug administration (time, insulin type, administration type -IV or SC-, dosage and other relevant information) has to be immediately registered in the data management by the administering nurse.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Data on drugs administered have to be stored in the data management where they can be also retrieved as part of the fever/sugar chart.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-431] Data/messages exchanged between the Reaction Device Hosting Server and the GP EPR SHOULD be authentic (message authentication), with integrity, and confidential. Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate		
	incorporates	REACTION-93	Confidentiality: Sensitive informatio... In Progress
	is incorporated by	REACTION-91	Authenticity: Processors of informati... Resolved
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	The security of messages transferred between the Reaction Device Hosting Server and the GP EPR must be ensured even after the message was received - this is true even if the message was received over a secure		

	communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.
Source/Originator:	FHG SIT
Fit Criterion:	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by [Matthias Enzmann](#) [21/Jul/10 12:38 PM]

Note that this covers the data/messages but not necessarily the entities involved in the communication.

Comment by [Matthias Enzmann](#) [21/Sep/12 2:00 PM]

Hydra (Smartlink) uses its own P2P protocol which uses XML Encryption and XML Digital Signatures to provided confidentiality and integrity/authenticity, respectively.

Comment by [Matthias Enzmann](#) [25/Sep/12 9:52 AM]

Note that EPR here means endpoint reference and NOT electronic patient record.

[REACTION-432] [Special examinations/treatments to be registered in fever chart](#) Created: 26/Jul/10 Updated: 19/Mar/13 Due: 31/Oct/13 Resolved: 19/Mar/13

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Issue Links:	<p>Depend</p> <p>depends REACTION-417 Dynamic data structure for In-hospita... Resolved</p> <p>depends REACTION-391 Data fields for the In-hospital gluco... Resolved</p> <p>depends REACTION-239 Special examinations/treatments to be... Closed</p> <p>Incorporate</p> <p>is incorporated by REACTION-421 Models and rules for insulin dose pre... Resolved</p>		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Alert & alarm subsystem, Data management, Glucose control algorithm		
Work package:	WP4		
Rationale:	For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. In such cases treatment must therefore be adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). However a problem may arise if the patient has to wait longer than expected due to unforeseen delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). The dose of insulin and/or OADs will therefore need to be adapted, the patient receives some food in the event of hypoglycaemia and receives insulin by injection in the event of hyperglycaemia.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	These events (special examination/treatments) have to be registered in the data management where they can be retrieved for the composition of the fever/sugar chart.		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [10/Apr/12 1:28 PM]

It has to be decided if special management for hypo or hyper episodes has to be included in the in-hospital prototype and also if the fever chart has to be implemented (it does not seem to be necessary).

[REACTION-435] [Outcomes of regular visits at primary healthcare centres](#) Created: 23/Jul/10 Updated: 05/Nov/12 Due: 31/Dec/12

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Malcolm Clarke
Resolution:	Unresolved	Votes:	0

Issue Links:	Depend depends REACTION-194 Regular visits/reviews at the Primary... Closed
Requirement Type:	Functional - Primary care pilot application
Sub-Component/s:	Data management, Web user interface
Work package:	WP4
Rationale:	Outcomes of monitoring should be recorded in the Clinical Portal.
Source/Originator:	D2.1 and workshops and D2.6.2
Fit Criterion:	Outcomes of the monitoring will be stored in a notes section on the clinical portal. This notes section should be able to be exported in order to attach to the EPR via a hyperlink. The outcomes of each visit have to be stored as much as possible in a structured way.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by [Stephan Spat](#) [13/Aug/10 10:05 AM]

main requirement subtype: Data structure

Comment by [Franco Chiarugi](#) [30/Apr/12 3:13 PM]

Partially implemented

Comment by [Malcolm Clarke](#) [18/Oct/12 7:00 PM]

Part of extended configuration

[REACTION-437] [Each role MUST be assigned to a set of permissible actions.](#) Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend depends REACTION-100 Access control: Access to sensitive i... Resolved		
Requirement Type:	Non-functional - Security		
Work package:	WP7		
Rationale:	Since some actions are reserved for specific roles it has to be decided which actions are permissible for which role.		
Source/Originator:	FHG SIT		
Fit Criterion:	According to the roles' needs, each role is assigned to a set of appropriate permissions.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-438] [Communication between the Reaction Device Hosting Server and the GP EPR MUST be authentic \(entity authentication\), with integrity, and confidential.](#) Created: 21/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Issue Links:	Depend is depended by REACTION-168 Remote Patient Monitoring (RPM) Resolved		
	Incorporate incorporates REACTION-93 Confidentiality: Sensitive informatio... In Progress		
	incorporates REACTION-90 Identifiability: Recipients and sende... Resolved		

Requirement Type:	Non-functional - Security
Work package:	WP7
Rationale:	It must be assumed that data transmission from the Reaction Device Hosting Server to the GP EPR and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.
Source/Originator:	FHG SIT
Fit Criterion:	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by [Matthias Enzmann](#) [21/Jul/10 12:39 PM]

Note that this covers the communication channel but not necessarily the data transmitted over this channel.

Comment by [Matthias Enzmann](#) [21/Sep/12 1:57 PM]

The communication between the Reaction Device Hosting Server and the GP EPR takes place in a trusted domain, i.e., within the GP's local area network. Hence, it can be assumed that authenticity, integrity, and confidentiality are given.

[REACTION-439] [Information should be cached in local storage to prevent loss in case of a node or communication failure.](#) Created: 23/Jul/10 Updated: 18/Oct/12 Due: 31/Aug/12 Resolved: 12/Jun/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Network management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stelios Louloudakis	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate		
	incorporates	REACTION-422	User transparency in case of communic... Resolved
	is incorporated by	REACTION-417	Dynamic data structure for In-hospita... Resolved
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Communication, Networking, PAN/BAN		
Work package:	WP4		
Rationale:	In case of network error the client application should be able to store temporary data. This will a) allow user to continue the process later and b) prevent corrupted / incomplete data to be uploaded to the main server.		
Source/Originator:	DoW		
Fit Criterion:	The functional test should include specific tests in order to ensure that there is no data loss in case of network failure.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Stephan Spat](#) [28/Jul/10 5:45 PM]

I would suggest to choose as requirement type "REACTION platform".

