News from the REACTION project

Stay abreast with developments in closed-loop diabetes monitoring

Issue #3 - published by the REACTION project - August, 2011

Supporting glycaemic control of patients with diabetes type 2 in hospital

A mobile glucose management system prototype has been designed by REACTION partners MUG, MSG and FORTH to support continuous glycaemic control of admitted patients with diabetes. The overall aim is to reduce the mortality and morbidity rate related to in-hospital hyperglycaemia.

Glycaemic control in the hospital of acutely ill patients with diabetes is often considered secondary in importance. However, studies demonstrate that in-hospital hyperglycaemia has been found to be an important marker of poor clinical outcome and mortality among diabetic patients and that intensive treatment of diabetes and hyperglycaemia shows positive results in terms of reduced mortality and morbidity. For this reason, patients suffering from diabetes require continuous glycaemic control during hospital stays including close monitoring of blood glucose and determination of suitable treatment strategies.

To support glycaemic control, REACTION partners MUG, MSG and FORTH have designed a first stage in-hospital glucose management system in close collaboration with clinical users. The result is an android-based mobile client/server application which visualises the most important measurement and insulin administration parameters and advises on the needed insulin dosage of the patient. The system is accessed through a touch screen tablet PC for easy use for nurses and clinicians at patient beds.

Measuring blood glucose, adjusting therapy and administering insulin

On a tablet PC the hospital staff can immediately access important patient data; where the patient is located, the date of admission to hospital and information about the current treatment and prescribed medication. Via the function Blood Glucose Measurement it is possible to retrieve the blood glucose value directly from the Laboratory Information System and document the measured values in the glucose management system. Physicians approve the current therapy for the patient (e.g. insulin medication, current insulin dosage, hypoglycaemia borders) using the function Therapy Adjustment. Finally, in Insulin Administration, the decision support protocol for insulin dosing suggests the needed insulin dosage of the patient based on the measured blood glucose values and food intake. No data is stored on the mobile unit, but on the backend server which also interfaces the Hospital Information System and ensures the calculations for decision support.

Different points of view concerning software

In designing the application for medical use, the challenge has been to consider a number of complex factors such as workflow requirements, usability, glucose control protocols and clinical safety. To understand the workflow and requirements, it was necessary to involve clinicians and the environment in which they work. For this purpose, a team of physicians, nurses and engineers from the Medical University of Graz, as well as engineers from the Institute of Medical Technologies and Health Management (MSG) at Joanneum Research, was established to develop the user interface design and the functionalities of the system. This proved to be a challenge since expectations to software differed considerably.

- The experiences through the iteration steps show that clinicians and engineers have very different points of view concerning software. While engineers often focus on gathering as much functionality as possible, clinicians prefer software which offers only the required base functionality but a sophisticated user interface, tailored to current workflow patterns, explains Stephan Spat, Researcher at MSG.

- A problem which has been encountered during the requirement analysis is that endusers often do not know what specific functions should be provided by a software solution. As a consequence, a paper mock-up which simulated the full system functionality on a mobile device was used as a trigger to give clinicians a preliminary idea as to how an in-hospital glucose management system, including a computerised decision

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In other news

Dissemination Events:

MIE 2011 - International Conference of the European Federation for Medical Informatics
26-31 August 2011, Oslo, Norway
MIE2011 is the 23rd International Conference of EFMI - the European Federation for Medical Informatics. The conference will cover various topics in the area of e-health, health informatics, telemedicine etc. There will also be commercial and scientific exhibitions.

MobiHealth 2011
5-7 October 2011, Kos Island, Greece
MobiHealth 2011 is the 2nd International ICST Conference on Wireless Mobile Communication and Healthcare. Partner FORTH is preparing a special session on "ICT Platforms and Technologies for the Daily Management of Chronic Diseases and the Support of the Ageing Population" with paper contributions from several REACTION partners. Three papers have been accepted: One prepared by partners FORTH, MUG and MSG titled 'A Mobile Android-based Application for in-hospital Glucose Management in compliance with the Medical Device Directive for Software', another paper titled 'Exploring new Care Models in Diabetes Management and Therapy with a Wireless Mobile eHealth Platform' by partners MSG, ALL and INJET and a third paper by FORTH titled "Developing advanced technology services for diabetes management: User preferences in Europe". Other papers are on the way.

