Indian Journal of Pediatrics (November 2023) 90(11):1110–1115
https://doi.org/10.1007/s12098-022-04459-8

ORIGINAL ARTICLE

Clinical Evaluation of a Wireless Device for Monitoring Vitals in Newborn Babies

Rajiv Aggarwal[1] · Vikneswaran Gunaseelan[2] · Delitia Manual[2] · Manoj Sanker[3] · Sabari Prabaaker[3]

Received: 16 June 2022 / Accepted: 13 November 2022 / Published online: 21 February 2023

Abstract

Objectives To evaluate the ability of the Nemocare Raksha (NR), an internet of things (IoT)–enabled device, to continuously monitor vitals for 6 h and its safety in newborns. The accuracy of the device was also compared with the readings from the standard device used in the pediatric ward.

Method Forty neonates (either gender) weighing ≥ 1.5 kg were included in the study. Heart rate, respiratory rate, body temperature, and oxygen saturation was measured using the NR and compared with standard care devices. Safety was assessed by monitoring for skin changes and local rise in temperature. The neonatal infant pain scale (NIPS) was used to assess pain and discomfort.

Result A total of 227 h of observations (5.67 h per baby) were obtained. No discomfort or device-related adverse events were noted during the study period. The mean difference between the NR and the standard monitoring was 0.66 (0.42 to 0.90) for temperature (°C); −6.57 (−8.66 to −4.47) for heart rate (bpm); 7.60 (6.52 to 8.68) for respiratory rate (breaths per minute); −0.79 (−1.10 to −0.48) for oxygen saturation (%). The level of agreement analyzed using the intraclass correlation coefficient (ICC) was good for heart rate [ICC 0.77 (0.72 to 0.82); p value < 0.001] and oxygen saturation [ICC 0.80 (0.75 to 0.84); p value < 0.001]; moderate for body temperature [ICC 0.54 (0.36 to 0.60); p value < 0.001] and poor for respiratory rate [ICC 0.30 (0.10 to 0.44); p value 0.002].

Conclusion The NR was able to seamlessly monitor vital parameters in neonates without any safety concern. The device showed a good level of agreement for heart rate and oxygen saturation among the four parameters measured.

Keywords Remote monitoring · Neonates · Sensor · Outcomes · Vitals · Medical device

Introduction

According to a 2019 WHO (World Health Organization) report, children have the greatest risk of mortality in the first 28 d after birth. As many as 47% of the under-5 mortality rates occurred during the newborn period. This has been attributed to a lack of quality care at birth and monitoring immediately after birth [1]. In 2017, India accounted for about one-fifth of the global under-5 mortalities. Thus, reformative measures will not only improve the Indian statistics but also have an impact at the global level. India is working to achieve the target of fewer than 10 newborn deaths per 1000 live births by 2030 as per the India Newborn Action Plan [2–4].

Innovations in neonatal care, especially use of technology for monitoring babies who are at high risk, and intervening at the earliest warning sign can play a significant role in achieving this goal [5]. While continuous monitoring has been shown to improve patient outcomes, it is resource intensive making it possible only in high-resource settings. Also, at times, it can be detrimental to the patients by restricting mobility, disturbing sleep, increasing the risk of infection from the devices such as intra-arterial or intravenous monitoring devices, requiring admission to high dependency units (increasing the cost of medical care) [6–9].

Wearable devices are being increasingly used in health care, both for inpatient monitoring as well as monitoring

✉ Vikneswaran Gunaseelan
vikneswaran.g.dr@narayanahealth.org

[1] Department of Pediatrics, Narayana Hrudayalaya, Bangalore, Karnataka, India

[2] Department of Clinical Research, Narayana Hrudayalaya, Bangalore, Karnataka, India

[3] Nemocare Wellness Pvt. Ltd., Hyderabad, Telangana, India

outside the clinic [10]. It involves the use of sensors for capturing various physiological parameters. The data acquired can be used to remotely monitor the well-being of newborns in real time. Conventionally, four vital parameters considered during routine monitoring of newborns are heart rate (HR), respiratory rate (RR), oxygen saturation (SpO_2), and body temperature. The Nemocare Raksha is an internet of things (IoT)–enabled smart wearable on the baby's foot was developed to continuously monitor these four vital parameters.

