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Extended summary

Non-contact techniques for the measurement of physiological parameters in Neonatal Intensive Care Units

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Abstract. The neonatal intensive care unit (NICU) is a department of the pediatric hospital specialized in the care of ill or premature newborn infants. NICU departments were born in the 1950s and 1960s with main aim to provide better temperature support, isolation from infection risks, specialized feeding, and greater access to specialized equipment and resources. NICU's patients are cared for in incubators or open care. Some low birth weight infants need respiratory support ranging from extra oxygen through head hood or nasal cannula to continuous positive airway pressure or mechanical ventilation. Usually in NICU public access is limited, and staff and visitors are required to take precautions to reduce transmission of infection. Today many other ancillary services are necessary for a top-level NICU. Other physicians, especially those with "organ-defined" specialties often assist in the care of these infants. In most of the cases patients recovered in NICUs has several health problems, possibility due to various illnesses. The most important thing about NICU do not make worse patient's health, through particular therapy or diagnostic devices. During the work of this thesis, the smallest patient weighed about 380 g, and he was height about 20 cm: this meaning that the NICU's patients can be small body sizes, consequently the size of ECG and EEG electrodes, infusion pumps, ventilator, thermometer, arterial catheter are relevant and can be considered extremly invasive for the patient. Moreover the direct contact with the biomedical instrumentation and with clinicians increases the risks of contagious illnesses. The possibility to reduce or minimize the contact between instrumentations and patients during the NICU's routine, is therefore of extreme interest. The main aim of this thesis it is to present a new measurement methods to assess some of the most important physiological parameters (vital signs) and to reduce the contact with the patient. In detail, the quantities to be measured are:

1. Heart Rate (HR), optically measured by LDVi,
2. Respiration Rate (RR), optically measured by LDVi,
3. Body Temperature, measured by IR thermo-camera (TC),
4. BloodSaturation (SaO_2), measured by Pulse Oximeter (PO).

Keywords. Non-invasive measurement techniques, vital signs monitoring Neonatal Intensive Care Unit, Laser Doppler Vibrometer, Thermography, Pulse oximeter.

1 Aims of this thesis

HR and RR are important values for determination of the patient status, in fact their variability shows how several is the patients' health.

Measuring HR and RR with LDVi allows to eliminate the ECG electrodes and the respiration probe. The technique consists to measure the velocity of wall-chest displacement causedby respiration and by heart rate pumping action. The measurement was operated using a LDVi pointed on the patient's skin, in the thorax area.

Third point consists to measure the skin temperature of different body districts of the patient with the aims of investigate:

- features of adipose brown tissue,
- infant's thermal comfort.

The study was made using IR TC. It was estimated the accuracy of device while measuring of infants skin, the angles, the atmosphere temperature moisture and in presence of heat source. Accuracy's study is an important step to understand if TC was able to measure small variation on infant skin. The proposed measurement method is completely without contact, allowing clinicians to reduce contagion risks and reducing the number of electrodes and probes to be directly applied onto the patient skin.

Finally we have investigated the possibility to individuate and reject fake SaO_2 data normally displayed on the patient monitor and caused by patient movement artifacts. SaO_2 fake data could cause under/over estimation of the real SaO_2 level present on the patient, causing possible wrong diagnosis and therapies. Fake data are identified through a check between the HR measured by electrical activity of the heart (II-lead signal) and PO, in case of a significant difference, the SaO_2 value is to be neglected. The good data are showed in real-time near infants in a LCD screen, in order to correctly support clinicians.

2 Oxygen Saturation

Pulmonary diseases are very common for newborns, and this is why the ventilation parameters are among the most important measurements in order to understand if lungs have a regular activity. In fact preterm lungs can undergo to an incorrect oxygen exchange, because the pulmonary tissues aren't completely generated.

One of the main physiological parameters is SaO_2, which is a relative measure of the amount of oxygen that is dissolved or carried in a given medium. SaO2 measured by PO . The main causes uncertainty of SaO2 measurement are: bad contact skin-probe, patient movement [1].