New Project Deliverables Released:

The following deliverables have been completed:

- D1-3 Plan for managing knowledge and intellectual property (Confidential)
- D3-3 SOLIANIS Impedance Spectroscopy CGM sensors (Restricted)
- D3-5 IMM IR breadboard device (Restricted)
- D4-2 Initial data structures, taxonomies and ontologies (Restricted)

support, could look, says Stephan Spat.

Through several steps of conceptualising, designing and testing, the results were integrated into an intuitive software system based on essential, but user-tailored functionalities.

The question of safety and privacy

One challenge is to understand what the physicians need, another is to safeguard the sensitive and personal information which is being processed. A key focus in REACTION is on security and data protection. Since tablet PCs will be connected wirelessly via computer networks (WLAN) or via mobile networks, misuse of data is possible. Therefore, to prevent confidentiality breaches, security measures have been taken such as incorporating data encryption and digital signatures. In this respect, REACTION partner Fraunhofer SIT from The Fraunhofer Institute for Secure Information Technology is developing a security service application (SSA) for tablet PCs running Google's Android Operating System.

- The SSA allows the glucose management system on the tablet to confidentially communicate with the hospital system, i.e. eavesdropping on the data transmitted is ruled out. It also supports mutual authentication between the tablet user and the hospital system to ensure that only authorised personnel can access or change the medical data of patients, explains Dr. Matthias Enzmann from Fraunhofer SIT.

For authorisation the SSA will include an identity management system that allows users to maintain and manage different identities or roles depending on the context at hand. In addition, strong accountability will be provided as an option.

- This means that sensitive actions of a health professional, e.g. an adjustment of a patient's treatment or a change of therapy can be digitally signed, binding the signer's identity to the requested action. This would be similar to the paper-based case today. Keeping such records in electronic form still allows for audits as electronically ordered actions can be traced back to the person who ordered them by way of her/his digital signature. In addition, it is easier to search for electronic records, they are accessible from any place (given proper authorisation) and require less space than paper-based records, says Dr. Matthias Enzmann.

Presently, the SSA allows for confidential communication and mutual authentication, though its identity management component is not yet complete. The support for strong accountability is not implemented yet and will be added later on in the project.

Validating the prototype

The next step will be to validate the protocol for insulin dosing on paper in a clinical trial at the Medical University of Graz. Based on the results, adaptations of the protocol will be integrated into the mobile software system. According to the medical device directive for software, all development steps will be documented and tested in detail. Finally, a second clinical trial will be conducted with a fully working mobile system for glycaemic control with decision support in the clinical environment of the Medical University of Graz.

In regard to the security aspect, the further configurement of SSA will entail assessing issues like ease of use and conformance to user expectation.

The current prototype is based on monitoring patients with diabetes type 2 since it uses an algorithm (Rabbit 2) for diabetes type 2, however, plans are to use the system also for glucose management of patients with type 1 diabetes, by integrating an algorithm based on a model developed by partner BAYER.

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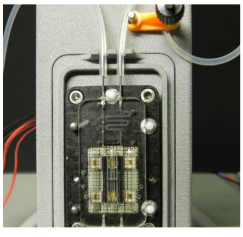
Sensor development in REACTION

An important part of the work in REACTION concerns the development of glucose monitoring sensors with no or minimal invasiveness and high accuracy.

In the first year of REACTION, focus has been on the development of sensors based on two different measuring techniques.

One type of sensor is non-invasive with measuring technique based on impedance spectroscopy. Changes in glucose level cause changes in the skin's impedance which is measured by electrodes in direct contact with the patient's skin. The second type is minimally invasive with measuring technique based on infrared spectroscopy. Using a subcutaneous micro-needle, absorption spectroscopy is performed on the interstitial liquid or blood.