This study was primarily undertaken to evaluate the ability of the device to continuously monitor vitals for 6 h and its safety in newborns. The accuracy of the device was also compared with the readings from the standard device used in the pediatric ward.

Material and Methods

This is a prospective observational study conducted in the pediatrics department of a tertiary care hospital in Bangalore during the period of November 2019 to September 2020. The study was approved by the institutional ethics committee (NHMEC S12/2019), and the study was registered prospectively in CTRI (ref no. CTRI/2019/06/019825). Written informed consent was obtained from the parents of all the study participants.

The study included forty newborn babies (either gender) weighing ≥ 1.5 kg. These babies were enrolled in a wellness baby clinic, where they are provided interim care and monitoring before being handed over to mothers after recovery from anesthesia or admission for medical reasons of the mother. The exclusion criteria were deformities that prevent proper application of the device, diagnosis of cardiovascular conditions, mean arterial pressure < 20 mm Hg, use of sedatives, and parents not willing to give consent.

The Nemocare Raksha (NR) is an IoT–enabled smart wearable on the baby's foot, which continuously and unobtrusively monitors four main vital parameters (blood oxygenation saturation, heart rate, respiration rate, body temperature). The device relays all the information over the hub to a central monitoring station (Fig. 1), from which the nurse or doctor can continuously and remotely monitor all the babies under their supervision.

The device consists of a Cortex M4F microcontroller processor backed by a 150 mAh rechargeable LiPo battery. There is a power button, along with two indicator LEDs and an audio buzzer. It has three optical heart rate sensor, a high-resolution 9-axis inertial measurement unit (IMU), and a negative temperature coefficient (NTC) thermistor. The device is compatible with Android devices version 6 or higher and has a Bluetooth 4.2 connectivity. The current version of the device weighs 20 g.

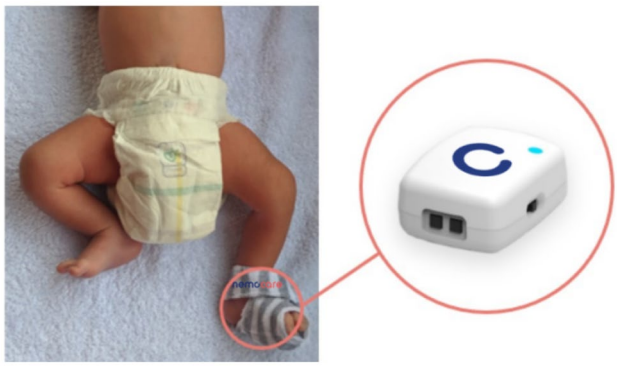

Fig. 1 Investigational device applied to a baby's foot

There is a set of LEDs of two wavelengths and a photodetector which is used for measuring heart rate and SpO_2 using the photoplethysmography (PPG) technique. The red and IR LEDs are operated more frequently as they are also used to measure SpO_2 and heart rate in real time. The minimum sampling frequency is 50 samples per second, and the LED trigger patterns look like this at 1000 samples per second (Fs = 1 kHz). The two wavelengths must be continuously triggered, and the order does not matter as the switching happens really quickly. The sensor data are communicated over the I2C protocol to the microcontroller (uC), and each data sample is 32 bits long.

The thermistor is a 10k NTC type. There will be two of them, one on either side of the board—one for body temperature measurement and the other for ambient surrounding temperature, which will be critical to cutting out false alarms. The IMU is used for motion detection. It comprises a MEMS accelerometer and gyroscope. The raw data are fed to a Kalman filter on the software end, and body positions and relative movements will be recognized. These data can be used for data compensation and to get a sense of the baby's sleeping patterns. This also helps with motion compensation, which allows the SpO_2 sensor to correct motion artifacts.

The indicator LEDs are used for low battery alerts and to indicate on/off status and distress states of the baby. The BLE communication module enables one to transmit data wirelessly to the hub (Android Tablet), from where it is sent over to the cloud for storage (has a 24-h storage capacity of data in case of bad connectivity and is lazy pushed) and unified, seamless access to the stakeholders (doctors, nurses, etc.).

