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HeartCycle: Advanced Sensors for Telehealth Applications *

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***Abstract*— Current treatment of Cardiovascular Disease (CVD) – the most frequent cause of hospitalization for people over 65 – involves changes of diet and lifestyle, requiring in addition physical exercise to support these. Nowadays, patients receive sporadic feedback at doctor visits, or later on, when facing symptoms. The *HeartCycle* project aimed at providing 1) daily monitoring, 2) close follow up, 3) help on treatment routine and 4) decreasing non-compliance to treatment regimes. The present paper illustrates a new toolbox of advanced sensors developed within the *HeartCycle* project. On-going clinical studies support these developments.**

I. Introduction

Cardiovascular Disease (CVD) is the world's leading cause of death [1]. Coronary Heart Disease (CHD) accounts for half of all CVD deaths. Current treatment entails recommendations from clinicians on medication, change of diet and lifestyle. Unfortunately, patients receive feedback only at doctor visits or when facing symptoms.

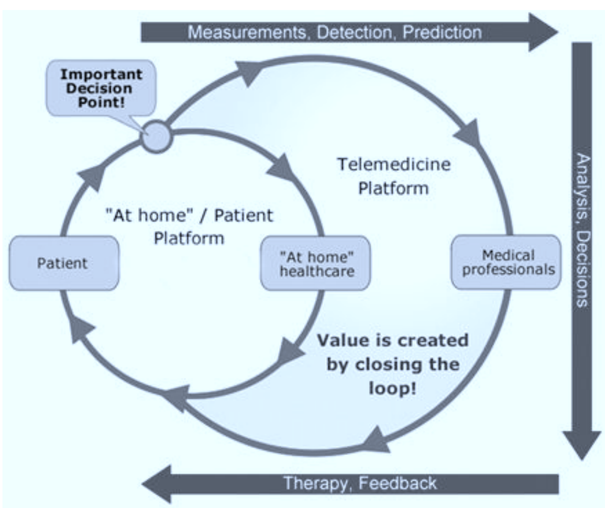

Figure 1. Compliance and effectiveness in heart failure and coronary heart disease closed-loop management provided by *HeartCycle*.

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The *HeartCycle* project provided a closed-loop disease management solution at two levels for CHD (Fig. 1): 1) at the patient level by interacting directly with him to support his daily treatment, by providing feedback on his health status and coaching him about diet, lifestyle, exercise and importance of adherence to the prescribed medication (non-compliance to the treatment regime being a major cause of suboptimal clinical benefit), and 2) at the medical level by bringing multi-parametric monitoring of vital signs, analyzing the data and providing automated decision support, in order to derive therapy recommendations.

II. Method

Starting from the application point of view, the *HeartCycle* system was designed and implemented as an integrated platform consisting of a toolbox of motivational tools and novel vital sign monitoring technologies.

A. A set of motivational tools

State of the art treatment methodologies are not able to create reliable and enduring treatment compliance. Current solutions are complex, as well as impractical and diverse, and not patient specific [2].

HeartCycle developed a motivational tool to interact with the patient. It helped the patient adhere to the medication and to adopt necessary changes in lifestyle, by providing personalized information about his health status, his progress in the management of his disease and by keeping him in contact with his physician and caregivers. The tool makes use of the information provided by the sensors, extracts high level information and provides feed-back.

B. Novel vital sign sensing capabilities

Vital sign sensing was a technology objective of the project, aiming at enabling measurements relevant for the *HeartCycle* application using methods that are easy-to-use by the target group of CVD patients. The following technologies, medically relevant for the application, were investigated, implemented and tested.

1) Gel-free smart electrodes

The electrocardiogram (ECG) is a key signal from which many heart parameters are extracted. State-of-the-art ECG requires gel-sticky electrodes, which in addition to be uncomfortable, require medical expertise in their placement. In addition, gel electrodes may cause skin irritation for long-term usage.

