Monitoring the temperature of the newborn through a wireless device with an alert system: development and proof of concept

Monitoramento da temperatura do recém-nascido através de um dispositivo sem fio com sistema de alertas: desenvolvimento e prova de conceito

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ABSTRACT

Introduction: The maintenance of the newborn temperature is one of the most relevant factors for his survival. Maintaining thermal control prevents several complications related to hypothermia and hyperthermia and reduces the chance of dying from different causes. Temperature monitoring systems are common in neonatal intensive care units. However, outside of this environment, the detection of hypothermia is still a challenge.

Objective: The objective of the study is to develop a prototype neonatal temperature monitoring system to alert thermal uncontrolled.

Method: In an observational cohort study, the temperature of 21 newborns was monitored in a conventional manner and by a new monitoring system under test. All were born with a gestational age above 35 weeks, healthy and were accommodated in a joint accommodation ward, in a public university maternity hospital. To this end, a prototype system consisting of a temperature sensor, a Wi-Fi emitter and a data collection and processing center was developed. The value measured by the prototype was hidden, as well as the warnings of thermal uncontrolled. The reliability of the temperature sensor was evaluated in an experiment that compared measurements made by the sensor with that of a conventional thermometer. In a real scenario, the temperature sensor was affixed to the skin of the newborn's infra-axillary region, the temperature being automatically measured every 10 minutes. The performance of the prototype was evaluated by comparing the episodes of thermal uncontrolled detected by the two measurement techniques, in relation to the closest pair of measures. The total set of measurements of the prototype was also analyzed. Hypothermia was characterized by temperature <36.5ºC and hyperthermia> 37.5ºC. The Kappa concordance analysis compared the results of the two measurement modes.
Results: The temperature measured by the prototype sensor and the conventional digital thermometer had an intraclass correlation coefficient = 1. In the care scenario, the average time to monitor the temperature of the newborns was 22:36 hours. The difference between the 115 pairs of measures performed by nursing in relation to those recorded by the prototype averaged 0.014 ºC (SD = 0.14). Comparing the measurement pairs, hypothermia was detected by nursing in 14 (66.7%) newborns and by the prototype in 15 (71.5%) newborns, Kappa index = 0.889. When all measurements performed by the real-time monitoring system were considered, hypothermia was recorded in 520/2809 (28.8%) measurements, while by the intermittent mode, hypothermia was recorded in 30/115 (26.8%). There were three episodes of hypothermia or hyperthermia detected by the new device, at times not monitored by nursing.
Conclusions: Temperature monitoring by a computerized system detected more thermal abnormalities than the conventional method. The developed prototype demonstrated its potential to offer continuous and simultaneous monitoring to a group of newborns hospitalized in a maternity unit.

Keywords: Infant, Newborn, Monitoring, Skin Temperature, Hypothermia, Wireless Technology.

RESUMO

Introdução: A manutenção da temperatura do recém-nascido é um dos factores mais relevantes para a sua sobrevivência. A manutenção do controlo térmico evita várias complicações relacionadas com a hipotermia e hipertermia e reduz a possibilidade de morrer de diferentes causas. Os sistemas de monitorização da temperatura são comuns em unidades de cuidados intensivos neonatais. No entanto, fora deste ambiente, a detecção de hipotermia continua a ser um desafio.
Objectivo: O objectivo do estudo é desenvolver um protótipo de sistema de monitorização da temperatura neonatal para alertar a temperatura não controlada.
Método: Num estudo de coorte observacional, a temperatura de 21 recém-nascidos foi monitorizada de uma forma convencional e por um novo sistema de monitorização em teste. Todos nasceram com uma idade gestacional superior a 35 semanas, saudáveis e foram acomodados numa ala de acomodação conjunta, numa maternidade pública universitária. Para tal, foi desenvolvido um sistema protótipo composto por um sensor de temperatura, um emissor de Wi-Fi e um centro de recolha e processamento de dados. O

valor medido pelo protótipo foi ocultado, assim como os avisos de temperatura não controlada. A fiabilidade do sensor de temperatura foi avaliada numa experiência que comparou as medições feitas pelo sensor com as de um termómetro convencional. Num cenário real, o sensor de temperatura foi afixado na pele da região infra-axilar do recém-nascido, sendo a temperatura medida automaticamente a cada 10 minutos. O desempenho do protótipo foi avaliado comparando os episódios de termómetro não controlado detectados pelas duas técnicas de medição, em relação ao par de medidas mais próximo. O conjunto total de medições do protótipo também foi analisado. A hipotermia foi caracterizada por temperatura <36,5ºC e hipertermia> 37,5ºC. A análise de concordância Kappa comparou os resultados dos dois modos de medição.
Resultados: A temperatura medida pelo sensor protótipo e pelo termómetro digital convencional tinha um coeficiente de correlação intraclasse = 1. No cenário de cuidados, o tempo médio para monitorizar a temperatura dos recém-nascidos foi de 22:36 horas. A diferença entre os 115 pares de medidas realizadas pela enfermagem em relação às registadas pelo protótipo foi em média de 0,014 ºC (SD = 0,14). Comparando os pares de medidas, a hipotermia foi detectada pela enfermagem em 14 (66,7%) recém-nascidos e pelo protótipo em 15 (71,5%) recém-nascidos, índice Kappa = 0,889. Quando todas as medições realizadas pelo sistema de monitorização em tempo real foram consideradas, a hipotermia foi registada em 520/2809 (28,8%) medições, enquanto que pelo modo intermitente, a hipotermia foi registada em 30/115 (26,8%). Houve três episódios de hipotermia ou hipertermia detectados pelo novo dispositivo, por vezes não monitorizados pela enfermagem.
Conclusões: A monitorização da temperatura por um sistema computadorizado detectou mais anomalias térmicas do que o método convencional. O protótipo desenvolvido demonstrou o seu potencial para oferecer monitorização contínua e simultânea a um grupo de recém-nascidos hospitalizados numa unidade de maternidade.