Prior to this clinical validation, the necessary tests for overheating, heat dissipation from the optical sensor to skin, electrical safety (leakage current or short circuiting), and wearable comfort were performed in accordance with ISO 14971 [11].

Eligible babies were screened from the ward and informed consent was obtained from the parents or legally appointed representative. After obtaining baseline clinical details, the NR was applied to the dorsum of the foot to continuously monitor the vital parameters [HR, RR (respiratory rate), SpO_2, and body temperature] for 6 h. Vital parameters were also monitored using the standard hospital protocol (considered standard for this study) at baseline, followed by every 1-h interval till the end of the study (6 h) by an independent person blinded to the NR values. Data collected from NR were downloaded in Excel format from the Nemocare patient management platform. For the purpose of comparison, vitals at one hourly interval corresponding to the time of standard care measurements were used.

Body temperature was monitored by a phoenix probe placed over the abdominal wall and connected to the warmer. The respiratory rate was measured manually by counting the movement of the abdominal muscles for one complete minute. Heart rate and oxygen saturation were measured by a probe placed on the index finger connected to the monitor (the GE Dash series, which is based on SET technology). *Safety assessment:* All the babies were monitored every 2 h for any skin changes and local rise in temperature at the site of application of NR. In addition, the neonatal infant pain scale (NIPS) was used to assess pain and discomfort during the study. The scale consists of six indicators related to facial expression, crying, breathing patterns, arms, legs, and state of arousal. Each indicator is given a score of 0 or 1, except cry, which is given a score of 0 to 2. All babies were observed for 1 min, and scoring was done. A total score of 0–2 is considered mild to no pain, 3–4 is considered mild to moderate pain, and > 4 is considered severe pain [12].

To minimize any unanticipated risk, babies were divided into three groups, beginning with the highest body weight and working down to the lowest body weight. Group 1: > 2.5 kg ($n = 15$); group 2: between 2 and 2.5 kg ($n = 15$); and group 3: between 1.5 and 2 kg ($n = 10$).

This is a pilot study with the primary objective of studying the safety of NR and its feasibility. Hence, no formal sample size calculation was done. Forty newborn babies were enrolled in the study and divided into 3 categories based on body weight. Group 1: > 2.5 kg ($n = 15$); group 2: between 2 and 2.5 kg ($n = 15$); and group 3: between 1.5 and 2 kg ($n = 10$). For each baby, vitals were obtained at baseline, followed by 1, 2, 3, 4, 5, and 6 h (end of study) expecting a total of 240 data points for the study.

Baseline clinical characteristics were expressed using descriptive statistics. Continuous variables were described using the mean and standard deviation or median with range, depending on the distribution of the data. Categorical variables were expressed using frequency and percentage.

The difference in vital parameters (namely HR, RR, SpO_2, and body temperature) between Nemocare Raksha and the standard method was analyzed using the one-sample *t*-test. The Bland–Altman plot was used to represent the difference in values between the two devices. The level of agreement for vitals between the two methods were analyzed using the intraclass correlation test with 95% confidence interval. A p value less than 0.05 was considered statistically significant.

Results

Forty newborn babies (55% male) were included in the study. A total of 227 h of observations, with an average of 5.67 h per baby, were obtained. In 35 babies (87.5%), complete 6-h monitoring was performed. Two babies did not complete 6-h monitoring due to device-related issue (low on battery due to incomplete charging); 2 babies were shifted to the ward and 1 was shifted for medical reasons. Mean gestational age was 36.08 ± 2.3 wk with a mean birth weight of 2.39 ± 0.6 kg (Table 1). At birth, all babies received basic care such as providing warmth and clearing secretions, and 38 babies received oxygen by bag and mask. The median Apgar scores were 8 and 9 at 1 min and 5 min, respectively.

