

New monitoring approach for Neonatal Intensive Care Unit

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Abstract— The Neonatal Intensive Care Unit (NICU) represents a complex and multi-in/output context aimed at monitoring and controlling biological signals and parameters in premature newborns. This paper details some methodological and design options for developing technologies that allow end-user composition and control through new approaches that integrate wearable monitoring, pervasive and unobtrusive computing research that already are introducing new perspectives in a wide range of applications. These options enhance biosignals monitoring capabilities and provide consistent user experiences in environments where different devices, services and processes typically co-exist. In particular we describe the notion of assemblies of monitoring devices, interpreted as the combination of sensors, tools and services in a distributed monitoring environment where they interact. We report on the importance of flexibility and user control in the use of such technological assemblies in a NICU, describing a prototype and preliminary results of such monitoring system.

I. INTRODUCTION

The introduction of digital technologies into health care settings demands that specific considerations related to the characteristics of the domain, the activities that take place therein and the different skills of the diverse actors involved is taken. The continuous control and monitoring of the patients' parameters are achieved through the collaboration of medical personnel and the cooperation of individuals with specific skills, heterogeneous backgrounds and varying organizational values [1]. Emergencies require the continuous re-definition of action-plans and re-arrangement of work flows, creating ad hoc solutions for each specific situation. The use of information technologies directly impacts the way in which the different tasks are carried out within these contexts by enabling new behaviors, and supporting new practices, but also by generating new problems, i.e. what happens during a system breaks down or when any failure occurs? The possibility of anticipating the occurrence of breakdowns and of permitting the inspection of digital devices is a key issue when introducing information technologies into this setting [2]. Indeed, managing the complexity of the health care means

allowing the different users to take control of the simultaneous processes being undertaken. In this paper we describe the developmental process of new digital technologies that have been designed to support the requirements of a critical setting like the Neonatal Intensive Care Unit (NICU) [3], [4]. This work has been developed at 'Le Scotte' Hospital in Siena (Italy), within the European Project PalCom (<http://www.ist-palcom.org/>).

A. The Neonatal Intensive Care

The care of premature newborns is a complex process that involves the use of a variety of machines and collaboration among a number of people with different skills and backgrounds (i.e. neonatal doctors, nurses, therapists and families).

Admissions to the NICU generally happen in emergency situations related to problems occurring during the delivery or during the pregnancy, when the infant's or mother's health status becomes critical. The incubator is the main stage for care: the baby lives inside this micro environment, which the medical team dynamically configures to alter the temperature, oxygen and humidity depending on the baby's conditions. The machinery surrounding the incubator represents a sort of extension of the incubator that can be attached or removed depending on the baby's current needs. The medical staff configures the incubator environment in order to keep the baby's body in place, to position sensors for the monitoring of vital parameters and to intervene for specific treatments, such as intubations and X-rays. The work practice of the neonatal team is based on the continuous combination and integration of data arriving from different sources [2, 4]. In this perspective, the way in which people make sense of what is going on, and how the continuous process of understanding is supported and connections are established and maintained, are crucial.

In order to get a comprehensive and shared understanding of the work practice at the NICU, a participatory design approach has been adopted during the four years of the project. Observation, focus groups and activity modeling sessions were conducted to collect initial requirements. Data

sessions with the medical staff were organized to generate concepts, to discuss initial design solutions and to define the technical requirements of the prototype. Observation data were used as a common reference background to analyze key aspects of the activity with related requirements. Different bricolage workshops based on the assembly and integration of various technologies and devices in order to make them work in practice were performed to simulate the design solutions by reusing and combining existing technologies [5]. Future Laboratories [6] were carried out to let users test functional application prototypes as realistically as possible in a controlled environment. In this way future practices were developed in cooperation with future infrastructures, environments, applications and devices, and all these aspects were evaluated and developed in the light of all the others. Different scenarios of use were developed for defining a new incubator system. They supported the design team in their interpretation of the user requirements that emerged through fieldwork activities, and the adaptation of the concept to daily practice in the neonatal ward. Moreover, the scenarios have been utilized as a means of sharing and evaluating the design ideas in the users group [4]. Key features of the new system have emerged from the participatory design work:

1) The use of wireless technologies to remove most of the wires which are now in the incubator, thus making it easier to move the child throughout the different areas of the NICU.

