33rd Annual International Conference of the IEEE EMBS
Boston, Massachusetts USA, August 30 - September 3, 2011

Medical application and clinical validation for reliable and trustworthy physiological monitoring using functional textiles: experience from the HeartCycle and MyHeart project

Harald Reiter, Jens Muehlsteff, Auli Sipilä

***Abstract*—Functional textiles are seen as promising technology to enable healthcare services and medical care outside hospitals due to their ability to integrate textile-based sensing and monitoring technologies into the daily life. In the past much effort has been spent onto basic functional textile research already showing that reliable monitoring solutions can be realized. The challenge remains to find and develop suited medical application and to fulfil the boundary conditions for medical endorsement and exploitation.**

The HeartCycle vest described in this abstract will serve as an example for a functional textile carefully developed according to the requirements of a specific medical application, its clinical validation, the related certification aspects and the next improvement steps towards exploitation.

I. Introduction

The HeartCycle project [1] develops technologies and services for Telehealth, which is to remotely monitor and manage patients at home. A key component of Telehealth is the regular monitoring of vital signs by the patient himself. This patient self-management provides the basic information for physicians to detect trends and worsening of patients' health status and to make medical decisions. Consequently, self-measurement needs to be accurate, reliable and easy-to-use for the patients. Starting in MyHeart [2] and continued in HeartCycle, a novel sensing method based on bio-impedance measurement in combination with a textile vest has been explored. In the management of chronic heart failure patients, non-invasive bio-impedance measurement on the thorax is a candidate to detect the amount of water in the lungs of patients. Increasing water in the lungs serve as a predictor for worsening health status as it was already shown by invasive measurements with implants [3] and could enable to initiate earlier medical intervention than today.

Manuscript received March 26, 2011. The HeartCycle project is partly funded by the European Community's Seventh Framework Programme in the context of the Information Society Technologies Programme Grant agreement FP7-216695. The MyHeartproject was partly funded by the European Community's Sixth Framework Programmeunder grant agreement n°IST-2002-507816.

H.Reiter is with Philips Research Europe, 5656 Eindhoven, The Netherlands (e-mail: harald.reiter@philips.com).
J.Mühlsteff is with Philips Research Europe, 5656 Eindhoven, The Netherlands (e-mail: jens.muehlsteff@philips.com).
A.Sipila, is with Clothing:+, FI-38700 Kankaanpää, Finland (e-mail:auli.sipila@clothingplus.fi).

II. Innovative Sensing Method at Home

Clinical practice today uses a bio-impedance system composed of an electronic box and four glued electrodes which trained medical staff position at the thorax during a patient visit. The whole measurement has to be done and supervised by a trained operator e.g. a nurse.

Our new approach foresees a wearable system with textile electrodes in combination with a textile vest. The vest allows a reliable self-positioning of the electrodes on the thorax day by day. The measurement which is not supervised by medical staff is taken by patients themselves at home and takes about 10 minutes each day.

This concept was introduced and demonstrated by the European project "MyHeart" [4]. The complete patient-centric system is shown in Fig 1 and included two textile-based new monitoring modalities one of these the Bio-Impedance Monitor to assess the thoracic fluid status.

Fig. 1. The "MyHeart" system developed for early detection and management of decompensation of heart failure patients by remote patient monitoring

III. Textile –based Monitoring

A. *Design process and User group characteristics*

Appropriate textile design requires, besides classical criteria for a textile like comfort and fashion that the design also ensures the new functionality in the design process for the specific group of patients. Aspects like the placement of electrodes on the body with an appropriate contact pressure, the integration of electrical components like cables and connectors and finding a suitable position of the electronic components have to be taken into account form the very beginning. Extensive user interviews and user tests bring essential insights in needs and wishes of the patients balanced by current textile technologies available for later mass production.