The mean difference between the NR and the standard monitoring (Table 2) was 0.66 (0.42 to 0.90) for temperature (℃); −6.57 (−8.66 to −4.47) for heart rate (bpm); 7.60 (6.52 to 8.68) for respiratory rate (breaths per minute); and −0.79 (−1.10 to −0.48) for oxygen saturation (%) (Fig. 2). The level of agreement analyzed using the intraclass correlation coefficient (ICC) was good for heart rate [ICC (95% CI) of 0.77 (0.72 to 0.82); p value < 0.001] and oxygen saturation [ICC (95% CI) of 0.80 (0.75 to 0.84); p value < 0.001], while it was moderate for body temperature [ICC (95% CI) of 0.54 (0.36 to 0.60); p value < 0.001] and poor for respiratory rate [ICC (95% CI) of 0.30 (0.10 to 0.44); p value 0.002]. There were no episodes of apnea, hypothermia bradycardia, or tachycardia reported during the study period.

A visual inspection for skin changes (redness, swelling, etc.) as well as an examination for local rise in temperature (due to heating) at the site of application of the device were done every 2 h till the device was applied. No adverse events were seen during the study. All babies had a total NIPS less than 2 (suggestive of mild to no discomfort) throughout the study period.

Discussion

The Nemocare Raksha device is a Bluetooth-enabled smart wearable device designed to be applied to a baby's foot for continuous monitoring of vital parameters. The device was developed with the required safety features as per ISO 14971. In this pilot study (the first in humans), safety of the

Table 1 Baseline characteristics of study population

Variables	Descriptive statistics ($N = 40$)
Gender Male (*n*, %)	22 (55.0%)
Gestational age (weeks)	36.08 ± 2.3
Birth weight (kg)	2.39 ± 0.6
Current weight (kg)	2.36 ± 0.58
Vitals	
Oxygen saturation (%)	95.10 ± 2.9
Temperature (℃)	36.55 (36.7–36.5)
Respiratory rate (breaths per min)	48.30 ± 7.0
Heart rate (bpm)	132.90 ± 15.8
Clinical characteristics	
Apgar 1 min	8.00 (7.0–8.0)
Apgar 5 min	9.00 (8.0–9.0)
Resuscitation at birth	38 (95.0%)
Prematurity	9 (22.5%)
Low birth weight	10 (25.0%)

Vitals captured at baseline using the standard device. Continuous variables entered as mean ± SD or median with interquartile range. Categorical variables expressed in frequency (percentage)

device in newborns and the feasibility of monitoring vital parameters seamlessly for 6 h were assessed. Accuracy was evaluated by comparing it with the standard monitor used in the neonatal ward. Forty newborns of either gender were enrolled in one of three birth weight categories. Each baby was monitored continuously for 6 h using the Nemocare Raksha device. Readings from the standard device were obtained at baseline, followed by 1, 2, 3, 4, 5, and 6 h, or end of the study.

The agreement of values between the NR and the standard device was analyzed using the intraclass correlation coefficient and one-sample *t*-test. Overall, heart rate (ICC 0.77; p value < 0.001) and oxygen saturation (ICC 0.80; p value < 0.001) showed good reliability, while it showed moderate reliability for temperature (ICC 0.54; p value < 0.001) and poor reliability for respiratory rate (ICC 0.30; p value 0.002). A correlation coefficient value of > 0.75 is considered as good agreement [13]. The authors did not find any suitable reference for a clinically relevant difference in newborn. The following criteria of 10 ± 10 beats per minute for HR, 3 ± 3 breaths per minute for RR, 0.5°C ± 1.0°C for temperature, and 3% ± 5% for SpO_2 were used for adults [14]. Based on the above criteria, there was no clinical difference in the HR, body temperature, or oxygen saturation measured between the NR device and the gold standard. The difference of 3% ± 5% may be too large to be considered safe in neonates. However, the present study showed a much smaller difference of 0.79 (−1.10 to −0.48) for SpO_2. There was a significant difference in the RR (mean difference of 7.60) between the NR device and the gold standard). This difference is because the RR was derived and not directly measured. These data can be used to improve further validation of RR in the upgraded device. Overall, the present study showed good reliability for the measurement of heart rate and SpO_2, while further improvement is needed for respiratory rate and body temperature.