An algorithm was developed, in order to eliminate fake SaO2 data during the treatment [2]. The algorithm rejects wrong SaO2 data Real-Time and it was validated through EGA.

Algorithm reduces the uncertainty infect when it didn't use (Figure 1) the uncertainty is about 6.1 % (k = 2) while when it was used (Figure 2) uncertainty is 1.9 % (k = 2). In particular case ,when there are arterial blood samples, the uncertainty is 1.1 % (k = 2).

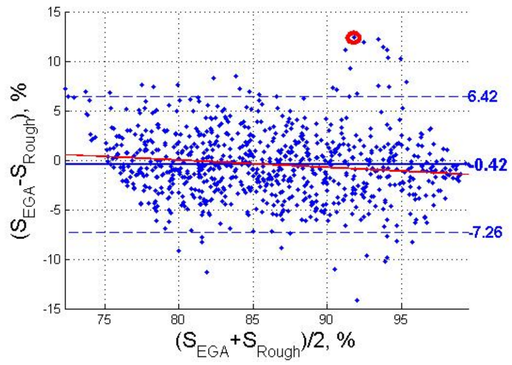


Figure 1: Bland Altman (95%) (3) of Blood Saturation data between EGA and PO (Pearson = 0.863)

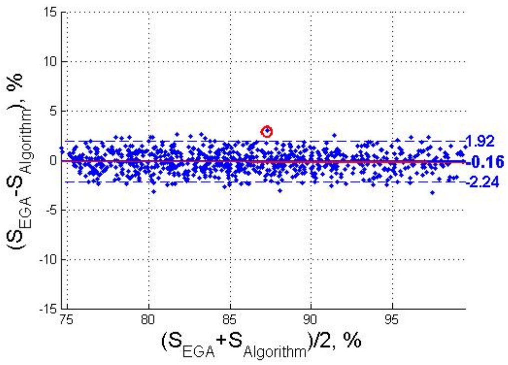


Figure 2: Bland Altman (95%) of Blood Saturation data between EGA and Algorithm (Pearson = 0.986)

The results were extracted through a specific M was used to compute data, because the data size i of 11587 hours (about 487 days). The *good* data (Validating SaO_2 data) are 88% of the total, 10166 hours, while the fake data are 9%, 1074 hours. The patient wasn't connected to MM for 348 hours due to treatments.

The usefulness of the algorithm is put in evidence also in figure 3. In this case the patient had a bad contact probe-skin from 1750th to 2900th seconds, in this period the SaO2 values were fake, while from 2900th to 3500th the ECG and PO probes weren't connected to the patient.

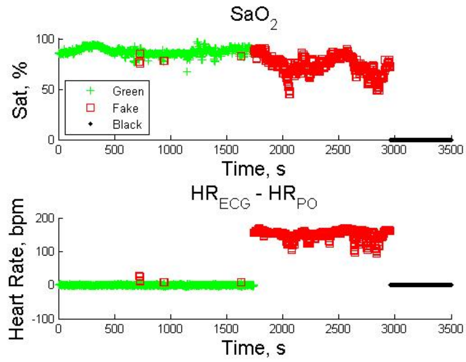


Figure 3: Exempla of how algorithm works

The SaO_2 fake data algorithm allowed to identify and to reject SaO_2 erroneous data caused by movement artifacts or momentary disconnection between the PO probe and the patient skin during acquisition.

As a first results it appears evident how, during our observation time, the algorithm shows that 12% of the time the SaO_2 data of the patient were erroneous, while 88% were good data. This could result in an extremely risk conditions not only due to the fact that during 12% of the total observation time, the patient is not correctly monitored, but also because the mean values are distorted and biased by such erroneous data, providing a distorted general idea of the patient status.

The algorithm allows to improve the efficiency of the therapy, for example, in fact sometime it reveals a big gap between the mean saturation data carried out by PO and visualized by the MM (86.7 %) and carried out by algorithm (96.6 %). This means that clinician observing the PO were able to augment the volume of the inhaled oxygen provided by the ventilator, while the correct saturation value was 96.6 %, computed by the algorithm. This is a relevant problem because the patient had no under hypoxia, but he had hyperoxia and the rising up inhale oxygen concentration could make the infant's heath worse.

