REGULAR ARTICLE

ACTA PÆDIATRICA
NURTURING THE CHILD
WILEY

Accurate neonatal heart rate monitoring using a new wireless, cap mounted device

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Abstract

Aim: A device for newborn heart rate (HR) monitoring at birth that is compatible with delayed cord clamping and minimises hypothermia risk could have advantages over current approaches. We evaluated a wireless, cap mounted device (fhPPG) for monitoring neonatal HR.

Methods: A total of 52 infants on the neonatal intensive care unit (NICU) and immediately following birth by elective caesarean section (ECS) were recruited. HR was monitored by electrocardiogram (ECG), pulse oximetry (PO) and the fhPPG device. Success rate, accuracy and time to output HR were compared with ECG as the gold standard. Standardised simulated data assessed the fhPPG algorithm accuracy.

Results: Compared to ECG HR, the median bias (and 95% limits of agreement) for the NICU was fhPPG −0.6 (−5.6, 4.9) vs PO −0.3 (−6.3, 6.2) bpm, and ECS phase fhPPG −0.5 (−8.7, 7.7) vs PO −0.1 (−7.6, 7.1) bpm. In both settings, fhPPG and PO correlated with paired ECG HRs (both $R^2 = 0.89$). The fhPPG HR algorithm during simulations demonstrated a near-linear correlation (n = 1266, $R^2 = 0.99$).

Conclusion: Monitoring infants in the NICU and following ECS using a wireless, cap mounted device provides accurate HR measurements. This alternative approach could confer advantages compared with current methods of HR assessment and warrants further evaluation at birth.

KEYWORDS
heart rate, infant, newborn, photoplethysmography, resuscitation, technologies, wireless

1 | INTRODUCTION

Approximately 10% of newborns require assistance at birth to establish breathing with 3% needing more sustained stabilisation or resuscitation.[1] Preterm infants often require more advanced stabilisation or resuscitation whilst avoiding hypothermia, known to increase mortality.[2,3] Heart rate (HR) is the most sensitive predictor of the infant's clinical status and the efficacy of any

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interventions, and international guidelines suggest the electrocardiogram (ECG) may be used in the delivery room to monitor it.[4] However, electrode application can be difficult, ECG monitors are not always available and electrical cardiac activity may not always equate to effective cardiac output.[5,6] Pulse oximetry (PO) is widely used on neonatal intensive care units (NICUs), but up-take in the delivery room is not universal [7] potentially because of the delay of a few minutes to obtain a reliable HR after birth due to poor peripheral perfusion and motion.[8] This could explain why PO underestimates HR when compared to ECG during the first minutes of life.[9,10]

Delayed cord clamping (DCC) for term infants is widely practised and could become more common for preterm infants, but there is a need to better monitor these babies during this transition to maximise the benefits of DCC whilst avoiding any adverse effects of delayed resuscitation.[11,12] Maximising placental transfusion requires the attending team to be confident of the baby's condition including an acceptable HR and avoidance of hypothermia. A non-intrusive, wireless, easy to apply HR monitoring system, which avoids the risk of hypothermia, could be advantageous in this setting.

We have previously described a prototype wired, forehead-mounted sensor studied in NICU patients that utilises reflectance-mode green light photoplethysmography (PPG) to measure HR.[13] This has the advantages that this wavelength of light (525 nm) is optimised for reflection-mode detection of blood flow and captures this at the forehead where brain perfusion shares arterial pathways via the carotid artery and so is less susceptible to poor peripheral perfusion.[14,15] This original device was held in place on the forehead by a spun bond laminate headband and successfully demonstrated that HR measurement by this method was feasible but had a Bland-Altman limit of agreement (LOA) of up to ± 12bpm. In addition, it was not compatible with current neonatal care due to its inability to accommodate endotracheal tube and CPAP attachments. Furthermore, the relatively large sensor (22 mm diameter), large electronic circuit boards and the presence of cumbersome wiring were less suited for bedside stabilisation of preterm infants during DCC.

This device has now been substantially modified (Video S1, Figure S1 and Figure S2) in terms of its practicality, and several major modifications have taken place including the following:

(i) A T-shape cap compatible with respiratory equipment fittings.
(ii) A miniaturised and ruggedised sensor (10 mm diameter).
(iii) Bluetooth (BT) wireless connection removing the need for trailing wires.