Comment by [Stelios Louloudakis](#) [02/Aug/10 9:05 AM]

When writing this, I had in mind the network error in terms of patients' mobile device network failure. On the other hand network failure is also an issue for other interfaces and users, so it could be considered as a general "Reaction platform" requirement type.

[REACTION-441] [Basic workflow in In-hospital environment](#) Created: 26/Jul/10 Updated: 01/Nov/12 Due: 29/Oct/12 Resolved: 10/Apr/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Service orchestration		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-223	Basic workflow for insulin treatment ... Closed

	depends	REACTION-224	Basic workflow is repeated 4 times a ...	Closed
	Incorporate			
	is incorporated by	REACTION-417	Dynamic data structure for In-hospita...	Resolved
Requirement Type:	Functional - In-hospital pilot application			
Sub-Component/s:	Data management, Glucose control algorithm, PAN/BAN, Portable user interface			
Work package:	WP4			
Rationale:	The basic workflow is based on measurement of blood glucose and evaluation of the necessary insulin (bolus or basal), based also on additional parameters and insulin administration.			
Source/Originator:	D2.1 and workshops			
Fit Criterion:	There should be the possibility of acquiring, storing and retrieving all the information generated during any basic workflow performed during any time of the day/night.			
Customer Satisfaction:	Extremely Pleased			
Customer Dissatisfaction:	Extreme Unhappiness			

[REACTION-442] [Management of complications](#) Created: 23/Jul/10 Updated: 19/Apr/13 Due: 30/May/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Eniko Kiss
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend		
	depends	REACTION-189	Other implications for type I diabeti... Resolved
	depends	REACTION-195	Data management should handle differe... Closed
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Data management, Risk assessment		
Work package:	WP4		
Rationale:	Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Data management should include the necessary structures for assuring the storage of all necessary information for the management of complications.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 10:04 AM]

main requirement subtype: Data structure

Comment by [Franco Chiarugi](#) [30/Apr/12 3:13 PM]

Partially implemented

Comment by [Malcolm Clarke](#) [18/Oct/12 6:55 PM]

The database has a model that is able to accept data from any new sensors. The IEEE 11073 and the home gateway are flexible to accept new sensors.

Comment by [Malcolm Clarke](#) [18/Oct/12 6:57 PM]

The clinician portal is designed to work in a generic way so that any new sensors can be added, to manage complications. The clinician portal is also designed to manage the several measurements together.

Comment by [Malcolm Clarke](#) [18/Oct/12 6:59 PM]

We also have to note that much of the management of the patient is handled by the existing EPR

Comment by [Chorleywood Health Centre](#) [08/Nov/12 10:57 AM]

I think this is looking at Risk factors. this has not been implemented so I am propose to reopen and for Tamas to review

[REACTION-443] [Data exchange with third party systems](#) Created: 22/Jul/10 Updated: 04/Oct/12 Due: 30/Jun/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Third-party system interfaces		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major

Reporter:	Franco Chiarugi	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend		
	depends	REACTION-61	Data exchange with third-party systems Closed
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Interface with HIS/EPR		
Work package:	WP10		
Rationale:	Ideally integrates information from outside the REACTION platform (e.g. Laboratory Information Systems in hospital or primary care with blood glucose and glycated haemoglobine).		
Source/Originator:	DoW		
Fit Criterion:	Should be able to import and export data in an interoperable way (e.g. HL7) to third-party systems.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by Stephan Spat [29/Jul/10 11:50 AM]
I would like to suggest to change the requirement type to "data interface".
Comment by Franco Chiarugi [29/Jul/10 12:20 PM]
OK
Comment by Franco Chiarugi [24/Oct/11 10:38 AM]
Work already started for the in-hospital prototype (will be finalized in v1.3). For the primary care we should wait for the detailed specs.
Comment by Franco Chiarugi [04/Oct/12 3:01 PM]
Data exchange with third party systems seems unfeasible in primary care environment (CHC) since the PCHIS is a closed system.

[REACTION-444] 6-month clinical checks Created: 23/Jul/10 Updated: 13/Mar/13 Due: 29/Mar/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Issue Links:	Depend		
	depends	REACTION-158	6-month clinical checks Closed
Requirement Type:	Functional - Primary care pilot application		
Sub-Component/s:	Backend middleware, Data management, Glucose control algorithm, Ontology/Terminology, Web user interface		
Work package:	WP4		
Rationale:	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).		
Source/Originator:	D2.1 (pag.44) and workshops		
Fit Criterion:	Specific fields (entries) have to be foreseen in ontologies and data management.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Stephan Spat [13/Aug/10 9:58 AM]
main requirement subtype: Data structure
Comment by Matts Ahlsen [15/Aug/11 2:52 PM]
Possibly allow for customizable temporal definitions of clinical checks?
Comment by Jira Administrator [19/Oct/11 9:25 PM]
RQ was marked QC Passed
Comment by Franco Chiarugi [30/Apr/12 3:13 PM]
Not implemented
Comment by Stefan Asanin [24/Sep/12 3:13 PM]
Partially implemented by the Service Orchestrator. It just needs to be configured for this purpose.
Comment by Stefan Asanin [11/Oct/12 3:12 PM]

According to latest deployment meeting at Brunel this requirement could be part of the functionalities to be given for "lists", e.g. auto generated actions etc.

Comment by [Stefan Asanin](#) [11/Oct/12 3:26 PM]

The upcoming "list" requirements by primary care will feed into how to construct 6-month clinical check ups in Service Orchestrator functions and the Rule Engine to allow automatised 6-month reminders etc. for this specific requirement.

[REACTION-448] [Alert / notification messages should be short enough in order to be delivered as SMS messages if necessary](#) Created: 23/Jul/10 Updated: 30/Nov/12 Due: 30/Jun/12 Resolved: 28/May/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	Basic Primary care prototype , REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stelios Louloudakis	Assignee:	Stelios Louloudakis
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Alert & alarm subsystem		
Work package:	WP4		
Rationale:	User's terminal mobile device will likely be used as a GSM mobile phone. Considering the advantages of Short Message Service (fast delivery, provides an alternative data path when an Internet connection is not available etc) the time critical messages for the patients should be able to be forwarded as SMS messages.		
Source/Originator:	DoW		
Fit Criterion:	functional tests when user is away from broadband connection.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [28/Jul/10 5:44 PM]

I would suggest to choose as requirement type "REACTION platform" or "outpatient pilot application".