Palavras-Chave: Lactente, Recém-nascido, Monitorização, Temperatura da pele, Hipotermia, Tecnologia sem fios.

1 INTRODUCTION

The body temperature is an important component of the vital signs and one of the main clinical parameters used for evaluation and monitoring of bodily functions. In newborns, thermal control is one of the most relevant factors for their survival, as well as for the prognosis after birth [1]. The maintenance of body temperature is considered essential in the set of immediate measures of assistance to birth [2]. There are several stress conditions that can lead to internal thermal uncontrolling, exceeding the ability to maintain the temperature considered ideal for vital functions [3]. One of the goals of neonatal care is to avoid hypothermia from the moment of birth, using procedures that prevent heat loss and that maintain body temperature within the normal range. In this way, its energy is conserved for the metabolic and respiratory processes [4]. Complications associated with hypothermia include more infection

morbidity, abnormal coagulation, acidosis, late readjustment of fetal to neonatal circulation, respiratory distress syndrome [1]. In addition, hypothermia can lead to reduced cardiac output, hypoglycemia and increased duration of drug action [3, 5], as well as being related to increased mortality [6].

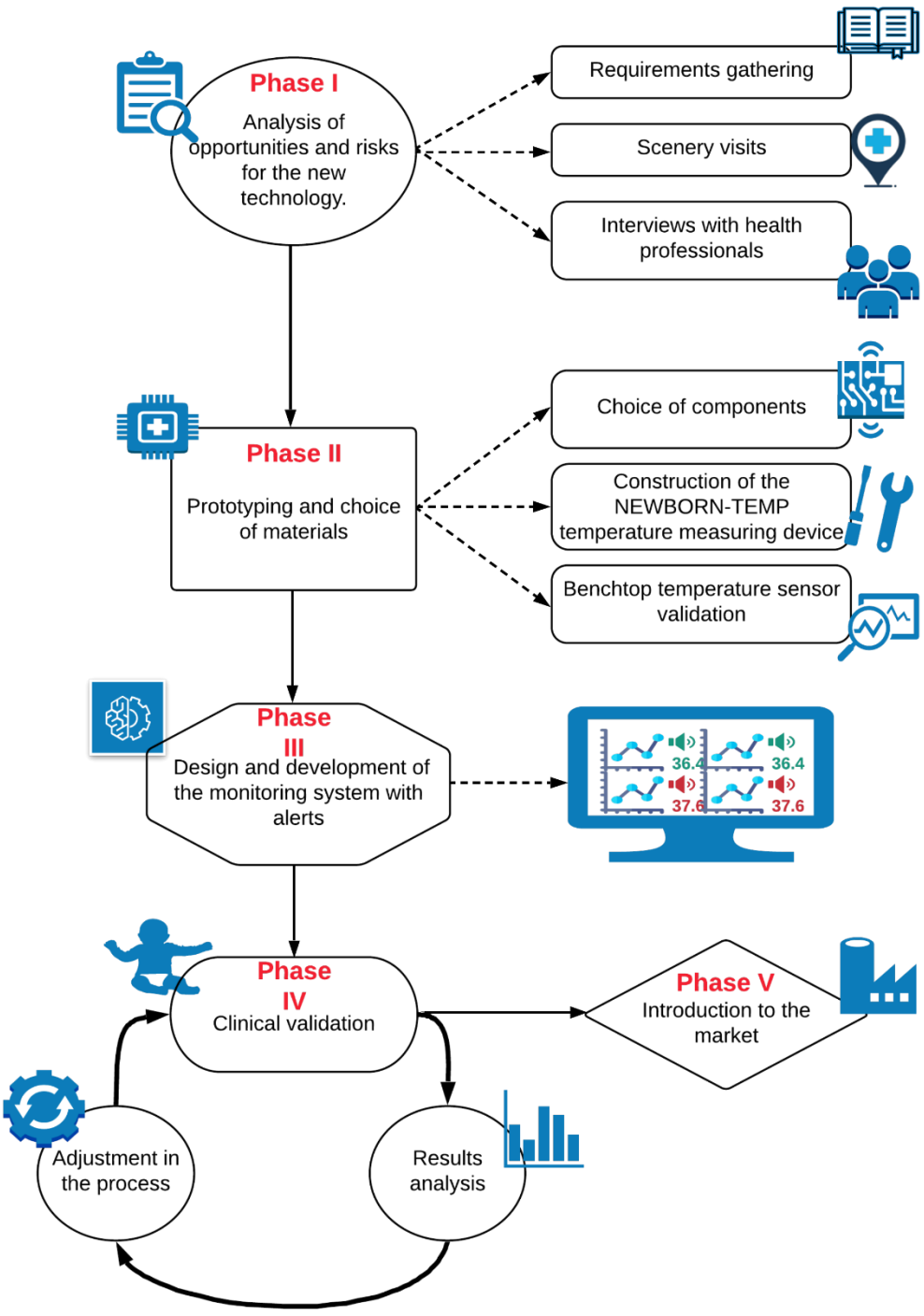
Since newborns do not communicate by speech, the systematic measurement of body temperature is an essential care for the detection of thermal uncontrolled. Sensors and integrated systems adjusted to the needs of neonates support healthcare professionals in monitoring vital parameters. In highly complex environments such as intensive care, premature or critically ill neonates need sustained monitoring with monitors [7]. These neonates are the ones who have a high risk for thermal uncontrolling and thus demand individualized care so that the appropriate treatment can be opportune, before the appearance of serious complications [5, 7]. On the other hand, those accommodated in joint accommodation with the mother are also subject to thermal uncontrolled, less frequently. For these, the standard technique is the intermittent temperature measurement by a conventional thermometer [8]. There are not many studies that have assesed the relevance of continuous temperature monitoring in such scenarios.