2) The use of an *ad hoc* network of sensors that can be embedded in wearable devices to suit many different situations, such as the first interventions on the baby just after the delivery as well as the transportation of the premature newborns from different hospitals to the intensive care unit.

3) The integration of a specifically designed mattress, on which the baby lays, able to detect the pressure points on the baby's body. The use of this feature will prevent pressure sores and postural problems frequently arising and will permit to investigate infant's micro-movements. Tests on the mattress are currently ongoing in the hospital.

4) The medical staff imagined different uses and combinations of the data that are detected by the biosensors and other devices. For example a web cam mounted on the incubator and an EEG sensor can be assembled to study any correlation between the baby's movements and the development of the central nervous system and convulsions. The respiratory movements and body pressure detection can be correlated to study the evolution of the spontaneous breathing of the child.

As already said, preterm newborns clinical picture is compromised by incomplete maturity of different organs and apparati. Fundamental physiological parameters that should be collected and continuously monitored during the neonatal care are [7], [8]:

- *body temperature*, an indicator of thermoregulation effectiveness;
- *heart rate (HR)*, an index of cardiac functionality and stress condition of the child;
- *breathing rate (BR)*, useful to evaluate frequent apnea events;

- *percentage of hemoglobin bounded with oxygen (SpO₂)*, to assess continuously the efficiency of respiratory system activity.

The paper describes an ongoing research carried out in the NICU of the Siena Hospital in Italy. A multidisciplinary research team composed of neonatal doctors, biomedical engineers, interaction designers and therapists has designed and developed innovative technologies to support the care of premature babies. Over the last four years, a prototype platform has been developed through participatory design and constant fieldwork. It includes: the "BioBelt", a sensitized band of textile fibers with embedded sensors and transducers, which ensures an unobtrusive monitoring of the heart rate, the breathing rate, the body movements and the temperature; the "assembly browser", a graphical interface that allows the doctors to construct loose-coupled assemblies of the different devices present in the NICU, with the objective of comparing the vital parameters collected by different devices like the respirator or the pulse oximeter, obtaining a more accurate monitoring and inspecting the assembly itself. This paper includes the early results obtained through test these technologies in their actual context of use.

II. MATERIALS AND METHODS

The Incubator prototype developed by the PalCom project re-conceives the NICU as an assembly of services and devices that are able to respond to the specific requirements of the setting [1], [2], [4]. In the PalCom project the assembly is a fundamental mechanism for service coordination. A system that is constructed by means of assemblies can be inspected in a service browser, making its inner structure visible at a certain level. This gives a better understanding of the system, and is particularly important when a system breaks down. Furthermore, the assembly concept targets construction of systems from services that were not originally created for cooperation with each other. The dynamic construction and deconstruction of assemblies implies that the available services are distributed and able to discover and interact with each other. The incubator prototype is an assembly composed of the incubator itself, the surrounding machinery as well as a number of technologies developed by the PalCom project.

The standard measurement of electric biosignals (e.g. ECG) by applying the Ag-AgCl electrodes and the gel on subjects' skin, does not fit the necessity of reducing interferences on premature child and optimizing his self-regulatory competences. Novel research within the domain of unobtrusive computing and textile technology provides interesting solutions for sensors and transducers integrated in non standard supports like clothes or furniture, in a way that hides them from user perception. In our prototype we use conductive yarns to create electrodes and pathways for ECG acquisition and a textile extensometer suitable for measuring chest dilatations. They are integrated into a Biosensor belt that is described below.