Comment by [Stelios Louloudakis](#) [02/Aug/10 8:59 AM]

Correct, I think that it is mainly a "Reaction Platform" requirement type.

Comment by [Stephan Spat](#) [13/Aug/10 10:06 AM]

main requirement subtype: data interface

[REACTION-449] [Personalized care plan](#) Created: 23/Jul/10 Updated: 05/Nov/12 Due: 31/Mar/13

Status:	Part of specification														
Project:	REACTION requirements														
Component/s:	Health professional sphere														
Affects Version/s:	Extended Primary care prototype														
Type:	Volere Requirement	Priority:	Major												
Reporter:	Tamas Toth	Assignee:	Malcolm Clarke												
Resolution:	Unresolved	Votes:	0												
Issue Links:	<table border="0"> <tr> <td>Depend</td> <td></td> <td></td> <td></td> </tr> <tr> <td>depends</td> <td>REACTION-203</td> <td>Care plan (defined for each patient) ...</td> <td>Closed</td> </tr> <tr> <td>depends</td> <td>REACTION-211</td> <td>Disease management plan, risk managem...</td> <td>Closed</td> </tr> </table>			Depend				depends	REACTION-203	Care plan (defined for each patient) ...	Closed	depends	REACTION-211	Disease management plan, risk managem...	Closed
Depend															
depends	REACTION-203	Care plan (defined for each patient) ...	Closed												
depends	REACTION-211	Disease management plan, risk managem...	Closed												
Requirement Type:	Functional - Primary care pilot application														
Sub-Component/s:	Backend middleware, Data management, Glucose control algorithm, Portable user interface, Web user interface														
Work package:	WP4, WP10														
Rationale:	A copy of the patients diabetes care plan will be entered onto the clinical portal (manually). This can be viewed by the patient on the patient portal. The care plan is based on a validated care plan used within primary care to aid the management of patients with Diabetes and is part of the current workflow to be incorporated into Reaction as per the clinical requirements.														
Source/Originator:	D2.1 and D2.6.2 Requirements specification														
Fit Criterion:	The care plan can be updated by the clinician within the clinical portal.														
Customer Satisfaction:	Very Pleased														
Customer Dissatisfaction:	High Unhappiness														

Comment by [Stephan Spat](#) [06/Aug/10 11:37 AM]

Main impact is on WP4.
Comment by Stephan Spat [13/Aug/10 9:55 AM]
main requirement subtype: data representation (semantics)
Comment by Franco Chiarugi [24/Oct/11 10:42 AM]
Waiting for the finalization of the detailed specifications for primary care. Also the meaning of personalization (exactly which parameters have to be personalized) has to be clearly defined. In any case the detailed definition of the personalized care plan has to be done in the context of WP8 (by clinicians).
Comment by Franco Chiarugi [30/Apr/12 3:13 PM]
Partially implemented
Comment by Chorleywood Health Centre [02/Oct/12 1:37 PM]
Part of the extended primary care prototype
Comment by Malcolm Clarke [18/Oct/12 6:54 PM]
This needs a consideration of the work flow to manage a care plan. I spoke to Michael Kirwan of DSheet, as he has created an interesting tool to manage workflow.

[REACTION-451] In-hospital prototype communication with REACTION platform Created: 29/Jul/10 Updated: 19/Mar/13 Due: 31/Oct/13			
Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	Extended In-hospital prototype , Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stephan Spat
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Communication, Glucose control algorithm		
Work package:	WP4		
Rationale:	The current design of the In-hospital prototype and the Primary care prototype does not consider the communication between these two prototypes (e.g. SOA). Thus, the data model should consider how the prototypes can be merged in future within the REACTION platform. A data/communication interface has to be defined.		
Source/Originator:	MSG focus group, prototype architectures		
Fit Criterion:	Communication and transfer of data between In-hospital and Primary care prototypes are possible.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

[REACTION-452] Communication between the Reaction Device Hosting Server and the EPR/EHR System MUST be authentic (entity authentication), with integrity, and confidential. Created: 20/Jul/10 Updated: 25/Sep/12 Resolved: 21/Sep/12																															
Status:	Resolved																														
Project:	REACTION requirements																														
Component/s:	Security and safety management																														
Affects Version/s:	Basic Primary care prototype																														
Type:	Volere Requirement	Priority:	Major																												
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann																												
Resolution:	Implemented	Votes:	0																												
Issue Links:	<table border="0"> <tr><td>Depend</td><td></td><td></td><td></td></tr> <tr><td>is depended by</td><td>REACTION-168</td><td>Remote Patient Monitoring (RPM)</td><td>Resolved</td></tr> <tr><td>Incorporate</td><td></td><td></td><td></td></tr> <tr><td>incorporates</td><td>REACTION-93</td><td>Confidentiality: Sensitive informatio...</td><td>In Progress</td></tr> <tr><td>incorporates</td><td>REACTION-90</td><td>Identifiability: Recipients and sende...</td><td>Resolved</td></tr> <tr><td>incorporates</td><td>REACTION-91</td><td>Authenticity: Processors of informati...</td><td>Resolved</td></tr> <tr><td>incorporates</td><td>REACTION-92</td><td>Integrity: Information, in particular...</td><td>Closed</td></tr> </table>			Depend				is depended by	REACTION-168	Remote Patient Monitoring (RPM)	Resolved	Incorporate				incorporates	REACTION-93	Confidentiality: Sensitive informatio...	In Progress	incorporates	REACTION-90	Identifiability: Recipients and sende...	Resolved	incorporates	REACTION-91	Authenticity: Processors of informati...	Resolved	incorporates	REACTION-92	Integrity: Information, in particular...	Closed
Depend																															
is depended by	REACTION-168	Remote Patient Monitoring (RPM)	Resolved																												
Incorporate																															
incorporates	REACTION-93	Confidentiality: Sensitive informatio...	In Progress																												
incorporates	REACTION-90	Identifiability: Recipients and sende...	Resolved																												
incorporates	REACTION-91	Authenticity: Processors of informati...	Resolved																												
incorporates	REACTION-92	Integrity: Information, in particular...	Closed																												
Requirement Type:	Non-functional - Security																														
Work package:	WP7, WP10																														
Rationale:	It must be assumed that data transmission from the Reaction Device Hosting Server to the EPR/EHR System and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.																														

Source/Originator:	FHG SIT
Fit Criterion:	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

Comment by [Matthias Enzmann](#) [20/Jul/10 6:07 PM]

Note that this covers the communication channel but not necessarily the data transmitted over this channel.

