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Designing for Reliable Textile Neonatal ECG Monitoring using Multi-Sensor Recordings

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***Abstract*—When designing an ECG monitoring system embedded with textile electrodes for comfort, it is challenging to ensure reliable monitoring, because textile electrodes suffer from motion artifacts and incidental poor signal quality. For the design of a comfortable monitoring system for prematurely born babies in the Neonatal Intensive Care Unit (NICU), we propose the concepts of 'diversity measurement' and 'context awareness' to improve reliability. Clinical multi-modal sensor data was collected in the NICU with the Smart Jacket connected to a state-of-the-art amplifier. We found that the ECG signals quality varied among sensors and varied over time, and found correlations between ECG signal, acceleration data, and context, which supports the feasibility of the concepts. Our explorative system level approach has lead to design parameters and meta-insights into the role of clinical validation in the design process.**

I. INTRODUCTION

PREMATURELY born babies are admitted to the Neonatal Intensive Care Unit (NICU) where their vital signs are monitored 24 hours a day. Continuous monitoring includes recording of the electrocardiogram (ECG), temperature, blood oxygen saturation (SpO2) and respiration, which are crucial for early diagnostics and accurate treatment. Currently, monitoring systems require numerous wired sensors patched to the fragile skin, which is uncomfortable for the baby and hampers parent-child interaction. The resulting disturbance, interruption of sleep, and lack of natural communication with parents all interfere with the babies' normal growth and development [1]. The Eindhoven University of Technology (TU/e) and Máxima Medical Center (MMC) are working towards the design of a Smart Jacket (Fig.1) [2] which will be an unobtrusive wearable monitoring system for neonates at the NICU specifically designed for during the time parents hold the baby on their bare chest (called Kangaroo care). Earlier design work on the Smart Jacket [2] showed there is a trade-off between comfort and reliability: Although textile electrodes offer more comfort, they are less robust due to poor skin contact and sensitivity to motion artifacts. These problems are also described in other studies, such as wearable ECG monitoring for athletics, elderly and (premature) babies [3-6]. Our proposed concept to improve reliability originates from the field of signal processing. It was inspired by the observation that the signal quality is greatly influenced by the amount of pressure applied to the textile sensor, depending on the posture of the baby. Therefore, when there is a redundancy of electrodes, there is a chance that there are always electrodes in good contact, which can be selected depending on context. We ask whether a redundancy of electrodes combined with sensor selection based on contextual information can lead to a more reliable and comfortable monitoring system design. The term 'context awareness' is defined in the field of signal processing as: *"Detecting a user's internal or external state. Context aware computing describes the situation of a wearable or mobile computer being aware of the user's state and surroundings, and modifying its behavior based on this information"* [7]. A relevant example is a mattress called BiSense [8] which monitors ECG and respiration by selection from redundant electrodes and application of context awareness; electrode selection is trigged by detection of motion. This system, and systems similar to it, faces robustness challenges when applied in the 'real' world. In case of the BiSense, the location of the accelerometer results in false motion detection, there is low correlation between artifact and sensor input and there are problems with accuracy in morphology of the ECG complex. This is where our multidisciplinary approach from the field of Industrial Design could contribute to the creation of a reliable monitoring system, by considering the complete system and exploring the fundaments on which design decisions are made affecting inter-disciplinary elements.

Fig. 1. Neonatal Smart Jacket

In this paper we explore the following question: Is it feasible that diversity measurement in combination with context awareness will lead to the design of a neonatal ECG monitoring system with textile electrodes that meets the

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standards for neonatal monitoring, and if so, how to design such as system? For feasibility 3 criteria must be met: Reliability (1): At all times there is at least 1 textile ECG signal that is just as good as the signal obtained by gel electrodes (golden standard). Diversity measurement (2): The signal quality of electrodes is not simultaneously affected by a single source of disruption and depending on context the electrode containing the best signal varies. Context awareness (3): a strong correlation exists between signal quality and contextual information, enabling optimal signal selection based on context. In this paper the multi-sensory system and experimental design are presented to demonstrate our approach. Clinical experiments with the Smart Jacket prototype on premature babies at Máxima Medical Center, the Netherlands were carried out to measure multi-modal data with textile electrodes, video and acceleration sensors.

