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ORIGINAL ARTICLE

Comparing pulse rate measurement in newborns using conventional and dry-electrode ECG monitors

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Abstract

Aim: Heart rate (HR) is the most important parameter to evaluate newborns' clinical condition and to guide intervention during resuscitation at birth. The present study aims to compare the accuracy of NeoBeat dry-electrode ECG for HR measurement with conventional ECG and pulse oximetry (PO).

Methods: Newborns with a gestational age ≥32 weeks and/or birth weight ≥1.5 kg were included when HR evaluation was needed. HR was simultaneously measured for 10 min with NeoBeat, PO and conventional ECG.

Results: A total of 18 infants were included (median (IQR) gestational age 39 (36–39) weeks and birth weight 3 150 (2 288–3 859) grams). Mean (SD) duration until NeoBeat obtained a reliable signal was 2.5 (9.0) s versus 58.5 (171.0) s for PO. Mean difference between NeoBeat and ECG was 1.74 bpm (LoA −4.987–8.459 and correlation coefficient 0.98). Paired HR measurements over 30-s intervals revealed no significant difference between NeoBeat and ECG. The positive predictive value of a detected HR <100 bpm by NeoBeat compared with ECG was 54.84%, negative predictive value 99.99%, sensitivity 94.44%, specificity 99.99% and accuracy 99.85%.

Conclusions: HR measurement with NeoBeat dry-electrode ECG at birth is reliable and accurate.

KEYWORDS
Electrocardiography, heart rate, neonatal transition, pulse oximetry

1 | INTRODUCTION

Foetal to neonatal transition at birth is a unique and critical process of physiological changes to adapt the foetus to extra-uterine life. Although most newborns adapt independently, roughly 10% of newborns receives some form of newborn life support (NLS).[1-3] Heart rate (HR) is the most important parameter to evaluate the newborns' clinical condition and to guide intervention by the caregiver during resuscitation or stabilisation at birth.[4-6] According to ILCOR guidelines, positive pressure ventilation should be commenced below a heart rate of 100 beats per minute (bpm) and below 60 bpm chest compressions should be commenced.[7]

Pulse oximetry (PO) and electrocardiography (ECG) are recommended for continuous and objective HR measurement at birth. PO has the benefit that it can also measure peripheral oxygen saturation (SpO_2) from the pulse wave but can be sensitive to disturbances such

Abbreviations: Bpm, Beats per minute; ECG, Electrocardiography; HR, Heart rate; HR_{ECG}, Heart rate by electrocardiography; $HR_{NeoBeat}$, Heart rate by NeoBeat dry-electrode electrocardiography; HR_{PO}, Heart rate by pulse oximetry; ILCOR, International Liaison Committee of Resuscitation; LUMC, Leiden University Medical Center; NICU, Neonatal intensive care unit; NLS, Newborn life support; NPV, Negative predictive value; PO, Pulse oximetry; PPV, Positive predictive value; PR, Pulse rate; SpO_2, Peripheral oxygen saturation.

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as motion and ambient light.[8] ECG is considered the gold standard to determine HR, as it is faster and reliable within seconds (s) after application.[9-12] Both techniques may not be readily available in low-resource settings. As a result, clinicians may resort to auscultation and/or palpation, which studies have demonstrated are inherently inaccurate.[4-6]

Laerdal Medical developed NeoBeat Newborn Heart Rate Meter (Laerdal Medical, Stavanger, Norway), a non-disposable dry-electrode ECG device.[13] The device has been developed specifically for low-resource settings.[14] A study in the maternity ward by Pike et al. has shown that NeoBeat is both fast and safe in use, correlating well with conventional ECG on the first day of life.[15] More recently, comparative studies by Bush et al. and Rettedal et al. have shown that NeoBeat is able to provide HR measurements fast and for a larger proportion of time compared with both conventional ECG and PO during resuscitation.[16,17] Nonetheless, more research on the accuracy of NeoBeat during resuscitation, specifically for HRs <100 bpm where intervention is indicated, is warranted. Therefore, the present study aims to test the accuracy of NeoBeat when compared to PO and conventional ECG with disposable electrodes during stabilisation of newborns at birth.