Comment by [Franco Chiarugi](#) [14/Jun/12 1:24 PM]

Main impact is on WP7

Comment by [Matthias Enzmann](#) [21/Sep/12 1:58 PM]

The communication between the Reaction Device Hosting Server and the GP EPR takes place in a trusted domain, i.e., within the GP's local area network. Hence, it can be assumed that authenticity, integrity, and confidentiality are given.

[REACTION-453] [Communication interface between REACTION Client and REACTION Server](#) Created: 29/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 28/Feb/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Communication		
Work package:	WP4		
Rationale:	A communication standard between REACTION client and server should be established (e.g. IHE-PCD01) in order to transport data from client to server side (and vice versa).		
Source/Originator:	Technical meeting Crete, E-Mail discussion between Stephan S. and Peter R. (2010-07-14)		
Fit Criterion:	Communication interface between REACTION Client and REACTION Server will be available.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Stefan Asanin](#) [28/Feb/12 2:10 PM]

Implemented as client and server is self-reflective and host same features.

[REACTION-454] [Content formatter](#) Created: 23/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Internal communication		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	PAN/BAN, Portable user interface, Web user interface		
Work package:	WP4		
Rationale:	A formatter for converting the acquired data to useful information for the patient shall be available.		
Source/Originator:	FORTH-ICS & FORTHNET internal focus group		
Fit Criterion:	Use a standard format or a verification mechanism.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 10:11 AM]

main requirement subtype: data representation (semantics)

Comment by [Matts Ahlsen](#) [15/Aug/11 3:49 PM]

For example HL7Parser. PDF handler to be developed and more if necessary.

Comment by [Stefan Asanin](#) [24/Sep/12 2:41 PM]
 HL7

[REACTION-455] REACTION data storage Created: 29/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Backend middleware, Data management, Security		
Work package:	WP4		
Rationale:	The REACTION platform should provide a storage module (database). Data gathered within REACTION should be stored here, as well as relevant data from external sources. The REACTION data storage should also use security mechanisms to include/exclude patient data access.		
Source/Originator:	Technical Meeting in Crete, architecture prototype.		
Fit Criterion:	The REACTION platform provides a persistence layer for data storage with emphasis on data security and data access.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-456] Nutrition information has to be stored in the data management Created: 26/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12																							
Status:	Resolved																						
Project:	REACTION requirements																						
Component/s:	Data Management																						
Affects Version/s:	Basic In-hospital prototype																						
Type:	Volere Requirement	Priority:	Major																				
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin																				
Resolution:	Implemented	Votes:	0																				
Issue Links:	<table border="0"> <tr> <td>Depend</td> <td></td> <td></td> <td></td> </tr> <tr> <td>depends</td> <td>REACTION-243</td> <td>Nutrition has to be taken into accoun...</td> <td>Closed</td> </tr> <tr> <td>Incorporate</td> <td></td> <td></td> <td></td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-417</td> <td>Dynamic data structure for In-hospita...</td> <td>Resolved</td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-391</td> <td>Data fields for the In-hospital gluco...</td> <td>Resolved</td> </tr> </table>			Depend				depends	REACTION-243	Nutrition has to be taken into accoun...	Closed	Incorporate				is incorporated by	REACTION-417	Dynamic data structure for In-hospita...	Resolved	is incorporated by	REACTION-391	Data fields for the In-hospital gluco...	Resolved
Depend																							
depends	REACTION-243	Nutrition has to be taken into accoun...	Closed																				
Incorporate																							
is incorporated by	REACTION-417	Dynamic data structure for In-hospita...	Resolved																				
is incorporated by	REACTION-391	Data fields for the In-hospital gluco...	Resolved																				
Requirement Type:	Functional - In-hospital pilot application																						
Sub-Component/s:	Context management, Data management, Portable user interface																						
Work package:	WP4																						
Rationale:	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation (the use of glycaemic index and load tables for various types of food might be taken into account). Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).																						
Source/Originator:	D2.1 and workshops																						
Fit Criterion:	The data management shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.																						
Customer Satisfaction:	Pleased																						
Customer Dissatisfaction:	Neutral Unhappiness																						

Comment by [Stephan Spat](#) [13/Aug/10 10:13 AM]
 main requirement subtype: data storage

Comment by [Franco Chiarugi](#) [10/Apr/12 1:20 PM]
 This requirement has been partially implemented. The details about the nutrition do not seem to be required, but this fact should be confirmed during the 3rd year.

[REACTION-459] [Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events](#) Created: 26/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Implemented	Votes:	0
Issue Links:	Depend depends REACTION-248 Ontologies and data management design... Closed		
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management		
Work package:	WP4		
Rationale:	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Matts Ahlsen](#) [15/Aug/11 4:12 PM]

Not only for inpatient scenario. Too broad summary.

Comment by [Jira Administrator](#) [19/Oct/11 7:59 PM]

RQ was marked Incomplete

Comment by [Stefan Asanin](#) [24/Sep/12 2:47 PM]

Implemented by the in-hospital prototype.

[REACTION-460] [Measurements of HbA1c](#) Created: 23/Jul/10 Updated: 13/Mar/13 Due: 30/Apr/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	REACTION Platform		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Architecture, Backend middleware, Data management, Portable user interface, Risk assessment, Web user interface		
Work package:	WP4		
Rationale:	The risk of developing diabetic complications is strongly affected by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy in outpatient environment and at the patient enrolment in the inpatient environment (updates are decided by clinicians).		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	Specific fields have to be foreseen in data management.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Jira Administrator](#) [12/Feb/13 3:54 PM]

R-182 was closed as being a duplicate of this RQ. Dependence Link to R-182 removed

Comment by [Stefan Asanin](#) [13/Mar/13 10:54 AM]

Needs to be connected to the care plan or the underlying service orchestrator.

[REACTION-462] [Interface for user inputs from portable computer in order to store data in In-hospital data storage](#) Created: 22/Jul/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 02/Mar/12

Status:	Resolved
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Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate		
	incorporates	REACTION-418	Context sensitive interface Resolved
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Backend middleware, Glucose control algorithm, Portable user interface		
Work package:	WP4, WP10		
Rationale:	For the In-hospital prototype user input should be possible. The user data should be stored in the data storage.		
Source/Originator:	D2.1, D2.5		
Fit Criterion:	User input can be stored in the In-hospital prototype storage for further processing.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Stephan Spat](#) [22/Jul/10 4:38 PM]

Main impact is on WP4.