A. The BioBelt

The Biosensor Belt is a sensitized band. The belt is made possible by a system of sensors inserted in the textile fiber that can be configured in combination with the parameters detected by the other machinery in the NICU, according to the specific monitoring needs of the child. In particular the biosensors belt is developed with embedded sensors and transducers for monitoring the heart rate (HR), the breathing rate (BR), the body movements (BM) and the temperature (T) [9]. Concerning the physiological parameters, the belt aims at facilitating a continuous HR, BR, BM and T monitoring with proper signal acquisition and pre-processing systems, thus ensuring an unobtrusive measurement [9], [10]. The Biosensor belt is made of cotton (recommended for neonatal and pediatric use) and lycra (to reduce contact instability by a better fitting from sensors to body). The belt is 65cm long and it is wrapped around baby's chest with two ends gently set on the cot. The belt can be adapted to fit the size of the baby and adjusted in a non invasive way to avoid the direct contact of scratchy material with the baby's skin. The tips are squeezed together with a buckle until the band fits newborn chest dimension. On the anterior side it is supplied by a pocket for external transducers. They consist of a NTC thermistor (B57550G550, Epcos, Germany) for body temperature measure and a linear accelerometer realized using Micro-Electro-Mechanical Systems (MEMS) technology (LIS3L06AL, STMicroelectronics, Italy) in order to sense movements of the thoracic wall related to newborn respiratory activity. A specification is due about the implementation of two modes of measuring respiration with our device. Respiratory patterns in premature newborns include paradoxical breathing (out-of-phase movements between abdomen and thorax) often resulting from partial or complete upper airways obstructions. Therefore a system capable of displaying both upper and lower chest areas breathing activities gives deeper information beyond breathing rate or central apnea events about the respiratory system.



Fig. 1 The prototype of BioBelt before being applied to the newborn in NICU at Siena Hospital.

Thanks to the Bluetooth® transmission system the BioBelt can wirelessly send the signals to a generic, remote position, thus offering new possibilities for the non-invasive monitoring of fundamental parameters for the child.

B. The Electronic Unit

The architecture is composed by an analogue preprocessing board able to acquire signals provided by the sensing wearable device and a transmission unit including a class II BT module to wireless transfer data to a computer standing outside the incubator. The ECG detection system complies to Holter specifications for children (providing a signal band extended to 55Hz) and was validated in previous works [11, 12]. The respiration activity circuit is a typical solution adopted in order to measure strain-gauge extension, but in this application we only need an indication of chest movement and dilatation amplitude, without requiring a calibration of both the circuit and the textile sensor. Also the temperature monitoring circuit adopted a typical hardware configuration suggested for accurate measures using thermistors, but in this case a calibration was performed comparing measures with different thermometers used in clinical practice. Results are shown in the following Tab. I.

Finally, the MEMS only required an active low-pass filtering to couple with the digital acquisition device. This latter has been implemented through a low power consumption 32-bit CPU based on ARM® architecture (STR7, STMicroelectronics, Italy), able to control both acquisition and transmission processes. The BT transceiver used was a commercial module, the PAN1540 (Panasonic, Germany). The device was designed in order to comply with the IEC 60601-1 standard for safety of medical electrical equipment.

Tab. II summarizes the signals provided by the device and their frequency band features.



Fig. 2 The electronic unit for the monitoring: it includes the analog front-end the digital board for basic data processing and the BT transmission module.

The experimental setup also implied a contemporary use of a portable pulseoxymeter (Radical7, Masimo Corp., USA) which provides beat-to-beat SpO₂ and HR measures. The neonatal photoplethysmographic probe was applied on infant foot or hand so that a typical NICU monitoring apparatus was reproduced. Co-existence of different instruments giving a non-invasive and unobtrusive measure of the same clinical parameter (e.g. HR) supports the standard redundancy inspection method which is quite recommended in such a critical environment like NICU [3].

TABLE I
TEMPERATURE MEASUREMENT:
ACCURACY VALIDATION WITH RESPECT TO A CLINICAL N1190
THERMOMETER (NECCHI, ITALY).

Temperature	Subjects			
	1	2	3	4
Belt	36.7 °C	36.5 °C	36.4 °C	36.2 °C
N1190	36.8 °C	36.4 °C	36 °C	36.2 °C
Error	- 0.1 °C	0.1 °C	0.4 °C	0 °C

TABLE I
BIOSIGNALS MEASUREMENT SPECIFICATIONS

Signal	Frequency Band
ECG Holter ¹	0.05 – 55 Hz
Breathing	<2 Hz
Skin Temperature	DC

C. Data processing

The developed QRS complex identification algorithm consists in an adaptation of the method originally proposed by Pan and Tompkins [13]. The preprocessing block has been modified in order to meet the requirements of a wearable application in terms of artefacts rejection and noise cancellation. The QRS detection algorithm incorporates adaptive thresholding techniques, searchback procedures and incremental refractory bounds. The resulting method was evaluated on the 24h MIT-BIH Arrhythmia Database showing a sensitivity of 99.88% and a positive predictivity of 99.75%.