II. Design of the System for Data Collection

Data in different modalities was collected simultaneously under various conditions that are common in the NICU. The multi-modal sensors consisted of textile electrodes (1 set electrodes on the back (RA3, LA3 & LL3) and 1 set on the front (RA2, LA2 & LL2), gel electrodes (1 set on the front (RA1, LA1 & LL1) plus a GND and reference RLgel), a 3D-acceleration sensor (ACM) and 1 video camera, as setup in Fig.2. The varying events were sleeping in the incubator in 3 positions, baby motions and external motions.

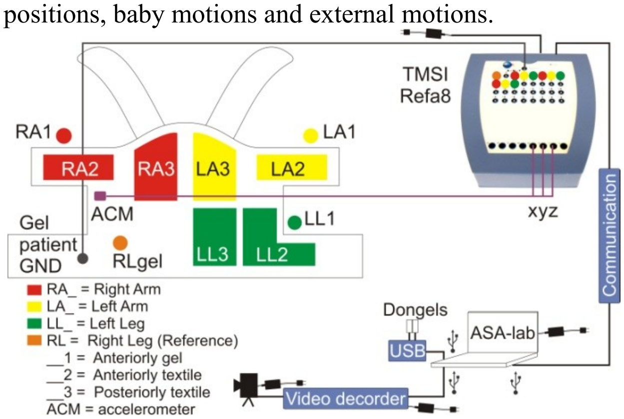

Fig. 2. Setup of multi-modal data collection

A. *Prototype, amplifier and software*

The prototype is an adjusted version of the Smart Jacket with integrated textile electrodes for ECG [2], to which a 3D-ACM from TMSI, Enschede, the Netherlands, is added (Fig.1). The new prototype comes in 2 sizes: M (waist 36-45 cm, 2200-3400 g.) and S (waist 27-34 cm, 1800-2200 g.). Silver textile electrodes are selected for data collection because these are hypoallergenic and did not considerably change properties after a few washing cycles. The electrodes are sized 80 mm x 40 mm because in these dimensions they have previously provided a stable ECG signal with low noise when the baby laid on them. The TMSI Refa8 amplifier in combination with the ASA-lab 4.7.3 software by ANT, Enschede, the Netherlands, was selected, because it enabled the safely collecting and reviewing of multiple unipolar ECG channels, 3D acceleration and video simultaneously. The Refa8's also offers high precision and modest filtering compared to clinical monitoring equipment. Unipolar ECG recording was chosen because it offered freedom in creation of leads (montages). The Refa8 amplifies the individual unipolar channels against a virtual reference (the average of all channels) and since the 'average' is present in both unipolar channels, after montage it is in theory eliminated. The signal quality of the textile channels may be lifted because the Refa8 amplifier uses a principle for common mode rejection that depends on the patient GND's gel electrode's skin contact. The sample frequency was set at 512 Hz based on the Nyquist-Shannon sampling theorem: The sample frequency must be minimally twice as high as the frequency band in which the ECG information lies. The American Heart Association (AHA) [9] states *that "the QRS complex of infants often contains important components as high as 250 Hz"* and uses this value for the standards of diagnostic 12-lead recording. Therefore, the sample frequency of 512 Hz was more than sufficient for neonatal monitoring. For the removal of undesired frequencies filters were applied, with carefully selected cutoff frequencies to preserve the ECG's valuable frequency components: (a) a notch filter was set at 50 Hz for use within Europe. (b) For the high pass filter a Butterworth filter with a 1.5 Hz cut off frequency was chosen, based on: *"The heart rate in beats (cycles) per minute (BMP), when divided by 60 (seconds per minute) forms a lower bound for the frequency content in Hz"* [9]. The HR of a new born usually lies between 100 BPM and 160 BPM (corresponding to 1.6 Hz and 2.7 Hz) therefore, the cutoff frequency value of 1.5 Hz just outside the HR frequency range is chosen for removal of electrode offset and baseline drift. (c) The TMSI Refa8 amplifier [10] contains a low pass digital FIR filter with a cutoff frequency of 0.27*sample frequency= 138.24 Hz (d) For reviewing purposes in this study, a low pass Butterworth 70 Hz filter was applied.