Another interesting result is the good saturation data percentage, in 24 subjects the good data are 88%, while not-good data are 9% and not-connected data are 3 % of the total.

This technique is a novel approach to reduce the inaccuracy of SaO2 data provided by PO. The proposed approach can easily be integrated on the present instrumentation (we have used the data output port of the existing monitors) or even can be used to side the present systems, because it doesn't need any new hardware. To operate, the system needs only the use of a valid ECG signal which, in general, is always present for NICU patients.

3 Non-contact measurement of Heart and Respiration Rate

Continuous monitoring of vital signs like heart and respiration rate is essential for patients recovered in NICU, it is fundamental in many clinical environment such as operation. In these places is very important to observe the signals as heart and respiratory rate which are related to the efficiency of the physiological activities and in general to the health status of the patient.

There is a significant interest in non-contact measurement procedure for HR and RR; the reason is that avoiding contact with patient could be indispensable for sure, this is the case for the small, low weighted patients like the one recovered in NICU.

Non-contact measurement procedure for vital sign monitoring will be conducted by the use of laser Doppler vibrometry (LDV), that appears to be good candidates for such tasks, allowing fully non-contact measurements and optimal metrological characteristics. In, [4], the use of LDV on human skin is firstly demonstrated and is used to qualitatively reconstruct the carotid pulse wave [5].

HR and RR are computing acording to [6].

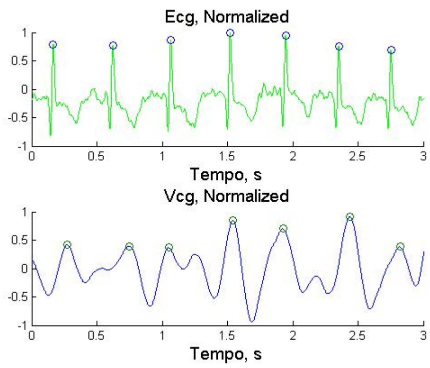


Figure 4: Exempla of HR signals

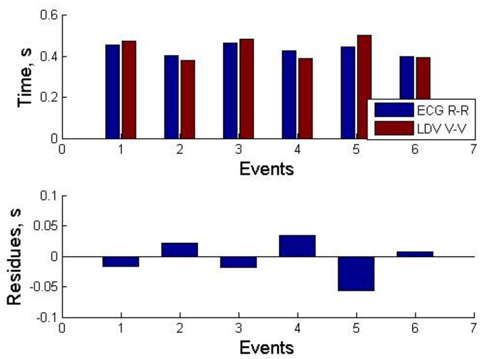


Figure 5: Correlation between HR extracted by ECG and by LDV

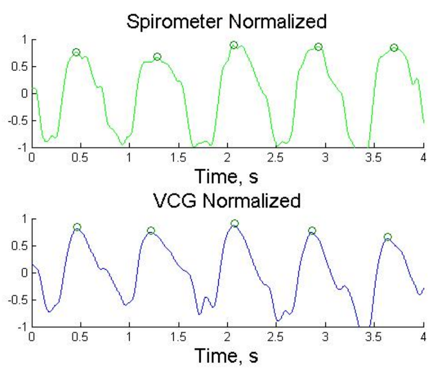


Figure 6: Exempla of RR signals

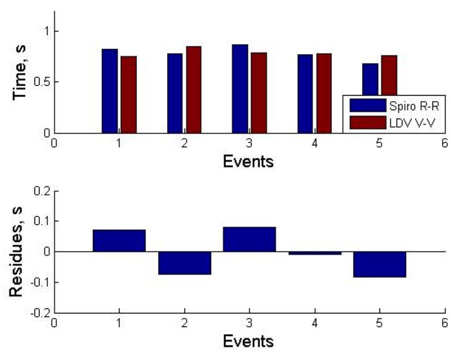


Figure 7: Correlation between HR extracted by Spirometer and by LDV

Patients under tests were 8. The HR compunting had an uncertantly of 38 ms with a coverage factor of 2, while RR computing had an uncertantly of 150 ms with a coverage factor of 2.