A vital signs monitoring system usually includes modules for data acquisition, processing and transmission, health status detection and power supply [9]. Those with alerts for abnormalities use computerization for early risk identification, sending a message to the user. In health care environments, this type of system has the potential to offer more safety to the patient, warning health professionals about abnormalities, allowing support for clinical reasoning and support for timely action, before clinical deterioration [10, 11]. The present study focuses on the neonatal care environment in joint accommodation and aims to develop and test a prototype of a computerized system for monitoring the skin temperature of the neonatal newborn on the first day of life, to alert the thermal uncontrolled.

2 METHODOLOGY

The present study is an exploratory of applied nature for the development of a prototype system which is composed of temperature sensor, signal transmission, capture software, data analysis and alerts for thermal uncontrolled. The design and construction methodology of the prototype followed the steps from I to IV, foreseen in the development of a new medical device [12], as shown in Fig.1.

Fig. 1 Stages of development of the device for monitoring the temperature of newborns



In Phase I, the system requirements were designed to be consistent with the user's needs and taking into account the newborns' own characteristics and risks. In Phase II, the choice of materials, prototyping, construction of the device and the experimental

validation of the temperature sensor were carried out. In Phase III the monitoring system with alerts was proposed, being validated in a real scenario, in Phase IV.

The set was tested in a maternity ward, evaluating its performance in a prospective cohort of newborns and monitored by the system on the first day of life. The non-invasive measurements of the skin temperature were collected continuously, processed and analyzed in comparison to the intermittent measurement, currently practiced in this care scenario. The study was carried out at a university hospital between August and December 2019. The research protocol was approved by the Research Ethics Committee of the Federal University of Minas Gerais (UFMG), CAAE registration: 61046016.5.0000.5149.

Survey of requirements for the system

The requirements survey involved the expectations of users and the needs of newborns. In order to guarantee maximum safety, effectiveness in temperature measurements and good system performance, scientific evidence from previous studies published in bibliographic bases has been raised. In addition, previous visits were made to the maternity unit and neonatal unit of the hospital where the system was implemented. Exploratory in nature, the interviews were conducted with the purpose of understanding the implementation scenario, clarifying doubts about current practices and identifying possible difficulties and challenges to introduce the proposed monitoring system. The survey of the requirements involved the choice of each element of the system, from the sensor that touches the child's skin to the way the health professional will receive alerts about the thermal variations of risk.

Prototyping and choice of materials

The choice of components prioritized the safety and biocompatibility of the materials with the monitoring by continuous contact with the skin of a newborn for 24 hours. Features such as size, resolution and accuracy, low energy consumption and cost-effectiveness have guided the selection. The system components used in prototyping are made up of a temperature sensor, data processor and WiFi signal transmitter, rechargeable battery and a monitoring center.

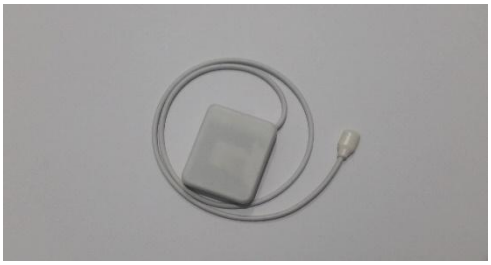
Fig. 2 illustrates the operation of the monitoring system. The temperature sensor was attached to the newborn's right infra-axillary region. The collected temperatures are sent to the data storage center, where they store and process the temperatures. A graph

with the last six temperatures collected is displayed in a browser that can be viewed on monitors, cell phones, computers, etc. ... if there is any thermal uncontrolled, an alert is issued so that the health professional can act in advance to avoid future complications.