Chronic Heart Failure patients are typically 75+ years old. They show all sorts of different body shapes from thin to tick as well as disease specific issues. Elderly people have their own requirements for clothing, where special emphasis has to be paid to sensitive skin, comfortability and dressing easiness of the cloths [5, 6]. In contrast to sport applications, medical textiles dedicated for elderly do not allow the use of shirts and bra solutions since dressing is a major problem in particular to pull a textile over the head and fasten small hooks. Easy-to-dress is necessary to allow accurate and repeatable positioning of the textile sensors on the body. Fig. 2 summarizes the design issues with some examples.

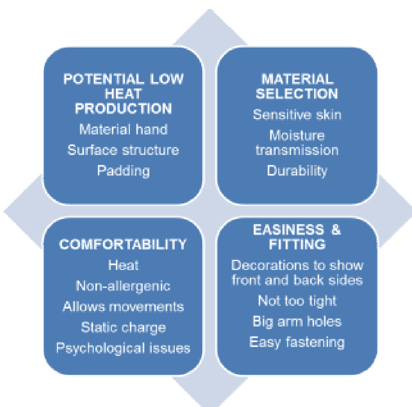

Fig. 2. Identified design issues related to the clothing of disabled and elderly people

Interviews are an essential part of the design process to identify pros and cons of possible textile embodiments. People were confronted e.g. with different closing systems like buckles, snaps, and zippers, where velcros and big buttons turned out as the most easy-to-use solutions. Breathability of the textile materials is emphasized and metals and man-made fibres is mentioned to be potential causes for skin irritation. Typically a design process has several itereations and is at the end a compromise of collected feedback and technical constrains.

B. Electrode characterization

An essential and crucial component in our system design is the right electrode to inject current or to measure body surface potentials. Ideal electrodes must have sufficient electrical properties, show long-term robustness and should not require any interaction with the end user. Easy integration techniques and low production costs can establish a mass market in functional textiles. Medical Ag-AgCl electrodes have very good electrical properties but they are normally glued to skin and use electrode paste. Therefore, this type of electrode is not suitable for the intended use case scenario.

Several electrode technologies have been evaluated in the past based on conductive rubber and conductive textile materials [7,8,9]. Significant differences of existing textile electrodes can be observed in terms of skin-electrode pressure sensitivity and skin-electrode impedance.

An unsolved problem of existing textile-based electrodes is their low performance in dry condition. This issue is of less relevance for sports applications, where the subject's sweat acts as electrolyte [8]. However, in our intended use case scenario with short term daily spot checks and a patient at rest, the patient has to apply conductive liquid on each particular electrode to reduce the skin-electrode impedance necessary for reliable measurements. This is a major source of potential wrong measurements. Dry electrode embodiments suitable for bio-impedance measurements are still an unmet need and improvements here would boost applications in using textiles in such applications areas.

C. Textile developments

Based on patient interviews and repeated usability tests we designed the first version of the washable vest within the MyHeart project shown in Fig. 3.

Fig. 3. The first version of the vest composed of a belt with four textile electrodes that can be adjusted to the vest and the bio-impedance device connected to the belt [4]

High importance was given to the adjustability of the vest to different body types as good skin contact and electrode positioning are crucial. Valuable feedback on this design was obtained in a large scale clinical validation (158 patients, 1 year trial duration).

An in-depth analysis of the first version showed many positive designs aspects of the first version like softness, lightness, easy-to-wear as underwear, and neutral color. However, few issues were identified as well related to dressing aspects and sensor placement. The ability to adjust the textile to different body shapes had to be improved and it was asked to make dressing easier.

Using this feedback new textile versions were developed and tested within the "HeartCycle" project. Fig. 4 shows different realized prototypes. We confronted patients with alternative concepts close to the first version as well as more cloth-like designs.

Fig. 4. Different investigated design concepts for an improved new vest

Finally, an integrated vest design was appreciated most, which is shown Fig. 5. It does not have a separate sensor panel anymore with the electrodes as permanent part of the textile structure. An elastic belt with an easy Velcro fastener on top of the electrode structure guarantees a good skin-electrode contact and big buttons provides an easy handling. The electronics is now located on the upper back. To give more comfort to the users, a functional knit was selected as the base material of the vest.