Key Notes

- The study was conducted to compare NeoBeat dry-electrode electrocardiography (ECG) with conventional ECG and pulse oximetry (PO) during resuscitation at birth.
- NeoBeat is equally accurate over time as conventional ECG during resuscitation at birth, and even superior to PO which frequently underestimates HR in the first minutes after birth.
- NeoBeat is a suitable device for HR monitoring in both high- and low-resource settings.

2 | MATERIALS AND METHODS

2.1 | Study design

A single-centre observational study was conducted in the Leiden University Medical Center (LUMC) in the Netherlands from October to December 2020. Newborns were eligible for inclusion in the study if they were born in the operating theatre by Caesarean section or in the delivery room of the maternity ward; had a gestational age ≥32 weeks and a birthweight ≥1.5 kg; and were, at the discretion of the caregiver, in need of HR monitoring on the resuscitation table. Inclusion occurred through perinatal assessment when the investigators were on duty. Newborns with thoracic congenital abnormalities of the thorax or whom were withheld NLS due to poor prognosis were excluded.

The sample size was estimated given a desired correlation of at least 0.70, an alpha of 0.05 and a power of 90%. This yielded an estimate of 17 infants.

2.2 | Study procedure

Three disposable ECG electrodes (Neotrode II; ConMed Corporation, Utica, New York, USA) were connected to the ECG monitor (IntelliVue MP30; Philips, Eindhoven, the Netherlands). For PO, the pulse-oximeter (Radical-7; Masimo, Irvine, California, USA) was set to maximum sensitivity and 2–4 s SpO_2 averaging and the SpO_2 probe (LNCS Neo Masimo SET; Masimo) was prepared for use.

Immediately upon birth data collection was initiated via PolyBench software (Applied Biosignals GmBH, Weener, Germany) which simultaneously records PO, ECG and a video feed of the resuscitation table. The patient was brought to the resuscitation table at the discretion of the caregiver. First, the SpO_2 sensor was connected to the infant's right hand. Conventional ECG electrodes were applied according to the manufacturer instructions and local guidelines. NeoBeat was placed around the infant thorax or abdomen, and data collection was initiated via the Liveborn app (Laerdal Medical, Stavanger, Norway). Two dry electrodes on the distal ends of the arch-shaped device contact the skin and measure the electrical activity of the heart from which the heart rate is calculated and reported on a small display. To allow for retrospective synchronisation of the different heart rates, the start of the NeoBeat recording was in view of the video feed. An overview of where each device was applied is available in Figure 1.

2.3 | Statistics

Analyses were performed using custom-written software in Matlab (Matlab R2019b; The MathWorks Inc., Natick, Massachusetts, USA). Continuous data were expressed as mean (standard deviation) or median (interquartile range) depending on their distribution, which were assessed with standard tests for normality. Correlation of HR readouts by NeoBeat and ECG was assessed during the first 10 min after birth by Bland-Altman bias analysis and Pearson's correlation coefficient (r). Continuous data were averaged over 30 s intervals and compared with ECG using a paired t-test (normal data) or Wilcoxon signed-rank test (skewed data). The time duration from application until a reliable HR report was defined as a HR within 10 bpm of HR_{ECG} for at least five consecutive s. Lastly, the sensitivity, specificity, accuracy and predictive values of a measured HR <100 bpm were determined for NeoBeat and PO in comparison with conventional ECG. The positive predictive value (PPV) describes the ability of a device to detect HR <100 bpm, while the negative predictive value (NPV) describes the ability to detect HR >100 bpm.