4 Contactless body temperature measurement

The body temperature is normally controlled by the parasimpatic system with a an high degree of control and it is maintained within specified limits in order to allow the normal body functions [7].

Thermoregulation is the ability of the body to keep its temperature within certain boundaries, even when the surrounding temperature is different. This process is one aspect of homeostasis: a dynamic state of stability between body internal environment and its *external* environment. If the body is unable to maintain a normal temperature and it increases significantly above normal, a condition known as hyperthermia occurs. The opposite condition, when body temperature decreases below normal levels, is known as hypothermia.

Therefore, we propose a novel contactless approach, based on the use of a thermocamera allowing very precise, multipoint and contactless skin temperature measurements. Data have been processed in order to provide the patient temperatures from different body parts and also to evaluate its thermoregulation ability.

Specifically, the aims are:

1. to design a procedure allowing contactless preterm patient skin temperature;
2. to propose a procedure based on the proposed measurement method able to identify patient ability for thermoregulation using different sites for body temperature assessment.

The measurement chain used to perform patient body temperature measurement is reported in Figure 8 and it is based on the use of: FLIR ThermaCAM S40, laptop PC with firewire port, Firewire (IEEE 1394) cable.

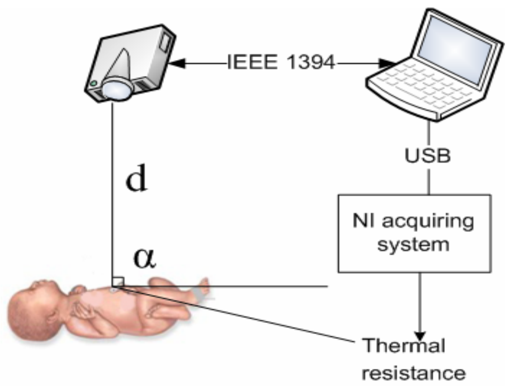


Figure 8: Experimental setup of acquiring temperature

The experiment was the application of a temperature gap at the patient while he was warmed up by radiant heat. The gap is shown in figure, the maximum I represents patient temperature that is 36.0 °C. When radiation device was switched off the skin patient was at environmental temperature that is about 24.0 °C. Temperature gap is of 12.0 °C, and this causes patient cooler and after if the patient were well than he'll thermoregulate else he'll not able to grow up his body temperature. Tests will go on as long as doctor stops the acquisition in order to do not aggravate health conditions. On average the test time is about 60 minutes. Each patient under test was monitored twice when he was were supine and twice when he was prone. In prone positions were extracted the intrascapular, hands and foot temperatures, instead in supine positions were monitored the place under liver hands and foot temperatures. Intrascapular area was chosen because under its there is brown adipose tissue, center of thermogenesis, while the liver one because the liver rise metabolic activities during a terminal shock.

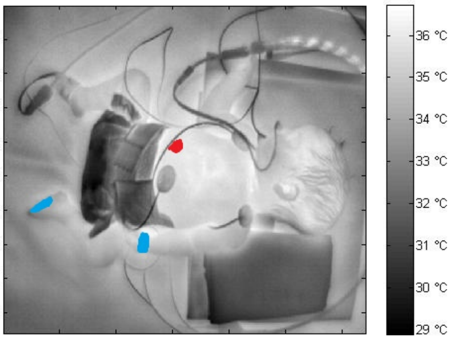


Figure 9 : Supine position

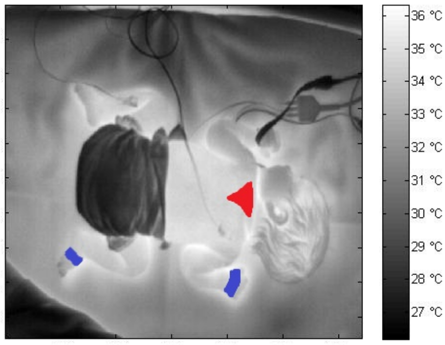


Figure 10: Prone position

Peripheral temperatures were extracted in the palm or in the back of hands and foot. The area of measurement was selected in order to have low deviation standard in all cases. The total tests are 40 and frame rate is two picture per minute. The acquisition were recorded in the night in order to not hamper the normal NICU operations.
In Figure 11 and Figure 12 are reported the temperature signals under thermal shock and their curves fitting. Central temperature decreases until the body generate heat, after rising. Instead peripheral temperature decreases, due to vasoconstriction.