The non-invasive impedance spectroscopy sensor is already widely developed by SOLIANIS. However, since accuracy of non-invasive glucose sensors typically is somewhat lower compared to invasive methods, a second minimally invasive method was investigated by partner IMM who developed a prototype based on infrared absorption spectroscopy which has been tested in-vitro.

ePatch for sensor integration

- D7-2 Concepts of trust and architectural implications (Restricted)
- D7-5 Safety issues in REACTION applications (Public)

Public deliverables can be downloaded from the project website after they have been reviewed and approved by the EC:
www.reaction-project.eu

The REACTION project is a 4-year project started in 2010. It is partly funded by the European Commission under the 7th Framework Programme in the area of Personal Health Systems under Grant Agreement no. 248590

Read more at:
www.reaction-project.eu

Another focus in REACTION is the development of a wearable ePatch which can integrate the glucose monitoring sensors and send data wirelessly to the REACTION platform. As a first step, partner DELTA developed a reusable ePatch for ECG measurements consisting of a disposable adhesive electrode and a reusable sensor unit containing a microprocessor capable of wireless communication via the ZigBee protocol.

The ePatch technology serves as the basis for sensor integration, allowing not only the integration of a glucose sensor, but also measuring other important physiological parameters, like heart rate and sweat formation, to detect hypoglycaemic events. The data can be transferred to the REACTION data server by wireless communication and fed into an algorithm developed by partner BAYER, allowing the estimation of the future glucose level and insulin dosage.

Validation, integration and improvement

Just before the end of the first project year, SOLIANIS discontinued all their activities and withdrew from the project. The REACTION partners will determine the further process for the non-invasive sensor prototype delivered to the project by SOLIANIS in addition to the continued development work on the minimally invasive sensor. Clinical validation trials with the minimally invasive prototype, which is based on an optofluidic chip coupled to a microdialysis probe, are planned to take place in the near future at the Medical University of Graz. As already indicated, future developments will also focus on integrating the glucose monitors into the ePatch as well as on improving the accuracy of the glucose monitoring sensors.

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REACTION concept demonstrator

REACTION developers have developed and presented a running demonstrator. The purpose is to demonstrate how different services and sources can be easily orchestrated into a single environment.

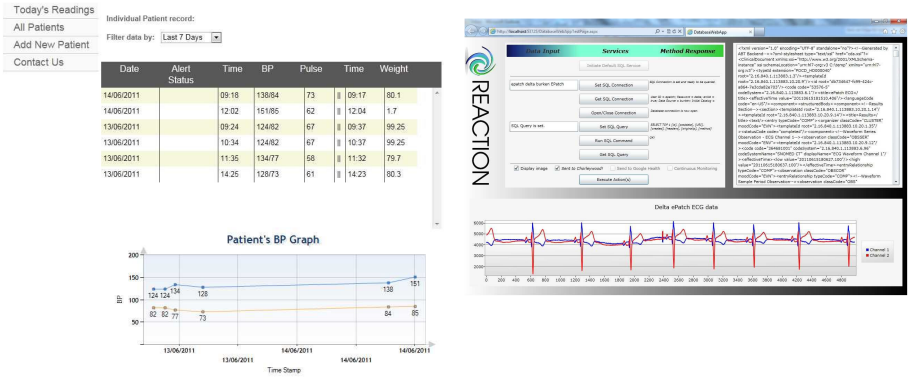
REACTION developers have built a first state-of-the-art solution prototype of the REACTION platform. The purpose of the concept demonstrator is to show the flexibility and interoperability of the platform and this was successfully demonstrated at the project review in Brussels on 15 June, 2011.

The concept demonstrator involved two persons acting as “patients” at geographically different sites with different sets of devices, a remote database at Chorleywood Health Centre with a clinician’s application for rendering data and a smart phone app for providing feedback to the patients.