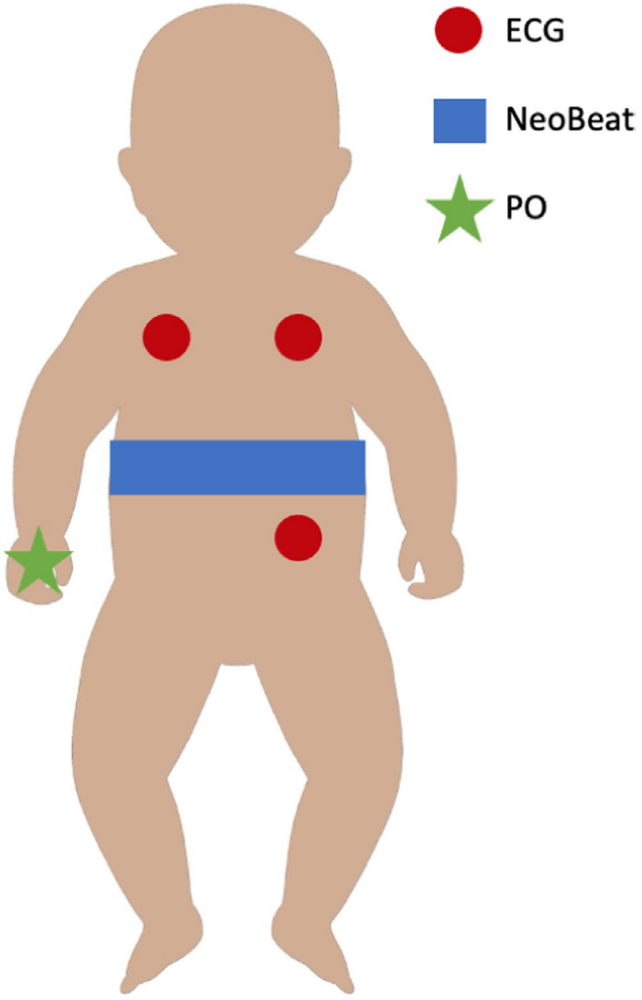

FIGURE 1 Schematic overview of devices and sites of application in infants. ECG = electrocardiography and PO = pulse oximetry

3 | RESULTS

Data were collected from 19 patients, of which a single patient was excluded because of technical problems with the data-recording device. Baseline characteristics and characteristics during stabilisation are summarised in Table 1. The mean (SD) time from application until a reliable signal was obtained was 2.5 (9.0) s for NeoBeat versus 58.5 (171.0) s for PO. An exemplary trend graph of the NeoBeat, conventional ECG and PO is provided in Figure 2. Bland-Altman analysis between NeoBeat and ECG for all patients showed a mean difference of 1.75 bpm and narrow limits of agreement (LoA; −4.987–8.459) (Figure 3). Variability in HR and difference appears consistent for increasing average. Overall, correlation between continuous NeoBeat and ECG data was strong (Pearson's correlation coefficient of 0.98) (Figure 4).

Paired HR measurements of all three devices were compared in intervals of 30 s. Average HRs reported by NeoBeat are nearly equal to average HRs reported by ECG (Figure 5). Although not statistically significant, PO underestimated gold standard HR obtained by ECG up to seven minutes after starting the measurement.

TABLE 1 Baseline and clinical characteristics of patients

Baseline characteristics	
Gestational age (median [IQR])	**39 (36–39) weeks**
Birth weight (median [IQR])	3150.0 (2287.50–3858.75) g
Caesarean section (n [%])	17 (94.4%)
Male sex (n [%])	6 (33.3%)
Stabilisation characteristics	
Apgar score 1 min (median [IQR])	9 (7–9)
Apgar score 5 min (median [IQR])	9.5 (8–10)
No respiratory support (n [%])	14 (77.8%)
Continuous positive airway pressure (n [%])	1 (5.6%)
Positive pressure ventilation (n [%])	3 (16.7%)

Finally, NeoBeat has high NPV, sensitivity, specificity and accuracy to detect HR <100 bpm compared with conventional ECG (Table 2). A trend graph of NeoBeat, conventional ECG and PO where NeoBeat reports HR <100 and ECG ≥100 bpm is provided in Figure 6.

4 | DISCUSSION

In the present study, we found that NeoBeat dry-electrode ECG accurately reports neonatal HR when compared to gold standard conventional ECG on the resuscitation table directly after birth. There was a low mean difference (1.75 bpm) and a high correlation coefficient (0.98). This was true throughout all of stabilisation, meaning NeoBeat reported an accurate HR at any point after birth. Any discrepancies were usually within clinically accepted ranges (10 bpm).