Non-invasive neonatal temperature monitoring at NICU is important for healthy development of the neonates and their quality of life later on. We have proposed a novel procedure, based on the measurement method studied, able to rapidly identify NICU's patient ability for thermoregulation, which is a good indicator to diagnosis some pathologies like hypothermia, and it allows to reduce the patient's heat exposition.

The measurement procedure operates without contact and with a low uncertainty and it allows to reduce the biological and electrical risks. The approach is potentially implementable in presently used incubators or warmer cull because it only need an optical access to the patient surface. Of course for eventual diffusion of the proposed approach, simplified and dedicated sensing architecture should be studied with special regards to the possibility to operate within the incubator volume and not from outside trough open window. Modification of the transparent wall material allowing the use of NIR camera would allow their use from outside.

Wide and still unexplored are the possibilities to use the continuous temperature data collection, from different patient districts, in order to put in evidence eventual patient warning conditions (such as the over passing of the temperature of 33°C in order to reduce the intracranial hemorrhage risks), which is clearly an issue in a Intensive Care Unit.

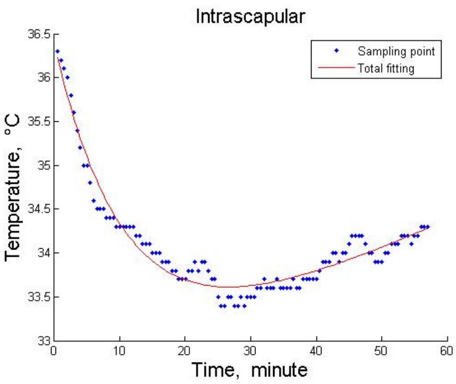


Figure 11: Typical waveform of central temperature

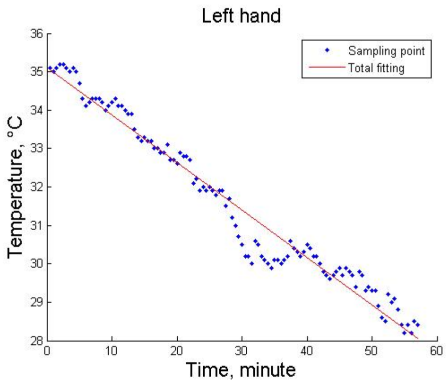
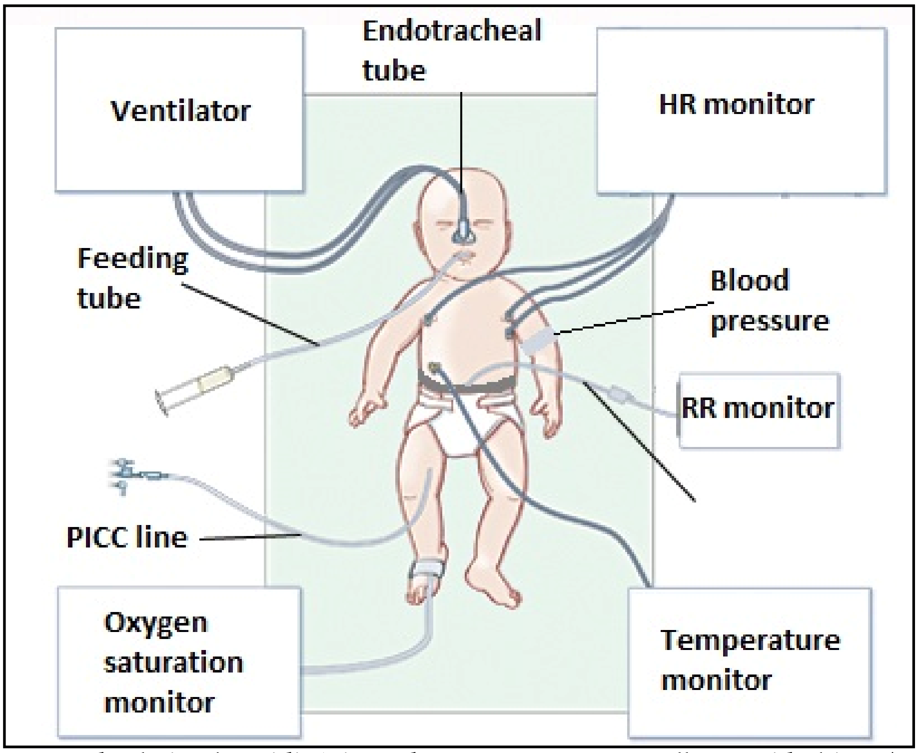