Newborn monitoring systems have seen minimal innovation in the last few decades. Adult systems are minimally adapted for use in pediatrics and are limited by the use of rigid sensors that use strong adhesives to attach to the neonates' skin and are connected to bulky units limiting movement of babies for feeding by mothers [15, 16]. The NR weighs only 20 grams (has the size of a 10-rupee coin) can be easily worn on the foot without any restricting movement. This can facilitate kangaroo mother care without interfering with the monitoring. NIPS (administered every second hourly, from baseline till end of the study) also did not show any discomfort or skin changes to the baby.

Table 2 The mean difference and level of agreement for the vital parameters between the standard device and the Nemocare device

Parameters	Mean difference (95% CI)	p value
Temperature (℃)	0.66 (0.42 to .90)	< 0.001
Heart rate (bpm)	−6.57 (−8.66 to −4.47)	< 0.001
Respiratory rate (breaths per minute)	7.60 (6.52 to 8.68)	< 0.001
Oxygen saturation SpO_2 (%)	−0.79 (−1.10 to −0.48)	< 0.001
Parameters	Intraclass correlation coefficient (95% CI)	p value
Temperature	0.54 (0.36 to 0.60)	< 0.001
Heart rate	0.77 (0.72 to 0.82)	< 0.001
Respiratory rate	0.30 (0.10 to 0.44)	0.002
SpO_2	0.80 (0.75 to 0.84)	< 0.001