The respiratory act detection procedure made use of the movement signal acquired by means of a triaxial accelerometer placed approximately at the level of the infants diaphragm and considering the only sagittally oriented axis. The identification process is based on a double expiratory/inspiratory peak-detection system which implements an adaptive thresholding of the steady-state tidal air estimation.

D. The PalCom node

This node is an I/O-device that functions as a bridge between existing devices in the NICU and the technologies developed by the PalCom project [3], [14].

E. The Assembly Browser

The Assembly Browser allows the neonatal team to discover, create and manage assemblies of services and devices [15]. A specific user interface has been designed to explore the assembly's features and to combine the assembly elements according to the monitoring needs of the newborns. In this way, the doctor can establish new correlations among the services and inspect the status of all the devices, both those that are running the PalCom architecture [6] and those that are integrated in the incubator setup through the PalCom-node. Indeed, in order to respond to the dynamic demands of the diagnostic work and to deal with the continuous emergencies in the neonatal ward, it is very important that devices can show their status and their affordances: i.e. make what they are doing, what they potentially may do, and what other devices they might connect. This aspect is especially critical in the case of malfunctions or system breakdowns. In those situations, in order to determine where the problem is, it is necessary to be able to see into the system, to find out what has gone wrong and how to correct the error, to visualize connections and be given an opportunity for recovering from the state of malfunction. The assembly browser allows the user to manage the dynamic configurations among the different services and devices available in the system, by providing means for inspecting the assembly and exploring the assembly's qualities. For example, the neonatal doctor can compare the values of the SpO₂ (monitored by the pulse oxymeter) with the diaphragmatic movements of the child (monitored by the BioBelt), in order to improve the monitoring of the hypoxia/apnea. This allows the neonatal doctor to investigate new correlations among the monitored values and experiment with novel usages of the existing devices.

III. RESULTS

The prototype for unobtrusive monitoring of preterms baby's biosignals has been evaluated during a session of pre-clinic trials on a group of four subjects. The children (from 2 to 12 months corrected age²) have been recruited among relatives or patients just dismissed from the NICU of 'Le Scotte' Hospital in Siena. This first testing session has to be intended as a preliminary assessment performed in a context which tries to reproduce the real clinical incubator setting. Concerning this, we submitted a proposal for an experimental study to the Italian Health Ministry that is now under evaluation, as we will discuss later.

A typical example of signals acquired through the unobtrusive monitoring system on the subjects is shown in Fig. 2 where it is possible to notice one accelerometer channel, recording thoracic wall movements during breathing, synchronized with ECG signal. The main reason of ECG wave quality depauperation is, of course, the instability of skin-belt contact due to subjects movements, notwithstanding QRS complexes could be identified for most of the records length thanks to a robust digital elaboration for R peaks detection. Moreover we can reasonably assume the problem will be

¹ Since the ECG signal acquisition is mainly directed to HR computation (HR range: 30 – 300bpm) a typical ECG Holter frequency band has been considered.

² The corrected age refers to expected date of confinement (EDC).

reduced during clinical trials on premature newborns in the incubators since they express a poor motility, especially during the first months of life.

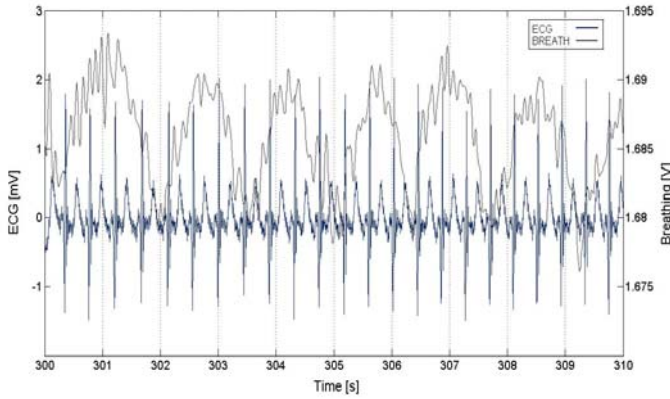


Fig. 3 An example of ECG signal and output voltage signal of the accelerometer related to breathing activity of the child.