B. *Subjects and analysis of risks*

Data was collected with 4 prematurely born babies. The recording durations varied from lasting minutes, up to a few hours. Stable prematurely born babies at the pediatrics department were selected as subjects, because neonates admitted at the NICU require certified monitoring that might interfere when connected simultaneously with the Refa8. The babies varied in age from 35 weeks and 5 days to 37 weeks and 4 days and in weight from 1934g. to 2276g. A safety analysis of the data collection setup was performed involving clinical physicists, a hospital hygiene and infection expert and a neonatologist. The setups stood the leakage current class 1 CF test, the prototypes had been cleaned according to hospital standards and stood the allergy test [11]. Furthermore, a medical staff member was present during the data collection. Permission was obtained from the parents and the MMC ethical commission approved the clinical testing.

III. CATEGORIZED RESULTS

A. Morphology alternative electrode locations

For reliable health monitoring the morphology of the ECG must contain complete and accurate information that is interpretable by medical professionals. For diversity measurement it is beneficial to have a high number of channels around the body that flexibly can be combined in montages. Posteriorly ECG monitoring however is unusual, except from in hospital practice e.g. when a baby repeatedly pulls the wires, which is why we looked into its effect on the ECG morphology. The '3-electrode bipolar lead system' (RA, LA and LL, providing I, II, III) is standard in NICU departments. The standard derivations according to the Einthoven triangle are constructed as following: I = LA – RA, II = LL – RA and III = LL – LA. A standard for posteriorly ECG monitoring was not found. Fig.3 shows the 3 derivations collected with the gel electrodes anteriorly (first), the textile electrode anteriorly (second) and textile electrodes posteriorly (third). The textile anteriorly recorded leads correlate well with the gel leads, however the textile posteriorly recorded leads deviate and contain smaller amplitudes. The deviation of the signals recorded posteriorly is most likely due to the fact that electrical signals for the heart activity propagate through the bio-electrically inhomogeneous body tissues and observe the heart vector from a different angle than anteriorly. A method for validation of posteriorly ECG recording is required, because all clinical information may be present nevertheless.

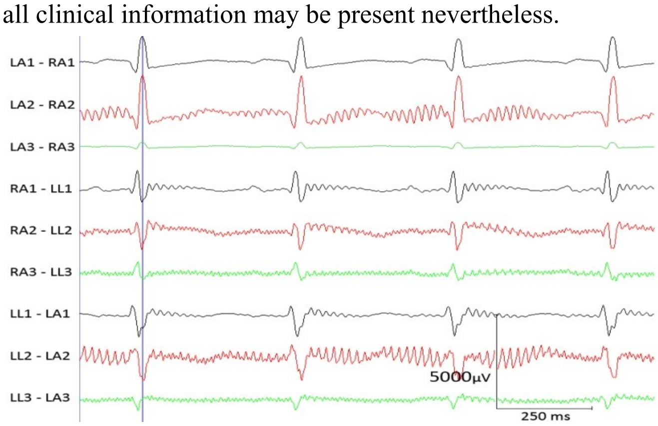

Fig. 3. ECG morphology

B. Reliability of the ECG signal

For validation of reliability, criteria 1, the aim was to compare the quantified ECG signal properties simultaneously collected by textile leads to gel leads, using the following techniques: A comparison in robustness by calculating the percentage of corresponding (within a tolerance) heart rate (HR) values. Secondly, comparison of the amount of noise, by comparing the signal noise ratio (SNR) [12]. The downside of a comparison is that when the presence of the control affects the experiment recording, a quantitative comparison becomes ineffective: In our recordings the presence of the gel electrodes together with textile electrodes caused flat lines. For validation an absolute standard is currently not available for use: Companies' methods are not public and the algorithms available are mainly constructed for reliability of HR peak detection in adult ECGs [13]. From plain observation of the measurement data, it is concluded that the textile electrodes generally were less constant in signal strength than gel electrodes, were more sensitive to motion and contained more noise. However, after selection and filtering, the ECG signal quality was just as good as the gel electrodes. Based on these observations the textile channels show potential for reliable monitoring.