Garments with embedded electrodes have been proposed [3]-[5]. Despite their innovation, past developments turned out to be very sensitive to motion artifacts; the origin of such artifacts being the reorganization of the charges at the interface junction of the electrode with the electrolyte. In

HeartCycle, a 1-lead ECG signal from gel-less electrodes was measured. Additionally, motion artifacts were successfully diminished via signal processing routines applied on the ECG signal, and by introducing information provided by other sensors, such as a 3D accelerometer located on the electrode, and direct measurement of skin contact impedance. The latter sensor was also used for the monitoring of breathing, while the former was used to derive the activity level and to classify it. A specific electronics at the location of the electrode was developed for housing the sensing and processing parts of the new sensor (Fig. 2).

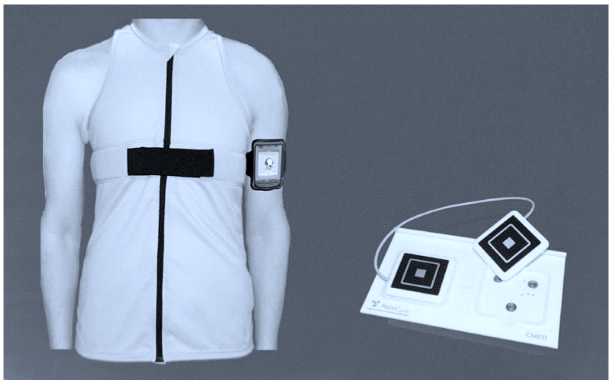

Figure 2. *HeartCycle* smart ECG electrodes, shirt and smartphone used for guided exercise.

The electrodes comprised a rechargeable battery, local processing, large local data storage (up to 500 hours of continuous logging) and data transmission over Bluetooth to a smartphone. The device automatically switched itself on when in contact with the skin (and off if too long away from skin), and recorded or streamed the data on request to the smartphone.

In *HeartCycle*, the novel smart ECG electrodes were used within guided exercise pilots: patients suffering from coronary heart disease performed exercise under the supervision of the system, according to their physician prescription, and received feedback via the smartphone worn on their arm (see Fig. 2). These smart electrodes were tested in pre-clinical trials and a small trial study (75 reference patients and 75 using the new sensor) is on-going in three European countries: Germany, United Kingdom and Spain.

2) Capacitive ECG

Compared to traditional conductive electrodes (wet, with gel), the major advantage of capacitive coupling is that there is no electrochemical half-cell potential which may vary with ion concentrations on the skin. The aim was in *HeartCycle* to make this technology wearable by integrating it within functional clothes. In addition, capacitive sensing was integrated in functional furniture like chairs [6]. The ECG signal was even measured through the cloth. In a pilot study, the results of capacitive ECG sensing were compared against ECG with contact electrodes.

3) Bed foil sensor for night use

Ballistocardiography (BCG) is a well-known research technique used for the non-obtrusive monitoring of the heart rate [7]. In *HeartCycle*, a novel BCG sensor was integrated into a bed mattress for continuous measurement during the night. A new sensor matrix with only eight channels was developed, as result of a trade-off between measurement accuracy, reduced complexity of the sensor, and optimal dimensions. Heart rate and respiration were extracted using multichannel signal algorithms. Embedded data processing was applied in order to reduce data flow and external processing needs.

Movement artifacts are the main restriction of the BCG technology. Specific signal processing algorithms were developed within *HeartCycle* in order to reduce them, and the accuracy of BCG interbeat interval (BCG IBI) measurement for sleep stages was shown [8].

4) Blood pressure and other parameters based on ECG, photoplesthymography and heart and lung sounds

Cardiac output (CO) and blood pressure (BP) are two important hemodynamic parameters that have significant diagnostic and prognostic value. CO change is the primary compensatory mechanism that responds to oxygenation demand. Currently, CO measurements are limited to hospital settings, and BP monitoring is based on sphygmomanometric occlusive arm-cuffs, which are clumsy, uncomfortable and suited only for periodic measurements. The systolic time intervals extracted from heart sounds can be correlated to CO and integrated with pulse arrival time to measure the Pulse Transit Time, which is known to be correlated to BP.