This study is among the first to determine the accuracy of NeoBeat dry-electrode ECG continuously during neonatal resuscitation at birth. The latter poses a very unique setting in which fast and reliable HR reports are essential to guide clinicians. Furthermore, NeoBeat was compared to devices that are, respectively, considered gold standard and standard practice in hospitals in high-resource settings. Two previous studies have looked at HR monitoring by NeoBeat in comparison with conventional ECG and PO during resuscitation, but with different primary outcomes.[16,17] Our findings demonstrate that HR measurements obtained by NeoBeat dry-electrode ECG correlate strongly with conventional ECG conform findings by Rettedal et al.[17] Pike et al. reported a slightly smaller mean difference (≤1 bpm) during their study in the maternity ward.[15] However, healthy newborns may provide more stable measurements compared with newborns undergoing physiological changes in transition. In addition, Pike et al. suggested that any discrepancies between NeoBeat and ECG might be attributable to the variability in averaging times, which is equally true for the present study.[15] However, the differences in measured HR are minimal and not clinically significant.

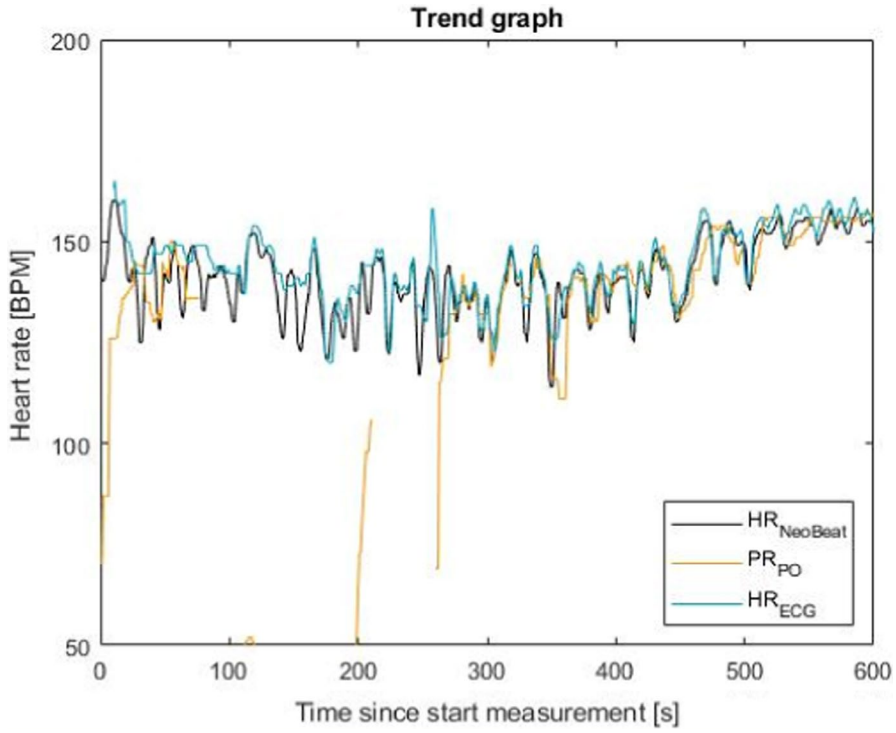

FIGURE 2 Exemplary trend graph of HR monitoring by NeoBeat, conventional ECG and PO. HR = heart rate, ECG = electrocardiography and PO = pulse oximetry