Statistical test used: One-sample *t*-test for mean difference

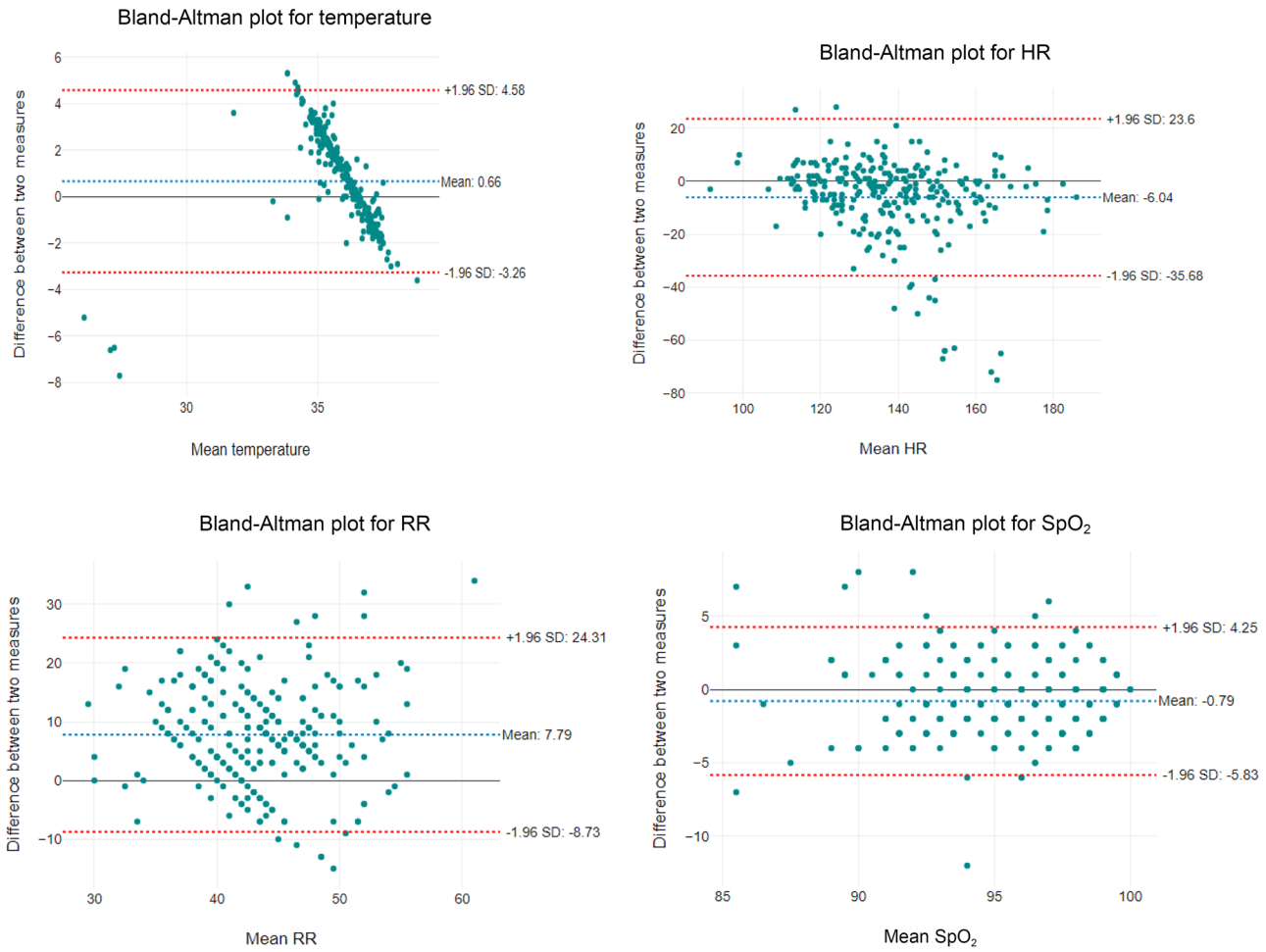

Fig. 2 The Bland–Altman plot for vitals between the investigational device and the standard care device. *HR* Heart rate, *RR* Respiratory rate, *SpO_2* Oxygen saturation

Populations in rural areas have limited access to modern health care facilities. Babies are delivered at home without any medical professional's help or are taken home immediately after delivery. The hub model and scalability of the NR device can provide a potential place for monitoring newborn remotely, even in resource-limited settings [17]. Depending on the context of healthcare, Nemocare-based monitoring can be implemented for remote home-based monitoring to avoid unnecessary hospital admissions or in wards (a "virtual ward model") for early identification of sick babies, thereby avoiding the need for ventilation and ICU admission [18–20]. Home assessment programmes have shown to reduce emergency consultations and organizational inefficiencies in patient care for various conditions [21, 22].

Since the device was clinically tested for the first time, the study was conducted in stable newborns in the NICU requiring regular monitoring. Also, the device was tested only for a short duration of 6 h. While these measures are taken to ensure safety, they are also potential limitations of the study. To maximize its utility, further testing for longer duration in sick babies admitted to intensive care units (preterm babies, babies with unstable vitals, and babies with cardiac problems) is planned.

Conclusion

The study showed the ability of the Nemocare Raksha device to seamlessly monitor vital parameters in neonates without any safety concerns. The device showed good agreement with standard devices for monitoring heart rate and oxygen saturation. Further calibration is needed to improve the accuracy of respiratory rate and body temperature.

Acknowledgements The authors thank the parents for consenting to the participation of their babies in this study. They acknowledge the staff of the Clinical Research Department, Sister Punitha Rani, and Ms. Madhu Rudra for helping in the data collection. The authors sincerely thank Dr Alben Sigamani, the former head of the Clinical Research Department, Narayana Hrudayalaya, Bangalore for his suggestions during the designing stage of the study and TBI-MSMF.

Authors' Contributions RA recruited subjects for the study and performed the final review for the manuscript; VG designed the study and prepared the initial draft of the manuscript; DM analyzed the data; MS and SP provided training on the investigational device, reviewed the manuscript, and provided inputs. The final manuscript was reviewed by all the authors. RA will act as the guarantor for this paper.

Funding The study was supported by a BIRAC grant (BIRAC/IKP0806/BIG-13/18) to Manoj Sanker.

Declarations

Conflict of Interest MS and SP are employees of Nemocare Wellness Pvt. Ltd. and were not involved in the designing, conduct of the study, and final analysis of data. However, the final manuscript was reviewed by both MS and SP.