Figure 11: Typical waveform of central temperature

5 Final conclusions

The actual procedures and instrumentations for the life support and therapy of newborn patient recovered in neonatal intensive care units present an high level of invasivity. The patient needs to be monitored as an adult for what concern the main vital signs (heart rate, respiration rate, blood pressure, arterial blood saturation, partial pressure of arterial oxygen) and sometimes he also needs to be maintained in special environmental conditions



(temperature and relative humidity) in order to support or totally provide him. As a results of such clinical conditions it results that the very small patient (NICU patients weight are in the order of few hundreds of grams) is literally surrounded by transducers, cables, catheters, heaters, UV lamps, etc. Consequently the biological risks as well the potential electric risks are issue to be considered. Moreover the access to the body patient for the clinicians daily therapy as well as just the parent's contacts is limited and can be particularly laborious.

With the present work, we aim to reduce the need to measure some of the vital quantities measured from the patient using contact sensors; we have proposed new non contact (or minimally invasive in the case of the arterial blood saturation) measurement procedures which significantly reduce the "load" of the instrumentation (sensor body and number of cables) and free the incubators volume from part of them.

The vital signs on which we have focused our attention are:

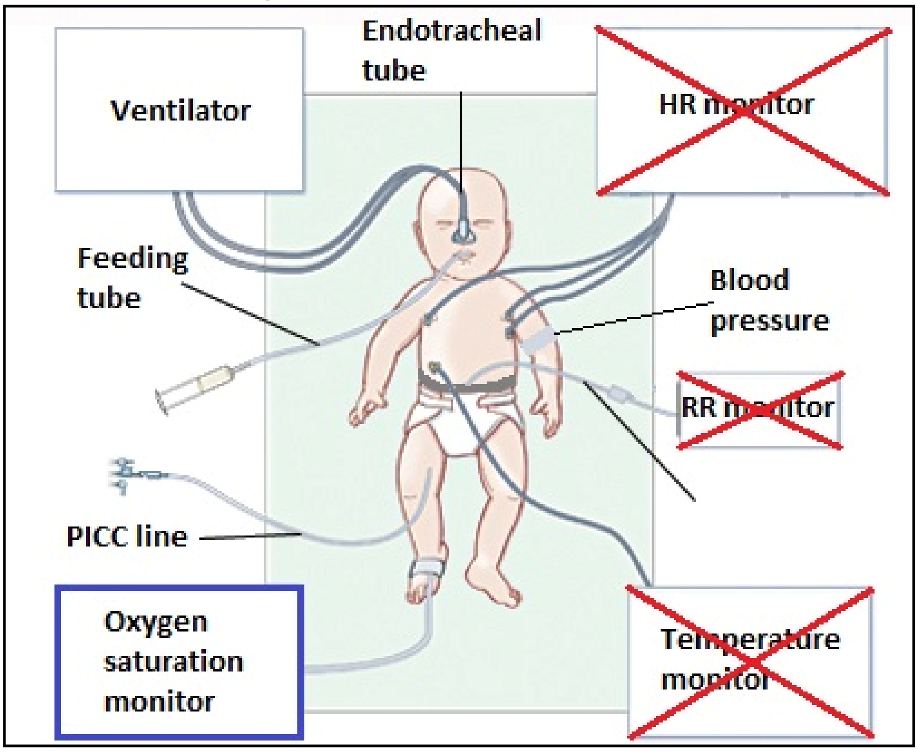
- Heart rate
- Respiration rate
- Arterial blood saturation
- Patient temperature