The interest in reliable detection of noise during heart sound acquisition was noticeable in the context of *HeartCycle* where people have to be monitored in their daily life and under uncontrolled environmental conditions. In this context, (i) the best combination of heart sound features, and (ii) their collection site were investigated to assess the most reliable method to estimate CO and BP. Furthermore, a novel data fusion approach was developed combining Pulse Transition Time features as well as heart sound features [9]. The sensor and signal processing algorithms were evaluated for assessing important cardiac variables such as contractility and cardiac output.

5) Thoracic reflective oximetry

Pulse oximetry (SpO_2) measures the oxygen content of arterial blood using photoplethysmography. As such, it is a key parameter of the cardio-pulmonary function and is routinely assessed in clinical environments. However, SpO_2 sensing is subject to motion artifact. As a matter of fact, the current technology measures SpO_2 by transmission at the fingertip or the earlobe, diminishing patients' comfort when used out of the clinics.

The interest of other locations than the fingertip was obvious in the context of *HeartCycle* where people have to be monitored in their daily life. A sensor located at the chest represented an important improvement in this context. However, the chest is a location more challenging than the finger phalanx. The signals from the chest are extremely weak and necessitated advanced multi-parameter de-noising technique. The assessment of the approach required the development and realization of a specific sensor, including the development of suitable signal processing algorithm to characterize and test the sensor for *HeartCycle* application. Fig. 3 shows the vest used to comfortably carry the multi-site sensors.

Rigid sensors were found inadequate to ensure good optical contact with the skin on the chest leading to sensing instability. Flexible sensor housing (rubber-like) and an enhanced multifunctional approach for ultra-low perfusion were tested in *HeartCycle*; note that perfusion levels at the chest are 5 to 10 times lower than at the fingertips. The sensor combined three pairs of optical channels spread over the chest, from which the oximetry data was extracted. 3D-accelerometers located close to each optical emitter-receiver were used for signal enhancement. Two textile electrodes (black squares at the bottom of the vest in Fig. 3) provided an ECG signal, also used for optical signal sampling purpose. The setup used for testing the performance of the sensor by N_2-induced hypoxia is also shown in Fig. 3.

Figure 3. Mini-vest used for thoracic oximetry (left handside), and setup during hypnoxia tests (right handside)

6) Impedance cardiography

The feasibility and usability of a novel wearable Impedance Cardiography (ICG) system for the *HeartCycle* objectives was tested using a portable ICG device (Niccomo ICG from Medis). Because of the number of needed electrodes, a textile-based solution was realized with particular care on the position of the embedded sensors and the cabling (Fig. 4).

Figure 4. ICG shirt and electrode position

The shirt ensured a good skin-electrode-contact by tight tailoring. A belt was added to improve the skin contact of the lower electrode-pairs. The other electrodes were included in the shirt collar (standard ICG electrode positions). In total, 12 different electrode positions were tested according to the morphology change and strength of the impedance signal.

7) Magnetic impedance for monitoring of respiration and cardiac activity

Like capacitive sensing, magnetic impedance sensing has the advantage of avoiding electrical contact with the body. The method detects changes in air and fluid distribution, monitoring thus the mechanical activity from the respiratory and cardiac system. The measurement of the electrical impedance of underlying biological tissue is performed by inducting small eddy currents and sensing the resulting re-induced voltages of these currents. Heart rate and heart rate variability (HRV) values are finally extracted.

The principles of inductive impedance monitoring are known for some time [10], but did not draw much attention. Single-coil and multi-coil sensor arrangements [11] were explored. Within *HeartCycle*, the technique was miniaturized in order to make the sensor wearable. The extraction of heart rate and HRV are not trivial as the magnetic impedance signal related to the lung is about 10 times larger than the heart signal. The optimal location for the coil was explored systematically. Methods to monitor arrhythmias and to asses cardiac pump function were investigated and open potential for further research.

III. Results

A. Gel-less smart electrodes

Pre-clinical trial of the effectiveness and performance of the gel-less smart electrodes were performed in Germany on 50 patients [12]. An excellent correlation between HR measured by the *HeartCycle* device and standard 12-lead ECG was found (r_s=0.97). All occurring arrhythmia were detectable (e.g. atrial fibrillation, ventricular ectopic beat). HR during exercise was evenly well correlated (r_s=0.74). These results point at the fact that the *HeartCycle* developed technology represents a significant step forward in the implantation of textile dry-electrode technology.