Fig. 2 Architecture of the neonatal temperature monitoring system

Temperature gauging and transmission device

a



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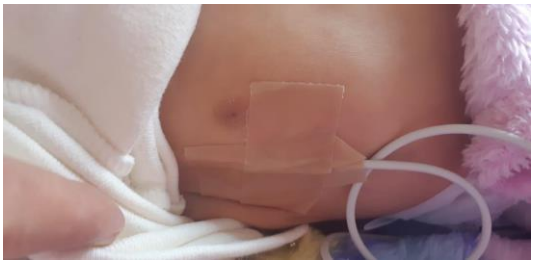
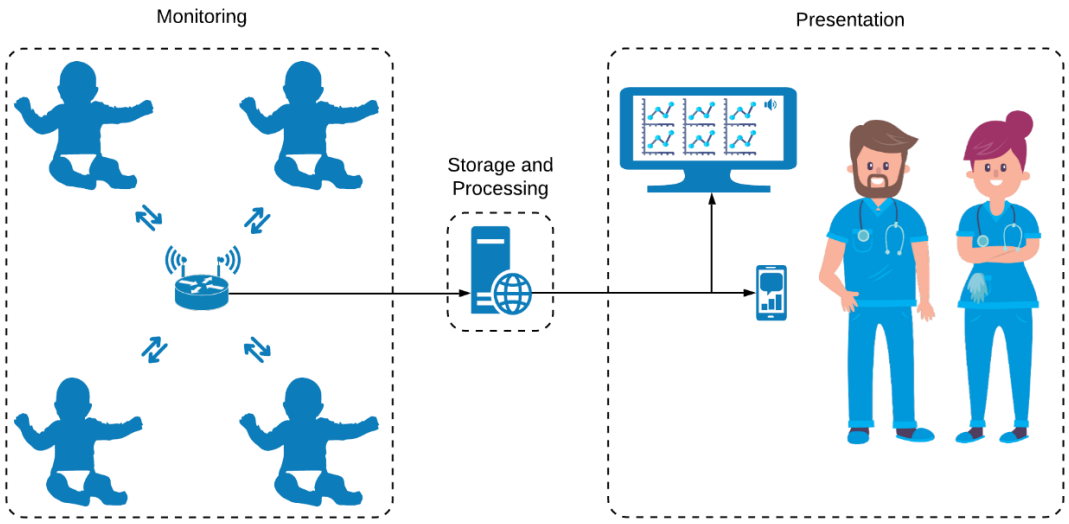
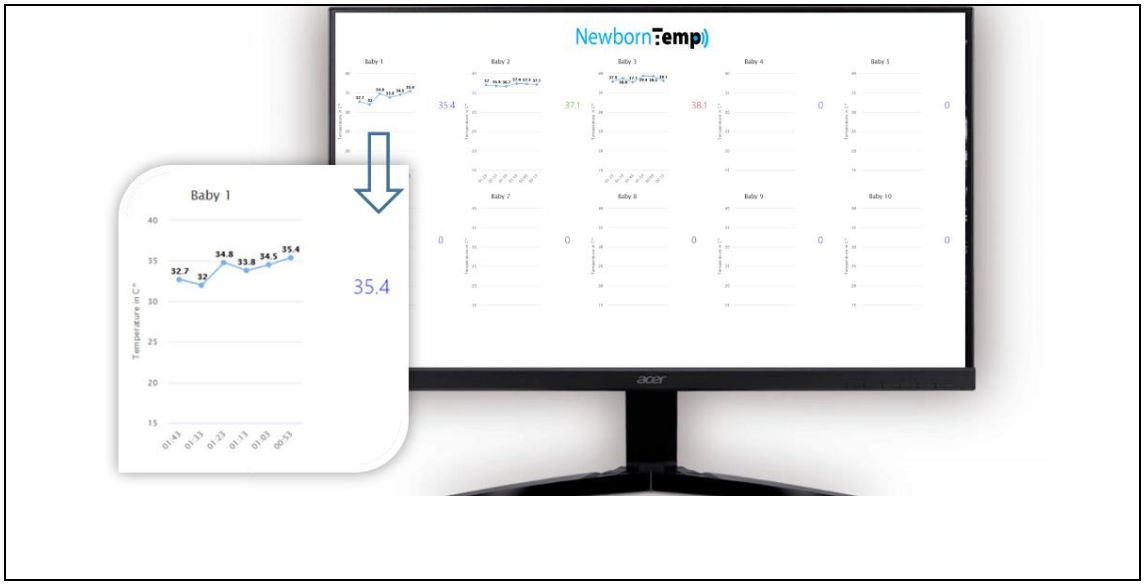


Communication system architecture



Presentation layer

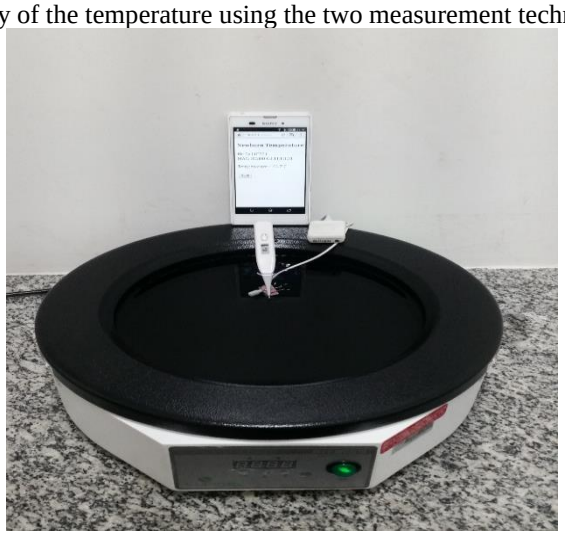
d



Temperature sensor validation

To assess the reliability of the temperature sensor, a bench test was carried out. To complete, two thermometers were submerged in a Lupetec BH 2015 histological water bath equipment (Fig. 3). One was the prototype sensor and the other a calibrated digital thermometer, of the same type used in the maternity ward. The experiment was recorded with a camera. The water was heated from 32.0 ºC to 43.0 ºC. The temperature values displayed simultaneously on the two thermometers were transcribed in a database.

Fig. 3 Standard thermometer and prototype submerged in a histological water bath to assess the effectiveness and reliability of the temperature using the two measurement techniques.