C. Signal quality related to context and diversity

We looked for diversity in signal quality, and for correlations between signal quality and contextual information. The 3D-ACM on the right chest and video provided contextual information. To gain insight into how single channels are affected by context, ideally the 'average' signal should be removed from the unipolar channels, creating a 'mono-polar' channel. Since the RLgel channel contained little cardiac signal, it was suitable for creation of mono-channels. We reviewed video together with the mono-polar ECG signals in ASA-lab. The unipolar channels were observed to vary in sensitivity to motion and noise, between electrodes and over time: e.g. a motion event did not affect all textile ECG channels. The 3D-ACM sensor detected motion well that affected the ECG, such as the baby's torso, arm and leg motion. We observed strong correlations between ACM data, ECG measurements and the contextual information, of which the hiccups were a good example. Recognizing hiccups as the cause of an artifact can be used to prevent false alarms. Fig.4 shows another usual phenomenon: after a motion event, the signal quality (SNR and sensitivity) changed. Therefore, a 3D-ACM located on the right chest could be an excellent trigger for an electrode selection process. The correlation between signal quality in an electrode location and its nearness to a motion event however was low: Motion caused artifacts in the sensitive channels and not necessarily in the nearest channel to the motion. Posture was not a good indication of local signal quality either: An obvious high signal quality where pressure was expected was not observed. On video it was unclear whether pressure was actually applied and how the weight of the blanket, arms and the torso affected this. We suggest impedance and/or pressure sensors as indicators for local signal quality, instead of motion or posture.

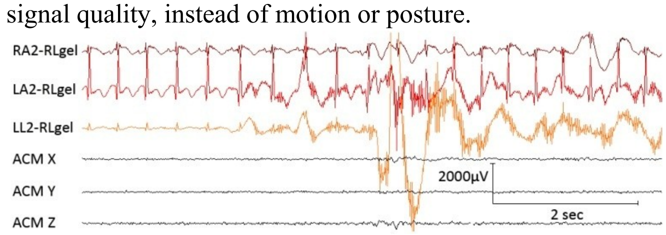

Fig. 4. Change in signal quality after motion artifact

IV. DISCUSSION

Our strategy to employ an amplifier of the highest quality such as the Refa8 and perform simultaneous measurements was chosen with the goal to avoid all unnecessary amplifier noise and other sources of variation except for the difference between textile and gel electrodes. However, the data contained multiple textile channels with flat lines, which clearly undermined criteria 1: robustness. Most likely the amplifier saturated because large DC offsets existed between the channels (AD convertor range: 300mV). Likely potential differences between the different types of electrodes and static in the textile-skin contact caused the variation in offsets. A test with the wireless bipolar ECG amplifier developed at IMEC/Holst-Centre with a MATLAB interface developed at the TU/e connected to the Smart Jacket [14] demonstrated that the silver textile electrodes did not necessarily cause inadequate skin contact: In measurements on a premature baby no flat lines occurred. In retrospect, the Refa8 appeared to not be a suitable amplifier for use with unipolar textile electrodes, because it is specifically designed to maintain DC offsets. Ad-hoc solutions for further development we suggest are: bipolar amplification, a wider AD range, high-pass filtering before amplification, one type of textile electrodes and/or coating the silver textiles with chloride. A different approach would be finding the cause for the potential differences to make informed design decisions. Recording ECG, motion and video multi-modally did turn out very useful and gave valuable insight. These modalities can be used simultaneously and cause no interference (unlike electrical measurements). We could conclude that designing an experiment for comparing an innovative design against a golden standard is more difficult than expected. An absolute standard does not exist yet and using the best equipment alongside the innovative design introduces new problems. Eventually, in the final product when regular patients will be monitored by textile electrodes with an amplifier that can handle large DC offsets these problems could be avoided, but in the validation phase we have to address them. Fig. 5 shows the essentials of the design process of this complex multi-disciplinary design. Ideally, we would like to have the complete system for exploration and validation to make informed design decisions. However, design decisions are taken already while creating a complete system. Furthermore, there are obvious limitations to the interventions in the NICU. Case specific workarounds and ad-hoc solutions are useful to gain insight, although due to the complex electrical skin contact properties any substitution of testing the complete design in a context close to the real application, won't be representative. Our approach of collecting data before building the entire system, has had the benefit of gathering design parameters as described throughout the paper. The data offers qualitative support for justifying the further development of textile electrode systems for this application. We found that the signal quality between sensors indeed varied among sensors and varied over time. We found correlations between motion artifacts (signal) and acceleration (context). For future development we suggest a wireless amplifier that handles large DC offsets, strictly textile channels, impedance measurement and the use of 1 3D-ACM sensor on the right chest for triggering an impedance measurement. The TU/e and the MMC continue the development of the Smart Jacket in collaboration with the Signal Processing Systems (SPS) group at the Electrical Engineering department (EE), working on an algorithm for multi-sensor recording with the goal of reliable and comfortable neonatal ECG monitoring. We also point out the importance of reliability as perceived by the parents, including perceived safety and *perceived* comfort. In our future 'design for parents-infant bonding' efforts, these aspects consequences on the design are the main topic.