Unfortunately the hypothesis of measuring chest dilatation through a textile extensometer running straight for all belt length failed because a useful sensor preload would have meant a too retenting bandaging of the baby. Further enhancement of the prototype is going to include an adjustment of strain gauge sensitivity in order to permit a more complete investigation of preterms respiratory system functionality.

Previously described post-processing algorithms have been applied on ECG and accelerometer output voltage signals in order to extract instantaneous HR and BR of children throughout the monitoring session. Together with the body temperature, these elements obtained by a calibration procedure of the temperature sensor, give a significant and consistent review of baby's health status. The validation protocol consisted in 15 minutes continuous monitoring with the sensitized belt and the commercial pulseoxymeter. The pulseoxymeter data were acquired via RS232 serial port of the laptop used for monitoring.

General results are shown in Tab. III.

TABLE III
RESULTS OF THE MONITORING FOR THE FOUR CHILDREN.

Subjects	1	2	3	4
Temperature [°C]	36.7	36.5	36.4	36.2
HR [bpm]	107±15	93±13	143 ±9	149 ±10
BR [acts/min]	28 ±8	29±10	42 ±7	44 ±8

Fig. 4 illustrates the pattern of HR, BR, SpO₂ outcomes from the different devices applied on one subject. Body temperature is not displayed since it is a constant variable (i.e. 36.4°C) throughout the duration of the monitoring.

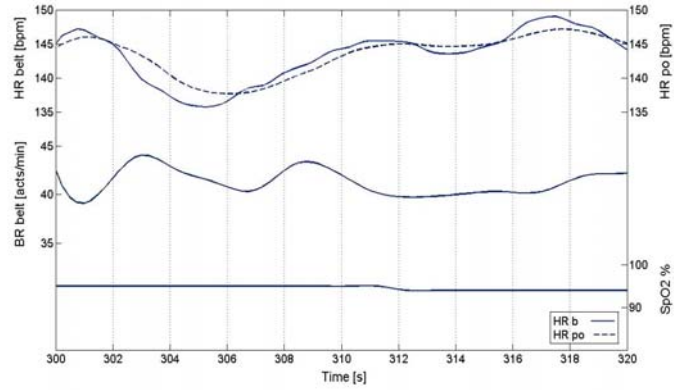


Fig. 4 An example of simultaneous monitoring via the unobtrusive prototype and a commercial pulseoxymeter. Waveforms refer to HR, provided by both belt (HR b, bpm) and pulseoxymeter (HR po, bpm), breathing rate (BR, acts/min) and oxygen saturation (SpO₂, %).

IV. CONCLUSIONS

Introducing new technologies in a NICU is a long and complex process: technological solutions are successful only if, beyond meeting functional requirements, they can be smoothly integrated in the socio-organizational context in which they are introduced. A proposal for an experimental study of the new incubator system developed by the PalCom project has been submitted to the Italian Ministry of Health and it is under evaluation by the Ethical Board of the 'Le Scotte' Hospital in Siena. The study will compare the use of the BioBelt and the Mattress with the instrumentation currently being used for the measurement of the temperature and the cardiac and respiratory frequencies, with the primary objective of assessing the use of these technologies as a non-invasive monitoring system. The study will involve a minimum of 20 newborns who are patients in the NICU and are subjected to assisted breathing or are gravely suffering. Every newborn will be followed for the entirety of its hospital stay until its transfer to the Neonatal Pediatric Unit, which corresponds with the cardio-respiratory stabilization. Furthermore since the new incubator allows the exploration, through the use of the assembly browser, of new possibilities of correlations that hopefully can improve the quality of monitoring and eventually of the care itself, the experiment will not only assess the technological dependability of the system but will also observe how the neonatal team will organize the work around the incubator by dynamically defining different configurations (assemblies) of the monitoring system where data are crossed ad hoc and confronted for a more accurate diagnosis.

The system will be also complemented by an environmental monitoring devices, i.e. the "Mattress", a mat made of a gel structure that is equipped with body pressure and temperature sensors, thus allowing the measurement and monitoring of pressure, temperature, respiration (indirect measurement from the rhythmical variation in pressure over time) and physical movements of the baby. Actually the prototype is under dry-run validation before clinical application.

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