Validation of the monitoring system in real scenario

Twenty-one newborns were selected for clinical tests. Inclusion criteria were gestational age between 35 and 42 weeks, having been born in the last 6 hours. Those

whose use of the sensor by contact was contraindicated were excluded. Participation was voluntary, and it is optional for parents to remove the sensor at any time, before 24 hours of follow-up. The neonatal care routines were not modified and the monitoring was not interrupted in the case of admission to the Neonatal Intensive Care Unit (NICU). Clinical data were recorded to characterize the children, as well as the time of onset, interruptions and duration of the temperature measurement by the system prototype.

The standard care of newborns in the study setting was the measurement of the intermittent axillary temperature, with a conventional digital thermometer, every 6 hours. The values recorded in the medical record were compared with those of the prototype, forming pairs with the average of the closest measurements captured by the system. The hypothermia episodes detected by the two measurement methods were recorded and compared.

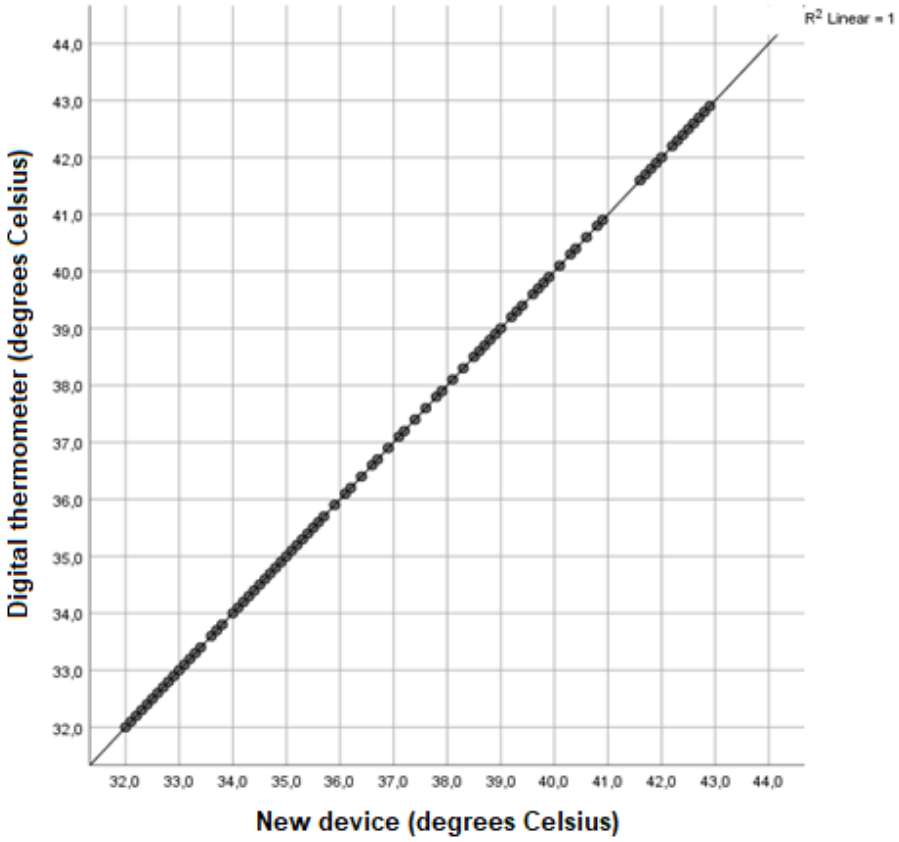
Statistical analysis

Categorical variables were described in terms of absolute and relative frequency and numerical variables by measures of central position (mean, median) and variability (standard deviation and amplitude), depending on the nature of their frequency distribution. The agreement between the measured temperature values were calculated by the correlation coefficient intraclass (ICC) and analyzed by plot of Bland - Altman [13]. The occurrence of neonatal hypothermia by the two measurement methods (conventional versus electronic monitoring) was compared using the Mc Nemar chi- square test and Kappa index. For this, the statistical software SPSS® will be used. The statistical significance of hypothesis testing will be 5%.

Results of Benchtop reliability test

All temperature values, measured by the two techniques, were coincident. The intraclass correlation coefficient between the 83 pairs of measurements recorded by the prototype and simultaneously by the digital thermometer was equal to 1. The result of the experiment was shown in Fig. 4.

Fig. 4 Reliability of the device for measuring different temperatures in relation to the conventional digital thermometer



Characteristics of newborns included in the study, according to the occurrence of hypothermia

Twenty-one newborns were monitored for an average period of 22:36 hours, minimum 05:49 and maximum 29:51 hours. All newborns were evaluated in a common cradle and only one of them was in **N**ICU N for a few hours. The abnormal temperature measured by nursing was detected in 15 (71%) newborns and hypothermia occurred in 14 (66.7%). Only 1 newborn had an episode of hyperthermia. Table 1 shows the characteristics of the newborns, grouped by the presence or absence of hypothermia. There was no difference between groups in relation to the characteristics of the newborn and the ratio at birth during the winter.