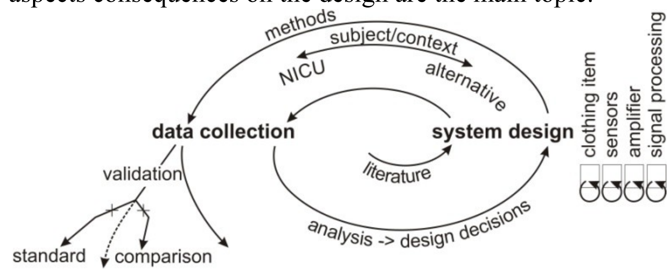

Fig. 5. Design process

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REFERENCES

[1] H. Als, *et al.*, *Journal of Developmental and Behavioral Pediatrics,* vol. 24, pp. 399-408, December 2003.
[2] S. Bouwstra, L. Feijs, C. Wei, and S. Bambang Oetomo,"Smart Jacket design for neonatal monitoring with wearable sensors", *BSN 2009*, pp. 162-167.
[3] O. Ciani, *et al.*,"Pervasive technology in Neonatal Intensive Care Unit: A prototype for newborns unobtrusive monitoring", *EMBS 2008*, pp. 1292-1295.
[4] L. Piccini, O. Ciani, E. Grönvall, P. Marti, and G. Andreoni, "New monitoring approach for Neonatal Intensive Care Unit", *pHealth 2008.*
[5] L. Van Langenhove, Ed., *Smart textiles for medicine and healthcare: materials, systems and applications*. England: Woodhead Publishing Ltd, 2007.
[6] A. Rullo, P. Marti, E. Grönvall, and A. Pollini, *Pervasive Health Conference and Workshops*, 2006, pp. 1-10.
[7] B. T. Korel and S. G. M. Koo, "A survey on context-aware sensing for body sensor networks", The Free Library, 2010.
[8] K. Niizeki, I. Nishidate, K. Uchida, and M. Kuwahara, *Medical and Biological Engineering and Computing,* vol. 43, pp. 716-724, 2005.
[9] P. Kligfield, *et al.*, *Circulation,* vol. 115, pp. 1306-1324, March 13, 2007.
[10] ANT B.V., Enschede, the Netherlands, "User manual for the physiological measurement system Refa8," 2004.
[11] W. Chen, *et al.*, *Journal of Healthcare Engineering,* vol. 1, pp. 535-553, 2010.
[12] C. Peters, R. Vullings, J. Bergmans, G. Oei, and P. Wijn, *EMBS 2006*, pp. 6092-6094.
[13] B. U. Kohler, C. Hennig, and R. Orglmeister, *Engineering in Medicine and Biology Magazine, IEEE,* vol. 21, pp. 42-57, 2002.
[14] W. Chen, *et al.*, to be presented at the Wireless Sensor Network conference, 2010.