[REACTION-463] [Context management for clinical \(lab\) values.](#) Created: 23/Jul/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 02/Mar/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Stephan Spat	Assignee:	Stephan Spat
Resolution:	Implemented	Votes:	0
Issue Links:	Incorporate		
	incorporates	REACTION-237	Annotation of blood glucose values, e... Resolved
	incorporates	REACTION-238	Update and entering of drug administr... Resolved
	is incorporated by	REACTION-366	Storage of events for context of meas... Closed
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Backend middleware, Context management, Data management, Glucose control algorithm, PAN/BAN		
Work package:	WP4		
Rationale:	Contextualization of measured values (e.g. blood glucose values) is important in order to support REACTION applications like decision support. For example pre- or post-meal glucose values have very different meanings for treatment. Therefore the data management model has to provide context management.		
Source/Originator:	D2.1, D2.5		
Fit Criterion:	The data management model support context management functionality for the inpatient prototype application.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Stephan Spat](#) [13/Aug/10 10:04 AM]

main requirement subtype: Data representation (semantics)

[REACTION-465] [Clinical evaluation report](#) Created: 26/Jul/10 Updated: 01/Nov/12 Due: 31/Jul/12 Resolved: 10/Apr/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Basic In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin

Resolution:	Implemented	Votes:	0
Issue Links:	Depend		
	depends	REACTION-230	Therapy adjustment in In-hospital env... Closed
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Data management, Glucose control algorithm, Portable user interface		
Work package:	WP4		
Rationale:	Supervision of glycaemia and associated treatment is performed once a day. The clinical evaluation report has to be produced daily. Adaptation of therapy or changes of medications has to be evaluated including by consultation with the duty-physician.		
Source/Originator:	D2.1 and workshops		
Fit Criterion:	A daily clinical evaluation report has to be stored and available in the Inpatient application.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-466] ([Web](#)) [Service to present decision support for glucose control to clinicians](#) Created: 22/Jul/10 Updated: 17/Oct/12 Due: 25/Oct/12 Resolved: 10/Apr/12

Status:	Resolved				
Project:	REACTION requirements				
Component/s:	Health professional sphere				
Affects Version/s:	Basic In-hospital prototype				
Type:	Volere Requirement	Priority:	Major		
Reporter:	Stephan Spat	Assignee:	Stephan Spat		
Resolution:	Implemented	Votes:	0		
Issue Links:	Depend				
	depends	REACTION-377	Electronic fever/sugar chart	Resolved	
	Incorporate				
	incorporates	REACTION-72	Provide decision support for insulin ...	Resolved	
	incorporates	REACTION-96	Visualization individual patient data...	Resolved	
Sub-Tasks:	Key	Summary	Type	Status	Assignee
	REACTION-469	Visualization of current "insulin on ...	Sub-task	Resolved	Stephan Spat
Requirement Type:	Functional - In-hospital pilot application				
Sub-Component/s:	Backend middleware, Data management, Glucose control algorithm, Portable user interface				
Work package:	WP4				
Rationale:	After processing of data by the glucose prediction algorithm, the results should be presented by the system to the physician. The physician can use the result for decision support. The service uses data stored in the data storage and user additional user input as input for processing.				
Source/Originator:	D2.1, D2.5				
Fit Criterion:	A service will be available to support physician with glucose control of patients.				
Customer Satisfaction:	Extremely Pleased				
Customer Dissatisfaction:	High Unhappiness				

[REACTION-467] [Semantics based data management](#) Created: 22/Jul/10 Updated: 01/Nov/12 Due: 24/Sep/12 Resolved: 24/Sep/12

Status:	Resolved				
Project:	REACTION requirements				
Component/s:	Data Management				
Affects Version/s:	REACTION Platform				
Type:	Volere Requirement	Priority:	Major		
Reporter:	Franco Chiarugi	Assignee:	Stefan Asanin		
Resolution:	Implemented	Votes:	0		
Issue Links:	Depend				
	depends	REACTION-62	Semantics based data management	Closed	
Requirement Type:	Functional - REACTION platform				
Sub-Component/s:	Architecture, Backend middleware, Data management, Ontology/Terminology				
Work package:	WP4				

Rationale:	The monitoring and other data need to be properly annotated with ontological descriptions.
Source/Originator:	DoW & technical meetings
Fit Criterion:	Relevant entries in the REACTION's databases are annotated with semantic concepts.
Customer Satisfaction:	Pleased
Customer Dissatisfaction:	Neutral Unhappiness

Comment by [Stephan Spat](#) [13/Aug/10 9:42 AM]

main requirement subtype: data representation (semantics)

Comment by [Stefan Asanin](#) [24/Sep/12 2:48 PM]

Both implemented using HL7 coded messages as well as the LinkSmart ontology.

[REACTION-468] [Provide regular update of data model for Health Care profil](#) Created: 23/Jul/10 Updated: 01/Nov/12 Due: 30/Sep/12 Resolved: 24/Sep/12

Status:	Resolved														
Project:	REACTION requirements														
Component/s:	Health professional sphere														
Affects Version/s:	Basic Primary care prototype														
Type:	Volere Requirement	Priority:	Major												
Reporter:	Stephan Spat	Assignee:	Stefan Asanin												
Resolution:	Implemented	Votes:	0												
Issue Links:	<table border="0"> <tr> <td>Incorporate</td> <td></td> <td></td> <td></td> </tr> <tr> <td>incorporates</td> <td>REACTION-75</td> <td>Maintain and continuously update a pa...</td> <td>Resolved</td> </tr> <tr> <td>is incorporated by</td> <td>REACTION-392</td> <td>Personal Health Status Profiles</td> <td>In Progress</td> </tr> </table>			Incorporate				incorporates	REACTION-75	Maintain and continuously update a pa...	Resolved	is incorporated by	REACTION-392	Personal Health Status Profiles	In Progress
Incorporate															
incorporates	REACTION-75	Maintain and continuously update a pa...	Resolved												
is incorporated by	REACTION-392	Personal Health Status Profiles	In Progress												
Requirement Type:	Functional - REACTION platform														
Sub-Component/s:	Backend middleware, Data management														
Work package:	WP4														
Rationale:	Most application depends on current clinical data (e.g. blood glucose). A mechanism for regular data updates should be provided.														
Source/Originator:	D2.1, D2.5														
Fit Criterion:	The Data Model for REACTION should provide a regular update mechanism for personal health care profiles.														
Customer Satisfaction:	Extremely Pleased														
Customer Dissatisfaction:	Extreme Unhappiness														

Comment by [Stefan Asanin](#) [24/Sep/12 3:20 PM]

Regular data updates can only strictly be set up by clinician's monitoring plan.