Table 1 Characteristics of newborns included in the study

	Total (n = 21)	**Hypothermia (n = 14)**	**No hypothermia (n = 7)**	**P**
Gestational age, weeks, mean (SD)	38.8 (1.5)	39.1 (1.7)	38.1 (1.1)	0.179 [a]
Weight, Kg, average (SD)	3.3 (0.4)	3.3 (0.4)	3.1 (0.5)	0.188 [a]
Male gender, n (%)	10 (47.6)	8 (57.1)	2 (28.6)	0.217 [b]
Antenatal infection * n (%)	2 (9.5)	1 (7.1)	1 (14.3)	0.599 [b]
Apgar 1st minute, median (AP)	9 (1)	9 (0)	9 (1)	0.913 [c]

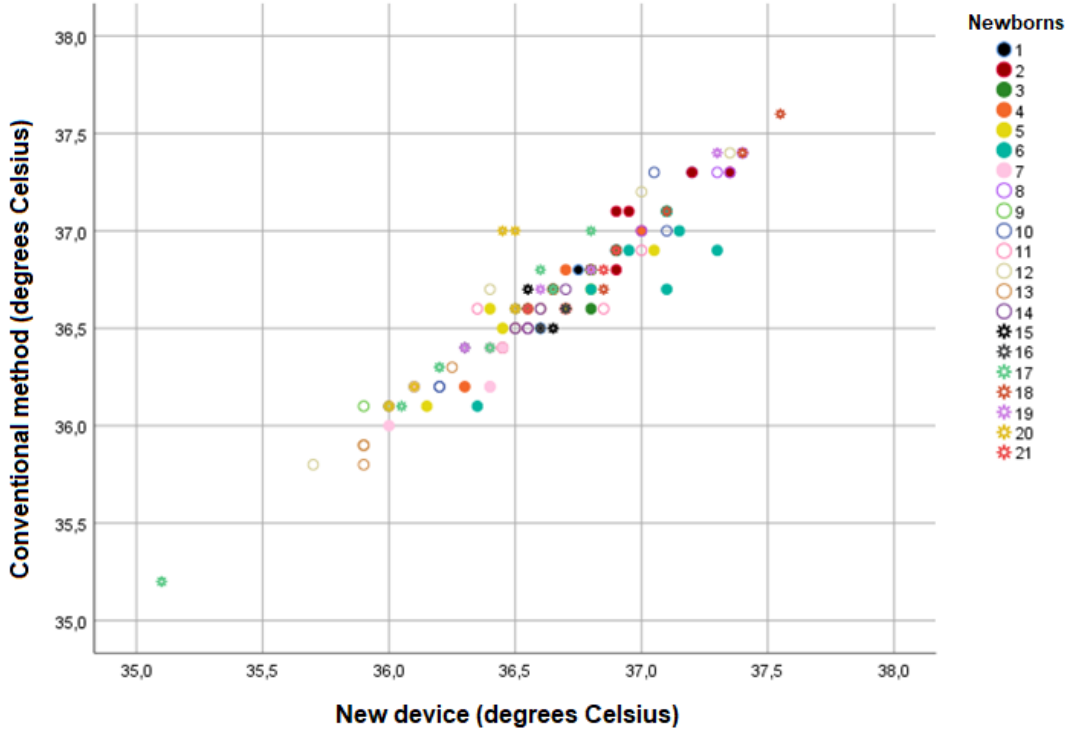
Apgar 5th minute	9 (1)	9 (1)	9 (0)	0.443 [c]
Single bath ** n (%)	19 (90.5)	13 (92.9)	6 (85.7)	0.599 [b]
Two baths ** n (%)	9 (42.9)	6 (42.9)	3 (42.9)	0.676 [b]
Winter birth, n (%)	8 (38.1)	6 (42.9)	2 (28.6)	0.525 [b]

* HIV, syphilis, toxoplasmosis. DP: Standard deviation. AP: Interquartile range.
** Number of baths during the study period.
a T-test of means. b Chi- square test. c Mann-Whitney test

Reliability test, in the clinical setting:

The 115 temperature pairs registered by the nurse in intermittent measurements and those recovered in the monitoring system were presented in Fig.5. The differences averaged 0.014 (SD = 0.14) ºC. At the extreme limits, two newborns had a disagreement of -0.4ºC and another of 0.5ºC.

Fig. 5 Reliability of the device for monitoring the temperature of newborns, in relation to the conventional method