Integrating devices and supporting continuous monitoring

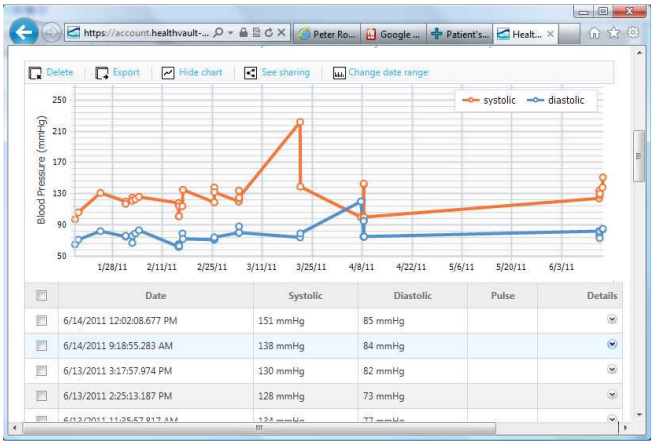
To illustrate the capability of the REACTION platform to integrate many different device types and support different protocols, one patient was measuring weight and blood pressure using Continua-certified devices and glucose level using a glucometer with a proprietary protocol. To show that the platform is capable of supporting mobility and continuous monitoring, the other patient was using a wearable ePatch equipped with an ECG sensor.

The measurements were transmitted to the remote observations database in a IHE-PCD01 message format and then displayed and rendered in different web browser interfaces for clinicians.

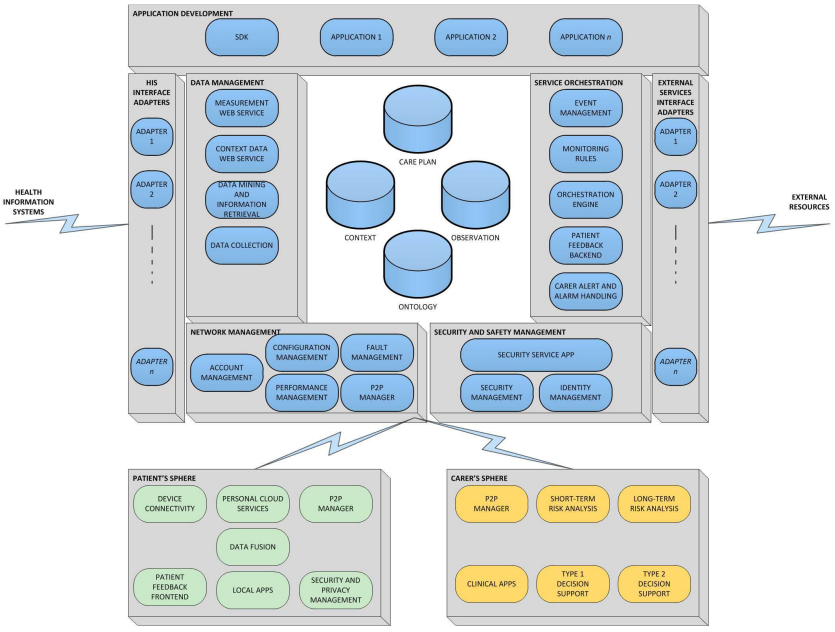


To illustrate the flexible options for exporting data, it was also shown how measurements could be uploaded to an external cloud-based health service where they could be analysed. Finally, patient feedback was

shown by sending data to a patient´s smart phone app.



Technically, the architecture behind the concept demonstrator consists of seven modules, each containing several components corresponding to different functions in the platform. In addition, there are two modules, one for the patient sphere and one for the carer sphere, establishing the remote service provision. For the review demonstration, the relevant modules were the Service Orchestration, Data Management and the Patient's sphere.



The purpose of the demonstration is to show the current software and hardware achievements. The different devices and the ePatch measure real physiological data and send it to a gateway. This gateway is in the Patient's sphere where it pushes data into a remote Observation database in the REACTION server. The concept demonstrator clearly shows how the REACTION data management and analysis of contextualised multi-parametric data can be orchestrated into a service with additional workflow and alarm management attached to it.

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