[REACTION-470] [The potential stigmatising effect of REACTION due to increased visibility should be decreased to a minimum.](#) Created: 24/Oct/11 Updated: 06/Nov/12 Resolved: 06/Nov/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Chorleywood Health Centre
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Look and feel		
Sub-Component/s:	Architecture		
Work package:	WP9		
Rationale:	Most diabetic patients experience diabetes as 'discreditable' individuals in terms of stigmatisation (See ethical analysis - task 9.1). For such individuals control over personal information is extremely important. Individual patients will not want to unnecessarily increase visibility of their condition as this will mean that they have reduced level of control over their personal information and will therefore have less ability to control who they reveal their condition to. Visibility of components and also electronic visibility of networking components should therefore be kept to a minimum.		
Source/Originator:	Most diabetics experience through as 'discreditable' individuals as described by Goffman stigmatisation and (See ethical analysis - task 9.1)		
Fit Criterion:	Patients should feel that a REACTION like platform will not result in an overall increase in the visibility of their		

	condition and consequently a reduction in their ability to conceal it, it they should wish to do so.
Customer Satisfaction:	Very Pleased
Customer Dissatisfaction:	High Unhappiness

Comment by [Chorleywood Health Centre](#) [02/Nov/12 10:16 AM]

I think that this requirement, is something that has and continues to be considered in the specification. This could be validated as part of the evaluation work? I would like to resolve this issue as being implemented and then update when we validate.

Comment by [Chorleywood Health Centre](#) [06/Nov/12 9:04 AM]

As per my previous comment. I believe this to be resolved as it has been considered in the development of the primary care system.

[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.](#) Created: 24/Oct/11 Updated: 06/Dec/12 Due: 31/Mar/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Chorleywood Health Centre
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Cultural and political		
Sub-Component/s:	Architecture		
Work package:	WP9		
Rationale:	Individual patients often use the opportunity to meet such groups as a coping mechanism for the stigmatising effects there condition can entail. A REACTION platform should not reduce such possibilities too much. Where such possibilities are drastically reduced alternatives should be offered, for example online social networking possibilities.		
Source/Originator:	See ethical analysis (task 9.1)		
Fit Criterion:	Individuals should not feel that a REACTION platform has eliminated their access to other patients and sympathetic health care professionals which represent an important coping mechanism for individuals that feel stigmatised.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Chorleywood Health Centre](#) [02/Nov/12 10:14 AM]

I think that this requirement, is something that has and continues to be considered in the specification. This could be validated as part of the evaluation work? I would like to resolve this issue as being implemented and then update when we validate.

[REACTION-472] [A portable sensor patch should have as reduced visibility as is technically feasible](#) Created: 26/Feb/12 Updated: 01/Nov/12 Due: 12/Dec/12

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Peripherals		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Jens Branebjerg
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Portable devices		
Work package:	WP3		
Rationale:	The lower the visibility of such equipment the less the chance that an individual's condition might become apparent to others in situations where the patient does not wish this to happen. This is important in connection with issues of stigmatization - see task 9.2		
Source/Originator:	VUB		
Fit Criterion:	Equipment should have as low a level of visibility as is technically possible.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [28/Mar/12 2:19 PM]
This requirement might be related to the "mobile" gateway where all the medical devices (eventually encapsulated in an ePatch) are communicating. In this case, the mobile gateway is not foreseen in the primary care pilot site (a static home gateway is foreseen), thus it seems that this requirement will have an impact only in the automatic glucose control (AGC) which at the moment is not in an advanced phase of specifications. Refinement of the requirement and assignment will be defined once the detailed specifications of the AGC system will be available. However, if this requirement is focused on the ePatch container, then it has to be taken into account in the current phase of development and assigned to the responsible partner (DELTA)
Comment by Franco Chiarugi [30/Apr/12 3:14 PM]
Partially implemented
Comment by Franco Chiarugi [10/Jul/12 1:30 PM]
Updated according to Peter Rosengren's comments

[REACTION-475] Log and log-in system Created: 26/Mar/12 Updated: 22/Oct/12 Resolved: 22/Oct/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended In-hospital prototype , Basic Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Matthias Enzmann
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Legal		
Work package:	WP9		
Rationale:	One requirement is a 'log-in system' used to identify and authenticate a given person when s/he accesses the medical data. Another requirement is a 'log system' that records who did what and when in an audit log. This would contribute to realise those "technical and organizational measures" capable of ensuring the traceability of those who access the data of patients. Besides robust log-in and log systems showing who has accessed information and when.		
Source/Originator:	D9. EU case law (e.g. I v Finland) ²		
Fit Criterion:	A log and log-in system has to be implemented, documented and tested.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by Franco Chiarugi [10/Apr/12 2:00 PM]
This requirement is currently at an advanced status of implementation for the in-hospital prototype.
Comment by Matthias Enzmann [22/Oct/12 5:32 PM]
Log-in and Log-out (explicit or implicit, e.g., through timeouts) are realised in the platform

[REACTION-478] The recovery for microdialysis based glucose sensors should be monitored to avoid recalibration Created: 30/Mar/12 Updated: 21/Dec/12 Due: 19/Nov/12 Resolved: 21/Dec/12			
Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Medical & environmental devices		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Thomas Klotzbuecher	Assignee:	Thomas Klotzbuecher
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional		
Sub-Component/s:	Portable devices		
Work package:	WP3		
Rationale:	Due to sensor fouling effects the recovery of a microdialysis catheter may change as a function of time, requiring sensor recalibration by a reference method. This could be avoided if an additional sensor is implemented measuring the change of recovery (e.g. ion density in the dialysate). This is relevant for microdialysis based glucose sensors.		
Source/Originator:	Lukas Schaupp		
Fit Criterion:	Recovery detection implemented		
Customer Satisfaction:	Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Thomas Klotzbuecher](#) [26/Sep/12 4:52 PM]

For the clinical trials to be performed with the microdialysis based sensor, it should be sufficient to measure the recovery change within the perfusate, instead of applying an additional sensor for monitoring the recovery. The CGM data can than be re-calibrated retrospectively if patient reference as well as perfusate reference measurements are present. If partners agree on such a procedure, the requirement can be considered closed!