References

1. World Health Organization. Newborns: improving survival and well-being. 2020. Available at: https://www.who.int/news-room/fact-sheets/detail/newborns-reducing-mortality. Accessed on 9 Feb 2022.
2. India State-Level Disease Burden Initiative Child Mortality Collaborators. Subnational mapping of under-5 and neonatal mortality trends in India: The Global Burden of Disease Study 2000–17. Lancet. 2020;395:1640–58.
3. Ministry of Health and Family Welfare, Government of India. INAP: India Newborn Action Plan. 2014. Available at: https://www.newbornwhocc.org/INAP_Final.pdf. Accessed on 10 Sept 2019.
4. Ministry of Health and Family Welfare, Government of India. National Health Policy 2017. 2017. Available at: https://main.mohfw.gov.in/sites/default/files/9147562941489753121.pdf. Accessed on 10 Sept 2019.
5. Ginsburg AS, Nkwopara E, Macharia W, et al Evaluation of non-invasive continuous physiological monitoring devices for neonates in Nairobi, Kenya: a research protocol. BMJ Open. 2020;10:e035184.
6. Chan PY, McNeil J, Nguyen T, Ryan N, Hopper I. Novel wearable and contactless monitoring devices to identify deteriorating patients in the clinical setting: a systematic review protocol. Syst Rev. 2020;9:104.
7. Nuttall G, Burckhardt J, Hadley A, et al. Surgical and patient risk factors for severe arterial line complications in adults. Anesthesiology. 2016;124:590–7.
8. Zargaran D, Hardwick S, Adel R, Hill G, Stubbins D, Salmasi AM. Sphygmomanometer cuffs: a potential source of infection! Angiology. 2015;66:118–21.
9. Hunter A, Johnson L, Coustasse A. Reduction of intensive care unit length of stay: the case of early mobilization. Health Care Manag (Frederick). 2014;33:128–35.
10. Hasan MNU, Negulescu II. Wearable technology for baby monitoring: a review. J Textile Eng Fashion Technol. 2020;6:112–20.
11. ISO 14971:2019 Medical devices — Application of risk management to medical devices. Available at: https://www.iso.org/standard/72704.html. Accessed on 8 June 2022.
12. Obiedat H, Al-Maaitah EI. Critique of the use of Neonatal Infant Pain Scale (NIPS). Neonat Pediatr Med. 2020;6:186.
13. Mukaka MM. Statistics corner: A guide to appropriate use of correlation coefficient in medical research. Malawi Med J. 2012;24:69–71.
14. Leenen JPL, Leerentveld C, van Dijk JD, van Westreenen HL, Schoonhoven L, Patijn GA. Current evidence for continuous vital signs monitoring by wearable wireless devices in hospitalized adults: Systematic Review. J Med Internet Res. 2020;22:e18636.
15. Chung HU, Kim BH, Lee JY, et al. Binodal, wireless epidermal electronic systems with in-sensor analytics for neonatal intensive care. Science. 2019;363:eaau0780.
16. Chung HU, Rwei AY, Hourlier-Fargette A, et al. Skin-interfaced biosensors for advanced wireless physiological monitoring in neonatal and pediatric intensive-care units. Nat Med. 2020;26:418–29.
17. Rao H, Saxena D, Kumar S, et al. Low power remote neonatal temperature monitoring device. Biodevices. 2014;28−38. https://doi.org/10.5220/0004798300280038.
18. Mansab F, Donnelly H, Kussner A, Neil J, Bhatti S, Goyal DK. Oxygen and mortality in COVID-19 pneumonia: A comparative analysis of supplemental oxygen policies and health outcomes across 26 countries. Front Public Health. 2021;9:580585.
19. NHS. Pulse oximetry to detect early deterioration of patients with COVID-19 in primary and community care settings, 2020. Available at: https://www.england.nhs.uk/coronavirus/publication/pulse-oximetry-to-detect-early-deterioration-of-patients-with-covid-19-in-primary-and-community-care-settings/. Accessed on 8 June 2022
20. Vindrola-Padros C, Singh KE, Sidhu MS, et al. Remote home monitoring (virtual wards) for confirmed or suspected COVID-19 patients: A rapid systematic review. EClin Med. 2021;37:100965.
21. Cruz J, Brooks D, Marques A. Home telemonitoring effectiveness in COPD: a systematic review. Int J Clin Pract. 2014;68:369–78.
22. Faes L, Bachmann LM, Sim DA. Home monitoring as a useful extension of modern tele-ophthalmology. Eye (Lond). 2020;34:1950–3.