By means of the proposed measurement procedures, it is possible to remove from the patient 3 electrodes, one sensing belt, 1 skin transducer and 5 samples. In particular, the incubator volume could be free by the presence of 4 ECG cables and there will be not the need to place the relative electrodes too (if there are not specific requirements link to the need of monitoring the electrical cardiac conduction). The patient could also be free by the use of respiration belt and of its cable normally used for the monitoring of the respiration acts. Which is not only of difficult installation by also cause of false alarm and imprecise measurement. Also contact methods for temperature monitoring is strictly limited to needed cases because of the invasivity of the sensor (which has a relatively large dimensions respect to the patient body); moreover the sensor needs to be kept in contact with the patient skin and adhesive or belt probes are used.

The contactless measurement procedures have also the indirect advantage to allow the patient to move and provide and easier access to his body; other indirect advantages are reached in terms of reduction of electrical and bacteriological risks.

Among the measurement procedure proposed in this thesis, only the oxygen blood saturation is still operated by standard contact transducer (pulse oxymeter); in this case, the focus was mainly on the possibility to reject false SaO2 data and consequently provide an higher quality of the patient condition, especially for long term recovered patients. The proposed approach provides also the indirect advantage to have more precise SaO2 data, for such specific type of patient, to be correlated with PaO2 samples by the dissociation curves (which are different from the known adult relations). The possibility to determine such curves for preterm patients is of extreme interest allowing continuous flow of Pao2 data not possible today, being PaO2 measurement possible only by blood sampling.

Respect to the previous scheme, with the proposed measurement procedures the incubator instrumentation still required for the baby monitoring and support will be the blood pressure monitoring, the pulse oxymeter (as commented before) and the life support systems (ventilator and feeding tube).



The patient temperature monitoring and the SaO2 rejection method proposed have also the advantage to allow the collection of more detailed and larger quantities of data on patient recovered for medium and long period of time, providing a more complete overview of their condition and evolution respect time and clinical treatments. Even of not primary importance, all the proposed configurations have been designed to be fully ineffaceable with data archives and data mining systems, allowing epidemiological and statistical analysis of data (as partially shown with the SaO2 data analysis of the 24 patients over the period of time of about 487 days.

All the proposed measurement approach are, of course, to be considered as prototype with still a large possibility of improvement for what concern the implementation and the integration with the commercial devices used in this area (especially incubators). In particular, in order to face primary the metrological aspects and show the validity of the designed approaches, we have used high quality measurements transducers designed for laboratory uses, in future, if some of these idea will be implemented, simplified version of such instruments could be used and probably special design requirements will be also needed. Under this point of view, it is already possible to individuate some aspects of interest for future work:

- Simpler and smaller version of the laser Doppler vibrometer (LDVi) used for heart and respiration rate monitoring; Presently, LDVi systems explore very large frequency range (up to hundreds of kHz) which are not needed for our scope and have high sensitivities available for the user, which most of the time, are not needed.

- Reduction of the LDVi optical dimensions (miniaturization) and robustness of the algorithm for the displacement assessment also in the case of large patient movements would be of extreme importance for a possible integration of the transducer directly into the incubator and as a possible signal output to the patient monitor.
- Simpler and smaller version of thermo-camera are already available on the market, but with lower accuracy and smaller sensor array dimensions; a balance between measurement requirements and smaller (and lower price) transducer should be individuated. Also for IR thermal monitoring it could be possible to image a dedicated transducer version to be integrated on the incubator or on the thermal cull providing continuous information on the patient thermal conditions (on different part of the body).
- The possibility to determinate experimental or analytical models of the SaO2 – PaO2 relation (dissociation curves) for pre-term patients would add the present PaO2 value (which can be considered of higher importance respect to the SaO2 data) to the patient monitor.
- The continuous monitoring of known specific parameters and indicators – such for example the alveolar gradient and the oxygenation index – as well as the definition of new ones would be possible and needs further investigation.

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