Comment by [Thomas Klotzbuecher](#) [21/Dec/12 9:13 AM]

The change of recovery through membranes of membrane based sensors, like the microdialysis, always might be a problem. At MUG it was shown that a change of recovery could be detected by measuring the ion density in the perfusate. However, for that mannitol has to be added to the perfusate which interferes with the IR transmission spectroscopy but since it would be present in both the reference and the measuring optical cell, this method still appears to be an option (was not tested yet). In REACTION the change of recovery is measured by collecting the dialysate and comparing the glucose values of which with patient reference and sensor data.

[REACTION-480] [Access control mechanisms should be able to process context information](#) Created: 28/Aug/12 Updated: 25/Sep/12 Due: 31/May/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Security		
Sub-Component/s:	Security		
Work package:	WP7		
Rationale:	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.		
Source/Originator:	Discussion with MUG/MSG/SIT		
Fit Criterion:	Availability of a control mechanism which decides whether a requested action may be granted or denied based on context information.		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		
Dependencies:	REACTION-99 , REACTION-100		

[REACTION-481] [Glucose Control Suite \(GCS\) - Matlab GUI](#) Created: 03/Sep/12 Updated: 10/Feb/13 Due: 31/Oct/12 Resolved: 10/Feb/13

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Thomas Eissing	Assignee:	Thomas Eissing
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Glucose control algorithm, Physiology models		
Work package:	WP3, WP8		
Rationale:	Implementation of a Matlab based GUI for the clinical validation of the closed loop glucose control algorithm		
Source/Originator:	D3.11, D8.2		
Fit Criterion:	Operable Interface on a laptop within a patients room in the clinic		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-482] [GCS - Interface to create individual model file](#) Created: 03/Sep/12 Updated: 10/Feb/13 Due: 31/Oct/12 Resolved: 10/Feb/13

Status:	Closed		
Project:	REACTION requirements		

Component/s:	Health professional sphere		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Thomas Eissing	Assignee:	Thomas Eissing
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Glucose control algorithm, Physiology models		
Work package:	WP3, WP8		
Rationale:	Interface to create Individual specifying: Race, Gender, Age, Weight and Height		
Source/Originator:	D3.11,D8.2		
Fit Criterion:	A new individual model file is created. The model initialization is initiated.		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-483] [GCS - Interface for Model Initialization](#) Created: 03/Sep/12 Updated: 10/Feb/13 Due: 31/Oct/12 Resolved: 10/Feb/13

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Thomas Eissing	Assignee:	Thomas Eissing
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Glucose control algorithm, Physiology models		
Work package:	WP3, WP8		
Rationale:	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		
Source/Originator:	D3.11, D8.2		
Fit Criterion:	Matlab GUI fitting rationale described above		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

[REACTION-484] [GCS - Interface for semi-automatic online glucose control](#) Created: 03/Sep/12 Updated: 10/Feb/13 Due: 31/Oct/12 Resolved: 10/Feb/13

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Automatic Glucose Control prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Thomas Eissing	Assignee:	Thomas Eissing
Resolution:	Implemented	Votes:	0
Requirement Type:	Functional - REACTION platform		
Sub-Component/s:	Glucose control algorithm, Physiology models		
Work package:	WP3, WP8		
Rationale:	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 enter dose Insulin manually		
Source/Originator:	D3.11, D8.2		

Fit Criterion:	Matlab GUI as decribed in rationale
Customer Satisfaction:	Extremely Pleased
Customer Dissatisfaction:	Extreme Unhappiness

[REACTION-485] GCS - Interface for online model optimization Created: 03/Sep/12 Updated: 10/Feb/13 Due: 31/Oct/12 Resolved: 10/Feb/13					
Status:	Closed				
Project:	REACTION requirements				
Component/s:	Health professional sphere				
Affects Version/s:	Automatic Glucose Control prototype				
Type:	Volere Requirement	Priority:	Major		
Reporter:	Thomas Eissing	Assignee:	Thomas Eissing		
Resolution:	Implemented	Votes:	0		
Sub-Tasks:	Key	Summary	Type	Status	Assignee
	REACTION-486	Define level of interaction for onlin...	Sub-task	Resolved	Thomas Eissing
Requirement Type:	Functional - REACTION platform				
Sub-Component/s:	Glucose control algorithm, Physiology models				
Work package:	WP3, WP8				
Rationale:	2nd part of the third Component of the GCS - Interface for the further individualization of the GIM model based on past glucose measurements, allows: - Visualization of: - Plasma and interstitial glucose - Plasma and interstitial insulin - Values of optimized parameters - Values of penalty function components (met constraints) - Level of manual interaction to be defined				
Source/Originator:	D3.11,D8.2				
Fit Criterion:	Matlab GUI as defined in rationale				
Customer Satisfaction:	Extremely Pleased				
Customer Dissatisfaction:	Extreme Unhappiness				

Comment by [Thomas Eissing](#) [10/Feb/13 5:41 PM]

Implemented without data visualization

[REACTION-492] Components should reflect national requirements, policies, guidelines or provisions Created: 06/Nov/12 Updated: 13/Mar/13 Due: 30/Jun/14					
Status:	In Progress				
Project:	REACTION requirements				
Component/s:	Health professional sphere				
Affects Version/s:	REACTION Platform				
Type:	Volere Requirement	Priority:	Major		
Reporter:	Malcolm Clarke	Assignee:	Stefan Asanin		
Resolution:	Unresolved	Votes:	0		
Requirement Type:	Functional - REACTION platform				
Sub-Component/s:	Architecture				
Work package:	WP10				
Rationale:	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.				
Source/Originator:	Malcolm				
Fit Criterion:	Components				
Customer Satisfaction:	Very Pleased				
Customer Dissatisfaction:	Neutral Unhappiness				

Comment by [Stefan Asanin](#) [07/Dec/12 3:20 PM]

Should be measured against subtasks.

Comment by [Stefan Asanin](#) [13/Mar/13 10:52 AM]

Specific national reqs, policies, etc. should be defined per component and the functionalities within.