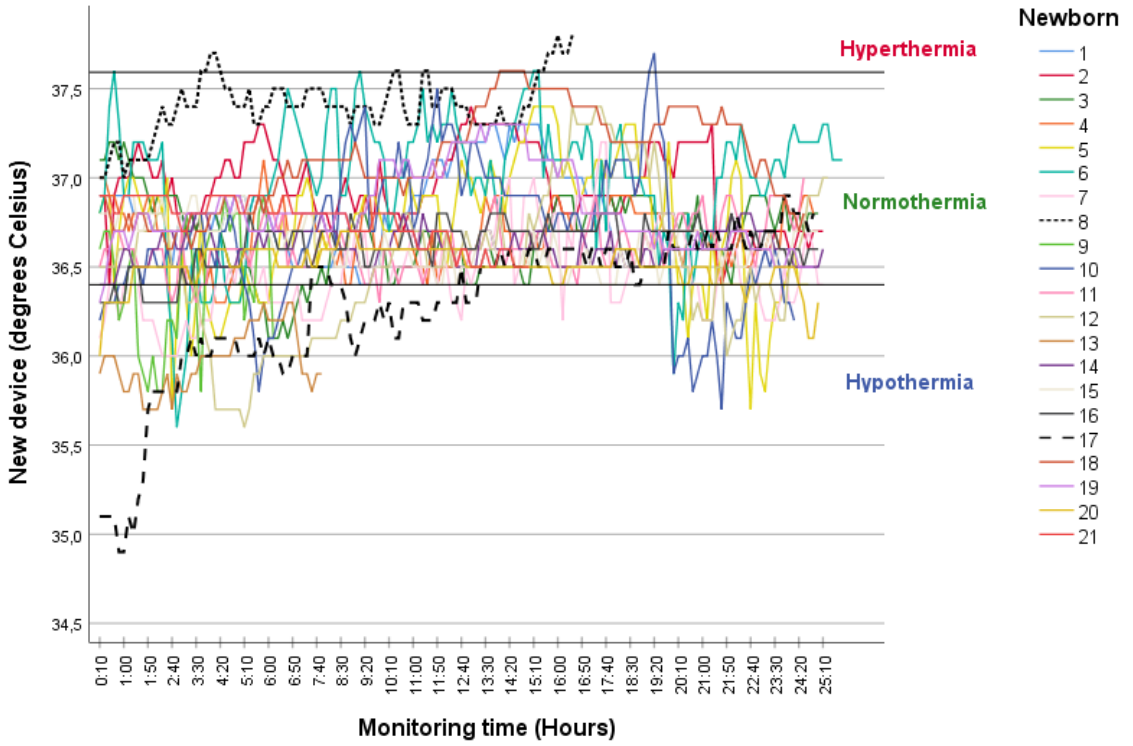
Detection of neonatal hypothermia

The conventional method of monitoring detected hypothermia in 14 (66.7%) newborns. The proposed device detected hypothermia in 15 (71.5%) newborns. This difference was not significant using Mc Nemar's chi-square test (p=1.0). The Kappa coefficient of agreement was 0.889. The new method under test detected hypothermia in 1 (4.8%) neonate that was not recognized by intermittent

monitoring. However, as the difference was not significant, it will not be possible to make inferences out of this sample.

However, when all measurements performed by the real-time monitoring system were analyzed, hypothermia was recorded 520 (28.8%) out of 2809 measurements. As for the nursing standard, using the intermittent mode, hypothermia was recorded 30 (26.8%) in 115 measurements. Hyperthermia was recorded 29 (1.03%) of 2809 measurements by the new device, while by the nursing standard, intermittently, only 1 (0.9%) in 115 measurements. In addition, there were three episodes of hypothermia or hyperthermia detected by the new device, at times not monitored by nursing.

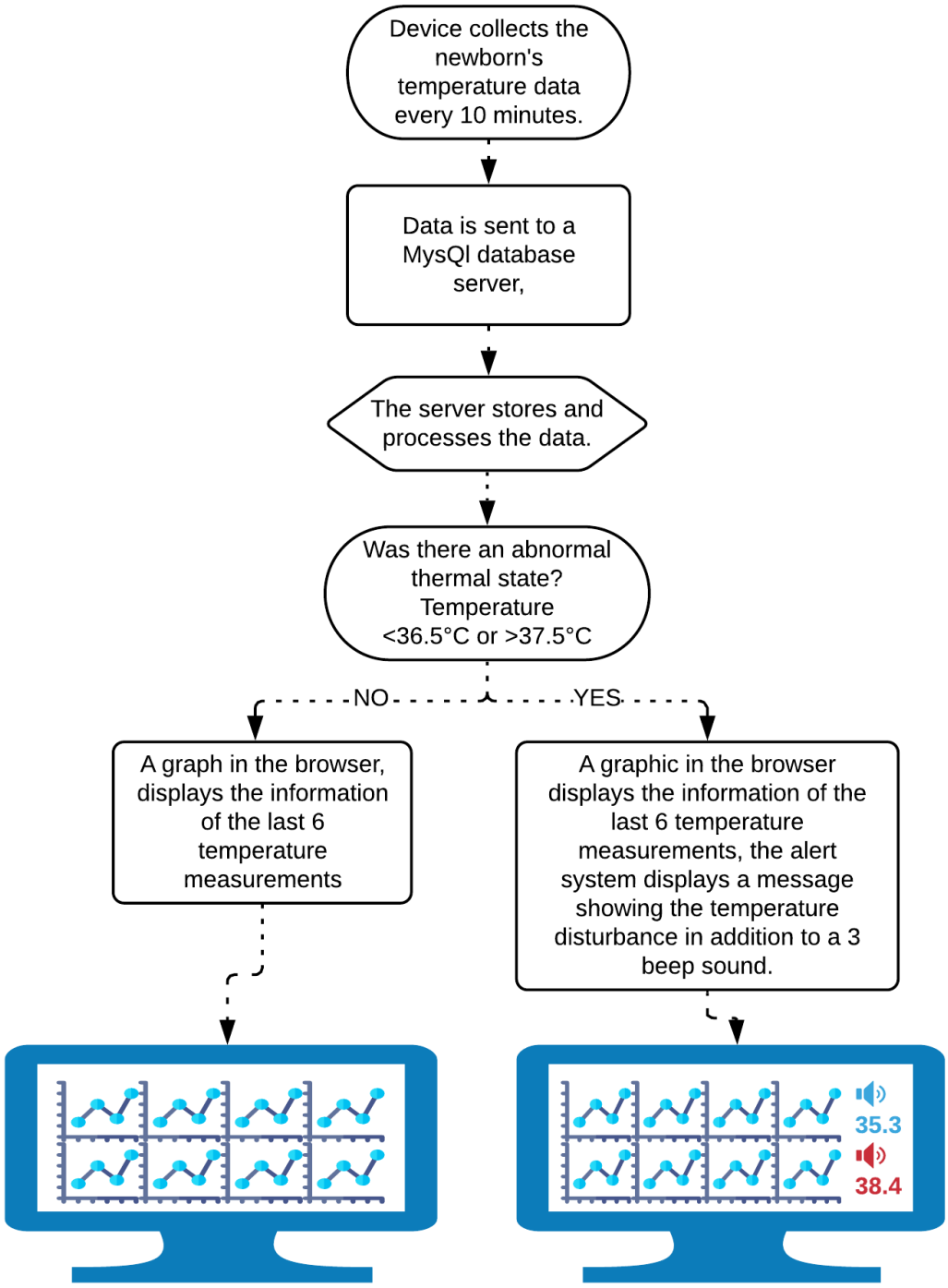
Fig. 6 Time line for monitoring the temperature of the 21 newborns by the prototype of the developed system