A trial study is currently on-going. It involves 75 reference patients treated with standard technologies and 75 patients using the *HeartCycle* sensors in three European countries (Germany, United Kingdom and Spain). The study will end in June 2013 and results will then be analyzed.

B. Bed foil sensor

Pre-pilot tests of the bed foil sensor system were performed on elderly and patients suffering of sleep disorders (28 patients) at the Sleep Centre of Tampere University Hospital, Finland. The heart rate estimated using BCG remained within 95%-interval of the heart rate from ECG signal [13]. Similar test were performed in sleep lab of Polytechnic University of Milan, Italy [14]. These results were used to setup a complete demonstration of the use case that will take place during the first semester of 2013 in United Kingdom and Spain, with a complete *HeartCycle* telehealth system and involving remote assistance and coaching by medical staff.

C. Blood pressure and other parameters based on ECG, photoplesthymography and heart and lung sounds

The results assessing the left ventricular ejection (LVET) using heart sounds are summarized in Table I. Data were obtained from two distinct groups: 33 healthy subjects and 35 patients suffering from various cardiovascular diseases [15].

TABLE I. Summary results for LVET estimation

Context	Error *(ms)* *Avg ± std*	Abs. Error *(ms)* *Avg ± std*	Abs. Error *(%)* *Avg ± std*	ρ
Healthy	1.50±16.52	12.90±10.41	4.86±3.92	0.65*
CHD	-10.44±22.79	19.28±16.02	6.46±5.37	0.78*

*Estimated values using Spearman's correlation.

The results for stroke volume are reported in Table II. They were obtained from the same study, using echocardiography as the gold standard.

TABLE II. STROKE VOLUME ESTIMATION RESULTS

Context	Error *(ml)* *Avg ± std*	Abs. Error *(ml)* *Avg ± std*	ρ
Healthy	1.99±13.17	10.53±8.13	0,62
CHD	-4.42±16.10	14.01±9.02	0,69

The overall measurement concept will be verified by two clinical studies in United Kingdom and Spain during the first semester of 2013.

D. Thoracic reflective oximetry

Reflective thoracic oximetry was tested on 20 subjects with SpO_2 values range from 84% to 100%. The study compared chest SpO_2 values to those provided by a reference fingertip pulse oximeter. Fig. 5 illustrates an example of chest sensor performance for an enrolled subject.

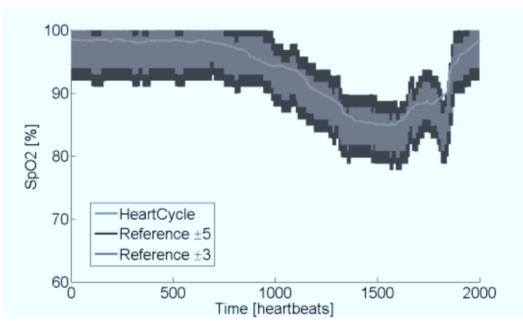

Figure 5. Thoracic oximetry compared to gold standard fingertip measurements during induced hypoxia maneuver.

Confidence intervals of ±3 digits were obtained more than 80% of the time and ±5 digits, more than 95% of the time. These results are suited with the standard requirements for oxygen saturation measuring devices (ISO 80601-2-61).

E. Impedance cardiography

As a result of the tests of the impedance cardiography sensor previously described, simulations were performed to identify and remedy to the inaccuracy of ICG to assess stroke volume (SV) for patients with heart failure. The effects of lung edema on the impedance cardiogram were analyzed by simulations using finite element method [16].

The baseline impedance (Z_0) and its maximum temporal derivative were analyzed because their relevance for calculating SV. The model itself had excellent correlation ($r = 0.94$) with measured signals. The LVET remained constant and Z_0 and its temporal derivative decreased. A decrease of the computed SV according to the standard algorithms and models could explain the inaccuracy of ICG used on heart failure patients [17].