[REACTION-493] [The user must be able to correct, rectify, block or erase personal data that has been disclosed - In-Hospital](#) Created: 06/Nov/12 Updated: 22/Nov/12 Due: 01/Sep/13

Status:	Part of specification		
Project:	REACTION requirements		
Component/s:	Data Management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Katharina Neubauer
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Legal		
Work package:	WP9		
Rationale:	<p>People make mistakes and novel information may render earlier decisions unfortunate. This goes for users and service providers alike. User control mandates that users can correct mistakes they, or the service providers, make with respect to their data. A step further is that users also have the possibility to reset choices they made. If users are not content with the way their data is used, they should be able to recall or change the access rights to their data.</p> <p>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.</p> <p>This is strengthened in the new proposal on a data protection framework of the EC.</p>		
Source/Originator:	DOW		
Fit Criterion:	<p>Levels of ex-post user control that can be distinguished are:</p> <ul style="list-style-type: none"> - 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 <p>Does the application show the user's rights to access, rectify, block or erase disclosed (personal) data and the procedures to execute these right?</p>		
Customer Satisfaction:	Very Pleased		
Customer Dissatisfaction:	High Unhappiness		

Comment by [Jira Administrator](#) [06/Nov/12 2:55 PM]

This is a Clone of R-151 for the In-hospital domain. To be reviewed and detailed by the Clinical Partner

[REACTION-494] [It should be possible to configure the application to different socio-cultural settings - Patient Portal](#) Created: 06/Nov/12 Updated: 04/Dec/12 Due: 07/Dec/12 Resolved: 04/Dec/12

Status:	Resolved		
Project:	REACTION requirements		
Component/s:	Patient sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Franco Chiarugi
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Cultural and political		
Sub-Component/s:	Architecture		
Work package:	WP9		
Rationale:	<p>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.</p>		
Source/Originator:	DOW		
Fit Criterion:	<p>The application should cater for configuring at least:</p> <ul style="list-style-type: none"> - 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. <p>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?</p>		
Customer Satisfaction:	Extremely Pleased		

Customer Dissatisfaction:	Extreme Unhappiness
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Comment by [Jira Administrator](#) [06/Nov/12 3:09 PM]

This is a clone of R-146 for the patient portal. To be reviewed after the Stockholm Integration meeting

[REACTION-495] [It should be possible to configure the application to different socio-cultural settings - Clinician portal](#) Created: 06/Nov/12 Updated: 18/Dec/12 Due: 07/Dec/12 Resolved: 18/Dec/12

Status:	Closed		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Extended Primary care prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Eugenio Mantovani	Assignee:	Malcolm Clarke
Resolution:	Implemented	Votes:	0
Requirement Type:	Non-functional - Cultural and political		
Sub-Component/s:	Architecture		
Work package:	WP9		
Rationale:	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.		
Source/Originator:	DOW		
Fit Criterion:	The application should cater for configuring at least: <ul style="list-style-type: none"> - 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?		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Extreme Unhappiness		

Comment by [Jira Administrator](#) [06/Nov/12 3:13 PM]

This is a clone of R-146 for the clinician portal. To be reviewed after the Stockholm Integration meeting

Comment by [Malcolm Clarke](#) [18/Dec/12 6:35 PM]

Language support is built in to portals

Comment by [Malcolm Clarke](#) [18/Dec/12 6:36 PM]

Language support is now implemented for terms

[REACTION-496] [Documentation of user interfaces - primary care prototype](#) Created: 10/Jan/13 Updated: 06/Mar/13 Due: 31/Oct/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Health professional sphere		
Affects Version/s:	Documentation		
Type:	Volere Requirement	Priority:	Major
Reporter:	Peter Beck	Assignee:	Franco Chiarugi
Resolution:	Unresolved	Votes:	0
Requirement Type:	Non-functional - Usability		
Sub-Component/s:	Portable devices, Portable user interface, Risk assessment, Web user interface		
Work package:	WP6, WP10		
Rationale:	Documentation for User Interface of all frontend applications.		
Source/Originator:	DoW		
Fit Criterion:	User manual for all frontend applications		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	Neutral Unhappiness		

Comment by [Franco Chiarugi](#) [06/Mar/13 2:15 PM]

Main impact is on WP10

[REACTION-497] [Management Functionality for the Identities used in the In-Hospital-Scenario](#) Created: 05/Feb/13 Updated: 05/Feb/13 Due: 30/Jun/13

Status:	In Progress		
Project:	REACTION requirements		
Component/s:	Data Management , Security and safety management		
Affects Version/s:	Extended In-hospital prototype		
Type:	Volere Requirement	Priority:	Major
Reporter:	Matthias Enzmann	Assignee:	Matthias Enzmann
Resolution:	Unresolved	Votes:	0
Requirement Type:	Functional - In-hospital pilot application		
Sub-Component/s:	Security		
Work package:	WP7		
Rationale:	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.		
Source/Originator:	Administrators from the hospital		
Fit Criterion:	Availability of a management application		
Customer Satisfaction:	Extremely Pleased		
Customer Dissatisfaction:	High Unhappiness		

[REACTION-501] [Second Prototype of the Glucose Control Algorithm \(GCA 2\) - Matlab GUI](#) Created: 10/Feb/13 Updated: 10/Feb/13 Due: 31/Oct/13

Status:	In Progress				
Project:	REACTION requirements				
Component/s:	Health professional sphere				
Affects Version/s:	Automatic Glucose Control prototype				
Type:	Volere Requirement	Priority:	Major		
Reporter:	Thomas Eissing	Assignee:	Thomas Eissing		
Resolution:	Unresolved	Votes:	0		
Sub-Tasks:	Key	Summary	Type	Status	Assignee
	REACTION-498	GCA 2 - Interface for online model op...	Sub-task	In Progress	Thomas Eissing
	REACTION-499	GCA 2 - Interface for semi-automatic ...	Sub-task	In Progress	Thomas Eissing
	REACTION-500	GCA 2 - Interface to create individua...	Sub-task	In Progress	Thomas Eissing
Requirement Type:	Functional - REACTION platform				
Sub-Component/s:	Glucose control algorithm, Physiology models				
Work package:	WP3, WP8				
Rationale:	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				
Source/Originator:	D3.12				
Fit Criterion:	Operable Interface on a laptop within a patients room in the clinic				
Customer Satisfaction:	Extremely Pleased				
Customer Dissatisfaction:	Extreme Unhappiness				