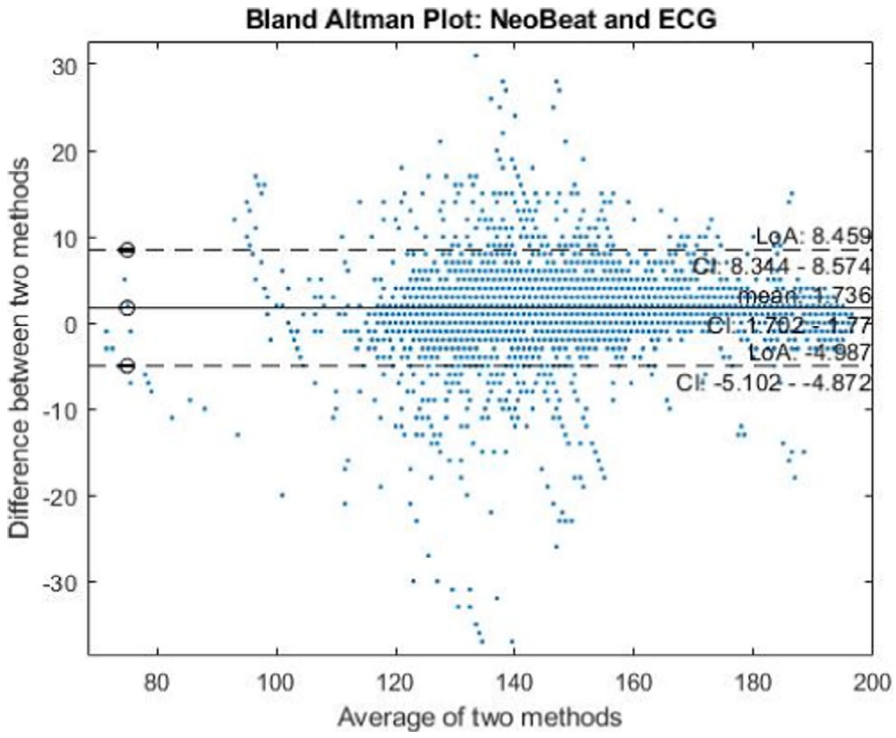

FIGURE 3 Bland-Altman analysis between NeoBeat and ECG for all patients. CI = confidence interval, ECG = electrocardiography and LoA = limits of agreement

The present study further suggests that NeoBeat dry-electrode ECG is superior to PO for measurement of HR. In line with van Vonderen et al., an underestimation of pulse rate in the first minutes after birth was observed in approximately 61% of patients.[18] The mean pulse rates are consistently lower than mean HR over 30-s intervals, but since the study was not powered to demonstrate this difference, it is not statistically significant. Rettedal et al. reported a similar underestimation of HR by PO, attributing this to poor peripheral perfusion.[17]

The PPVs indicate that nearly all HRs <100 reported by PO are false-positive. The moderate PPV of NeoBeat originates in a single patient where for a handful of time instances NeoBeat reports HR <100 and ECG ≥100 bpm. For the majority of these instances, NeoBeat remains within the reliability margin, as the difference with ECG is <10 bpm. The question is how much PPV contributes when it is based on a number of time points of a single patient. Nonetheless, performance of NeoBeat exceeds performance of PO.

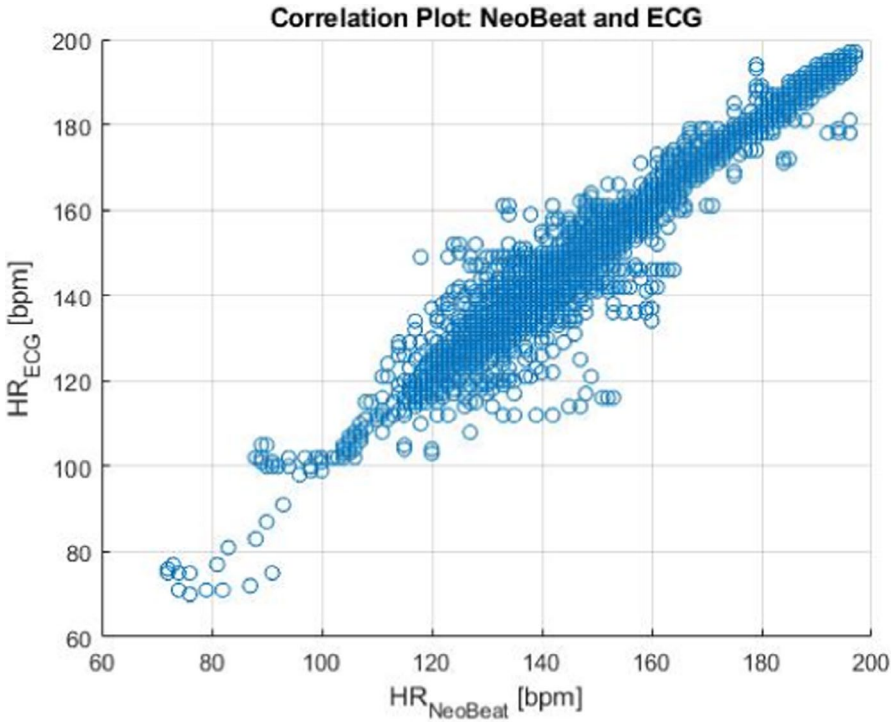

FIGURE 4 Correlation between ECG and NeoBeat for all continuous data. HR = heart rate and ECG = electrocardiography