IV. DISCUSSION AND CONCLUSION

HeartCycle aimed at research, develop, and validate innovative improvements for the next generation of tele-monitoring systems. To deliver accepted results, *HeartCycle* conducted validations implementing the proposed sensor solutions in patients' homes and showed the effectiveness of the proposed innovations. The aim was to demonstrate that the technical monitoring and user interaction solutions could be used by patients with minimal medical assistance in their homes, not compromising quality of health care delivery. To be accepted by the medical community, it is very important that the *HeartCycle* sensors deliver reliable measurements in order to perform health status assessments that medical professionals can base their decisions on. This is a prerequisite for closing the loop and enabling efficient healthcare and cost effective disease management.

The advanced sensors that were developed showed the suitability and sometimes limitations of these techniques for home use. They offer opportunity for new approaches for the treatment of CHD patients, where the patients are in the closed-loop disease management and where telehealth is used to support it.

REFERENCES

[1] C. Mathers and al., *Global Health Risks, Mortality and burden of disease attributable to selected major risks*, WHO 2009, pp. 2-18

[2] A. Wilson, *The issue of patient non-compliance: response to a costly health problem*, white paper.

[3] M. Pacelli, G. Loriga, N. Taccini, R. Paradiso, "*Sensing Fabrics for Monitoring Physiological and Biomechanical Variables: E-textile solutions*", Proceedings of the 3rd IEEE-EMBS, International Summer School and Symposium on Medical Devices and Biosensors, MIT, Boston, USA, 2006.

[4] J. Luprano et al. "*Combination of body sensor networks and on-body signal processing algorithms: the practical case of MyHeart project*" Wearable and Implantable Body Sensor Networks, 2006. BSN 2006 International Workshop, IEEE, 2006

[5] E.P. Scilingo, A. Lanata, A. Tognetti, "*Sensors for Wearable Systems*", Wearable Monitoring Systems, Springer, 2011, pp. 3-25

[6] L. Gourmelon and G. Langereis, "*Contactless sensors for surface electromyography*", Proc. of the 28th Annu Int Conf IEEE Eng Med Biol Soc, pp. 2514-2517, New York City, USA, 2006

[7] E. Pinheiro, O. Postolache, P. Girão, "*Theory and Developments in an Unobtrusive Cardiovascular System Representation: Ballistocardiography*". Op. Biomed Eng Journal 4, 2010, pp. 201–216

[8] G. Guerrero-Mora, "*Sleep-Wake Detection based on Respiratory Signal Acquired through a Pressure Bed Sensor"*, EMBC 2012

[9] J. Muehlsteff, P. Carvalho, J. Henriques J, R.P. Paiva, H. Reiter, Conf Proc IEEE Eng Med Biol Soc. 2011;2011: pp.876-879

[10] P. Trajan and R. McFee, "Electrodeless measurements of the effective resistivity of the human torso and head by magnetic induction", IEEE Trans. on Biomed Eng, vol. 15(4), 1968

[11] S. Leonhardt, A. Aleksandrowicz and M. Steffen, "Magnetic and capacitive monitoring of heart and lung activity as an example for personal healthcare", Proc of the 3rd IEEE Eng Med Biol Soc International Summer School and Symposium on Medical Devices and Biosensors, Boston, USA, 2006, pp. 57-60

[12] E. Skobel and al., *Evaluation of a Newly Designed Shirt-based ECG Rehabilitation for Coronary Artery Disease*, European, Journal of Preventive Cardiology, 2013

[13] J. Kortelainen et al., "*Multichannel bed pressure sensor for sleep monitoring*" Computing in Cardiology (CINC) 2012, Kraków, Poland

[14] M. Migliorini and al., "*Monitoring nocturnal heart rate with bed sensor*", BSI, Como, Italy, 2012

[15] P. Carvahlo et al., "*Beat-to-beat Systolic Time-Interval Measurement from Heart Sounds and ECG*", Physiol. Meas. 33(2):177-194, 2012

[16] M. Ulrich, "*Simulation of Lung Edema in Impedance Cardiography*", Computing in Cardiology (CINC) 2012, Kraków, Poland

[17] M. Ulrich, "*Evaluation of a Swine Model for Impedance Cardiography – A Feasibility Study*", – International Workshop on Impedance Spectroscopy (IWIS) 2012, Chemnitz, Germany