Alert system for the thermal uncontrolled of the newborn

A software was developed to display a graph with the values of the last six temperature measurements, measured with an interval of 10 minutes. The interface is capable of presenting the simultaneous monitoring of more than one newborn. The system alerts you with any message on the monitor and a three-beep for any abnormal measurements. Neonatal hypothermia was signaled when the temperature value was below 36.5 ºC and hyperthermia above 37.5 ºC, as recommended by WHO [8]. Fig. 7 shows the flow and processing of information.

Fig. 7 Diagram of temperature data flow, processing and display of alerts for abnormal values



3 DISCUSSION

The most relevant contribution of this study was to validate the concept of a system capable of monitoring the newborn's temperature reliably. In addition, the prototype was able to detect more episodes of temperature change than the conventional method. When all the device's measurements were analyzed, every 10 minutes of interval,

the system proved to be potentially valuable to assist health professionals in monitoring the temperature of newborns in joint accommodation, alerting the thermal uncontrolled.

The bench tests were a coincident as all temperature values measured simultaneously by the prototype sensor and standard thermometer. We attribute this result to the exhaustive search for more accurate and effective components to be used in humans. The stages in the development of the prototype guided the best practices for the development of new health products [14]. The same temperature sensor and similar methodology were used to assess the reliability of the measurements, in a recent study that monitored the physiological signs of newborns, including temperature, in a neonatal intensive care unit [15].

In the clinical scenario of joint accommodation analyzed, a significant number of newborns with some episode of hypothermia was identified by the conventional technique 14 (66.7%) and by the system under test 15 (71.0%). This finding is explained by the strictness of the nursing care protocol with newborns, since the season, the bath, children's characteristics such as weight and gestational age, among others, were not directly related to the occurrence of hypothermia (Table 1). In fact, hypothermia is a common event in newborns monitored in hospitals, with a prevalence range of 32% to 85%, as presented in a systematic review [16].

Regarding the reliability of the measurements in a clinical setting, the present innovation presented here showed an average difference of 0.014 ± 0.14 º C in relation to the conventional technique. The finding is similar to other devices developed for similar purposes. The result of monitoring the temperature of newborns in the epigastric region, for about an hour, reached an accuracy of ± 0.5 ° C in relation to conventional axillary measurements [17]. The authors suggest future analyzes that include an appropriate sensor calibration and clinical validation for a longer period, since the clinical tests were only one hour in duration. A temperature sensor belt containing textile conductive threads embedded in bamboo fabrics showed a measurement accuracy of ± 0.1 ° C [18]. However, such validation was based on only one newborn and will require complementary assessments.

This study has limitations, which must be considered when interpreting its results. One of them refers to the difficulty in controlling the measurement bias in the measures taken by the nursing team. Even though the study protocol tried to minimize the error, offering a calibrated digital thermometer with measurement instructions, it was not possible to make sure that the guidelines were met by the on-call staff, during the 24

hours of monitoring. Another potential error is in the transcription of the values collected for medical records. On the other hand, the maximum difference between the measurement system and that recorded test No clinical records was 0.5 °C. The sample with 115 temperature pairs in 21 newborns was important to obtain a greater diversity of users of the system and children, expanding the external validity of the results and providing values that could be presented with appropriate statistics. The pilot validation in a blind care scenario gave credibility to the comparisons between the two methods of measuring the temperature. However, neither the data collected nor the temperature disturbance alerts were made available to the user, although the analysis software is fully developed. The efficiency of the presentation layer in communicating the alerts, as well as the health team's attitude towards the messages were not evaluated.

The study showed evidence that this technology was sufficiently explored in the four premarket stages of the development of new health devices [14]. It was shown to be relevant in the scope of newborn care, since the results showed improvements in temperature monitoring, in relation to the current practice in joint accommodation. The development team involved specialists in the fields of medicine, physics, bioengineering and computing, which contributed to a safe, accurate and effective system model. In addition, product development with a focus on the needs of the scenario and counting on the user's involvement in the validation process were essential to speed up its construction.

The assessment of body temperature is one of the oldest and best known methods of alerting to illnesses [19]. However, substantial temperature information must be available, in a timely manner, to support the care provided by healthcare professionals. Digital technologies can improve the measurement process and offer differentiated outputs that can interact more effectively with its users.

4 CONCLUSION

The monitoring of the temperature by a computerized system detected more thermal abnormalities than the conventional method. The prototype, developed, showed its potential to offer continuous and simultaneous monitoring to a set of newborns hospitalized in a maternity unit, with immediate alerts of changes in skin temperature

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