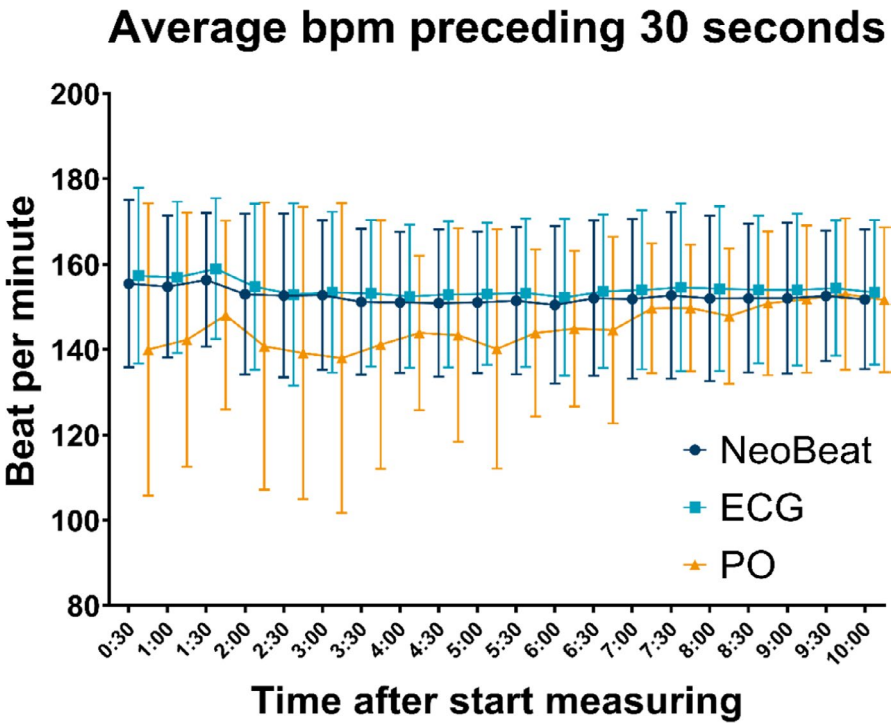

FIGURE 5 Paired average HR measurements over 30-s intervals of NeoBeat, ECG and PO. ECG = electrocardiography and PO = pulse oximetry

TABLE 2 Device specifics with regard to conventional ECG

	PPV	NPV	Sensitivity	Specificity	Accuracy
NeoBeat	54.84%	99.99%	94.44%	99.99%	99.85%
PO	0.97%	99.76%	15.00%	99.76%	99.68%

Accurate HR measurement is important as clinical decision-making is based on HR. Both treatment for false-positive low HRs and lack of treatment for false-positive high HRs should be avoided as much as possible. NeoBeat may, therefore, be more reliable than PO in a setting of neonatal resuscitation where conventional ECG is unavailable.