Fig. 5. The new "HeartCycle" vest

Based on this design, significant improvements have been made in enhanced signal quality and usability aspects. This new vest is being tested in clinical studies.

D. On-Body Electronics and Algorithms

Our bio-impedance monitor is a wearable device that is attached to the vest via an easy-to-use connector and works fully automatically with minimal patient interaction. The advanced algorithms are designed for the extraction of the medical relevant information and the trend detection.

E. Clinical validation

To be able to convince medical stakeholders, clinical validation of the monitoring solution is requested. We designed the MyHeart clinical trial with 6 clinics in Spain and Germany. A part of this 1-year trial with 158 patients enrolled evaluated the bio-impedance solution with very promising results on reliability, usability and acceptance.

F. Certification

To be able to validate our monitoring solution on patients in unsupervised situations, we provided medical certification according to medical standards and tried to exploit smart textiles for medical applications. The textile vest is considered as accessories and has to fulfil the requirements for the medical device – ISO 10993 (Class 1 – Category A). Biological safety tests are required including testing for toxicity (cytotoxicity, genotoxicity), (mechanical) skin irritation and microbial contamination (washing advice). The HeartCycle vest described in this abstract will serve as an example for a functional textile carefully developed according to the requirements of a specific medical application, its clinical validation, the related certification aspects and the next improvement steps towards exploitation.

It is a huge step from sports application e.g. Polar shirt to medical textiles with all the regulations and the needed certificates.

G. Exploitation

For exploitation the necessary steps from a textile prototype to a functional textile device have been explored in HeartCycle. Considerations for mass production of the whole textile system including assembly of tissues, electrodes, electrode materials, cables and connectors have been investigated. In addition all biocompatibility tests need to be fulfilled. An optimized design Fig. 3 is currently in further validation by patients.

IV. Conclusion

Deep insight knowledge on requirements of textile sensing technologies, on algorithms to extract the medical relevant information from these sensors, on the medical applications and understanding the needs of the usually elderly patients are needed. A close cooperation of experts from all these fields is required to provide a monitoring solution accepted by all medical stakeholders. Elderly patients as users are a challenging target group as dressing is a major issue therefore usability testing and patient feedback present an important part of the development process. Clinical testing is a prerequisite to gain acceptance and endorsement by medical stakeholders. Certification for functional textiles in medical applications requires additional efforts but functional textiles are a promising technology for e.g. Telehealth.

References

[1] H.Reiter, HeartCycle: Beyond building demonstrators. A structured approach to develop, implement and validate healthcare innovations in tele-monitoring, EMBC 2010

[2] J. Habetha, The MyHeart project: A framework for personal health care applications Computers in Cardiology, 2007,pages: 137 - 140.

[3] F. Garcia et.a. Automated Daily Transmission of Implant-based Impedance Data to Detect Intrathoracic Fluid Accumulation, DOI 10.1515/BMT.2010.191

[4] J. Habetha, H. Reiter, R. Willmann and S. Reddy, „TeleHealth improves chronic disease management of heart failure", Medica Mundi 52(3), pp 22-30, 2008.

[5] H. Meinander, M. Varheenmaa: Clothing and textiles for disabled and elderly people. VTT Research Notes 2143, Espoo 2002 (Fin). Report is written as part of the European EASYTEX project

[6] A. Sipilä, J. Muehlsteff Home-Based Heart Disease Management by New Functional Garment, Avantex 2009, Frankfurt am Main

[7] J. Muehlsteff, O. Such, Dry electrodes for monitoring of vital signs in functional textiles, 26th IEEE EMBS 2004, Vol. 26, 2212-1215

[8] J. Muehlsteff, et.al., Wearable Approach for continuous ECG- and Activity Patient Monitoring, 26th IEEE EMBS 2004, Vol. 26, 2184-2187

[9] M. Ulbrich, S. Leonhardt, Charakterisierung textiler Elektroden für den Home Care Bereich"; IEEE Workshop Medizinische Messsysteme, Mühlheim a.d. Ruhr, Deutschland, 5. Nov., 2010