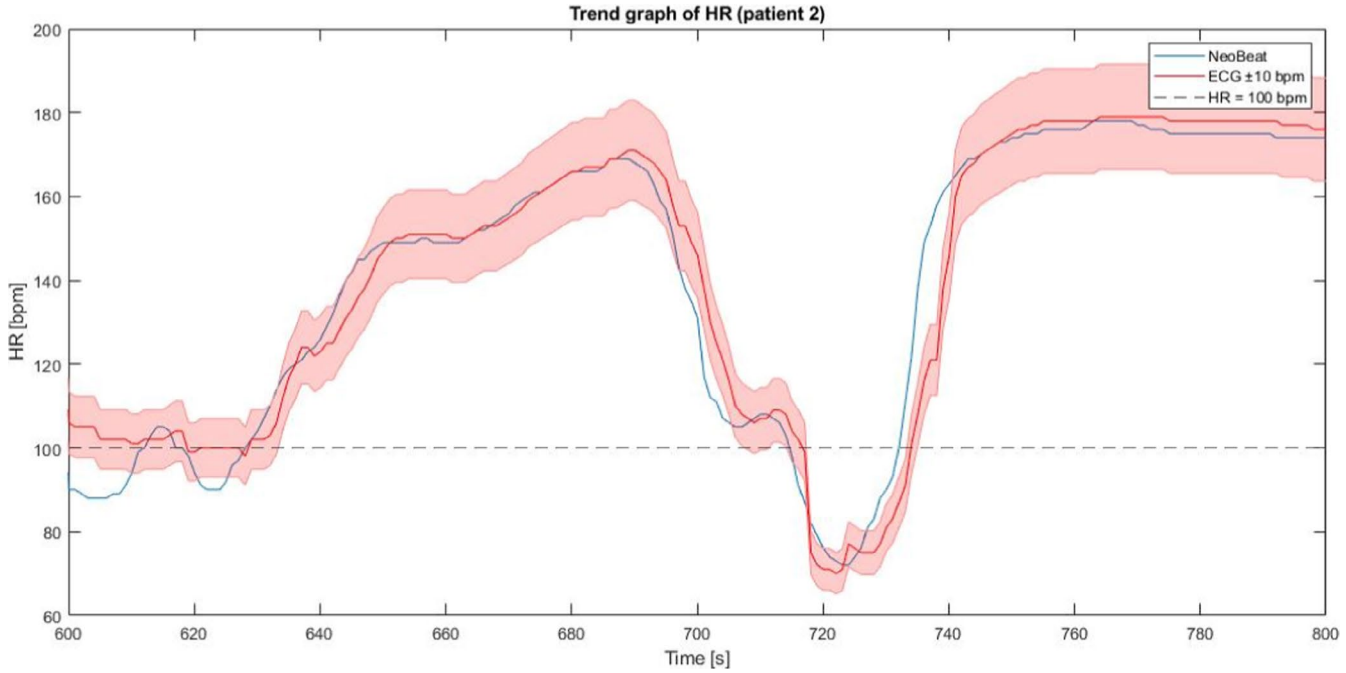

FIGURE 6 Trend graph of HR monitoring by NeoBeat, ECG and PO. The shaded-red area around ECG represents the reliability margin within 10 bpm of HR_{ECG}. The dashed horizontal line represents the cut-off value (HR = 100 bpm) for intervention on the resuscitation table. Two moments in time can be identified where a discrepancy exists between $HR_{NeoBeat}$ (<100 bpm) and HR_{ECG} (≥100 bpm). HR = heart rate and ECG = electrocardiography

While it is clear the accuracy of PO can be hampered by artefacts, other possibilities for the measured difference should be taken into account. The method in which HR is measured with ECG and PO is completely different; while ECG measures electrical conductance and QRS complexes are counted, PO measures mechanical and counts pulse pressure waves. HR is counted by ECG, but does not give information on the contraction force of the heart, while the pulse pressure wave is dependent on cardiac output and vascular resistance.[19,20] Large physiological haemodynamic changes occur at birth, and it might be possible that we measure a true difference between electrical signal and the pressure pulse wave reaching peripherally.

The difference in how HR is measured should also be taken into account, when developing other methods to measure HR at birth. In addition, replacing ECG by PO cannot be recommended when measuring oxygen saturation is necessary for oxygen titration.

This study was conducted in a high-resource setting, while NeoBeat was designed for low-resource settings.[13,14] In addition, the influence of environmental factors on NeoBeat performance was not determined. However, according to the device specifics NeoBeat is able to monitor HR in temperatures up to 40 degrees Celsius and/or in up to 90% humidity.[13]

A limitation of the present study is that the subjects were mostly healthy, term newborns. As such, the a priori probability of a low HR due to haemodynamical instability was low. This may influence the generalizability of the results to preterm infants. It should be noted that NeoBeat can only be applied in infants from a gestational age ≥32 weeks and a birthweight ≥1.5 kg. Nonetheless, it is expected that a similarly strong correlation between NeoBeat and ECG will be observed when the a priori probability of a low HR is higher, as the technique used by NeoBeat is highly similar to conventional three lead ECG. In NeoBeat, the HR is determined from preceding RR intervals, given that signal quality is sufficient, and varies with HR changes. The reference monitor has a similar approach where the last 12 RR intervals are averaged, given HR >50 bpm and an absence of premature ventricular complexes.

5 | CONCLUSION

The present study demonstrates that NeoBeat dry-electrode ECG is equally reliable and accurate over time as conventional ECG on the resuscitation table in healthy newborns. NeoBeat is quick, reliable and easy to use, making it a suitable device for HR monitoring in both high- and low-resource settings.

ACKNOWLEDGEMENT

Not applicable.

CONFLICT OF INTEREST

None to declare.

INFORMED CONSENT

Written informed consent to participate and to publish data was obtained in written format from the parents.

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