The primary aim of this study was to assess, via a clinical trial, the accuracy and reliability of this new cap mounted newborn HR device the SurePulse VS (fhPPG) (SurePulse Medical Ltd). The study was designed to satisfy the regulatory requirements of the CE Medical Devices Directive 93/42 and its 2007 amendment for measuring HR compared to PO, with ECG as a gold standard. A secondary aim was to investigate acquisition time.

Key notes

- Wireless, continuous heart rate (HR) monitoring of newborns using a cap mounted device (fhPPG) could be beneficial during delayed cord clamping, especially in preterm infants.
- Using electrocardiogram HR as a gold standard, a novel fhPPG performed similarly to pulse oximetry in the neonatal intensive care and immediately after caesarean section birth.
- The fhPPG is an accurate, wireless alternative to current methods of HR monitoring in newborn infants.

2 | MATERIALS AND METHODS

2.1 | Study population

This prospective observational study was conducted at the Nottingham University Hospitals NHS Trust, UK following ethical approval (NHS Health Research Authority Yorkshire & The Humber—Sheffield Research Ethics Committee 15/YH/0522). Informed parental consent was obtained prior to infants being enrolled in the study, and evaluations were performed in the NICU and on babies born by elective caesarean section (ECS). For the NICU phase, infants were included if they were >22 weeks gestation, required HR monitoring and were deemed clinically stable by the attending team. Inclusion criteria for the ECS phase were infants ≥37 weeks gestation with no obvious requirement for resuscitation, based on antenatal history, and delivered by planned caesarean section.

2.2 | Study design

There were two phases to this study, the NICU and ECS. On the NICU, an appropriately sized fhPPG cap was fitted to the infant's head and connected wirelessly to a bespoke synchronised data-logging system via the inbuilt wireless BT module. As part of their routine care, infants had 3 neonatal ECG monitoring electrodes (PD50-F4C, SKINTACT, Leonhard Lang GmbH) attached and connected to a CARESCAPE Monitor B450 (General Electric Healthcare) with Masimo SET® for SpO2 (Masimo). A transmission mode PO sensor (LNCS Neo, Masimo) was attached to the wrist of the right hand and connected to the same monitor. An in-house designed system using LabVIEW 2014 (National Instruments) simultaneously collected synchronised data from all devices and displayed waveforms from each device in real time on a laptop (Lenovo Y50 20378, Lenovo Group Ltd). In keeping with normal practice, if any device presented a poor signal output the electrodes or optical sensors (head or wrist) were repositioned. Up

to 30 minutes of raw physiological data were collected with the infant in their cot or incubator.

During the ECS phase, the same monitoring system described above was deployed. Following birth, the baby was shown to parents before being placed on the resuscitaire. All monitoring equipment was attached in the same sequence for each patient by the research team. The fhPPG cap was fitted, ECG leads attached and a PO sensor attached to the wrist of the right hand[16-18] and raw data collected for up to 20 minutes.

The B450 monitor generates HR data which provides ECG and PO values every 5 seconds. All fhPPG HR data extracted were averaged over the same 5 seconds window for direct comparison.

Slow and rapidly changing HRs can be unpredictable in the NICU and ECS settings. To ensure the fhPPG HR algorithm can effectively extract a wide range of rapidly changing HRs, as experienced during newborn care, we subjected the algorithm to simulated HR data covering 25-250 bpm using the Japanese Industrial Standard (JIS T 1303:2005, revised 2018).[19] Although the JIS is designed for testing foetal heart rate monitors, it appropriately models newborns as the HR baseline and variation are similar to those of the foetus.[20] A simulated PPG signal was input across the JIS range of HRs, the algorithm's performance tracked and linear regression applied to evaluate the overall performance.

2.3 | Data analysis

HR data from either PO or fhPPG were excluded if there was no ECG (the gold standard) HR comparator, a protocol violation occurred or a device was detached from the patient. To ensure good quality gold standard data, erroneous ECG HR data, as previously observed,[13] were excluded if there was no discernible QRS complexes or there had been an algorithm drop out. If the ECG HR value deviated by >20% from the other test devices (PO and/or fhPPG), the RR interval on the raw ECG trace corresponding to that time point was manually checked and excluded if the manual ECG HR check deviated from the reported ECG HR by >10%.

The success rate was calculated as the percentage of time during which the device in question was attached to the patient and reporting a HR once all three devices were simultaneously outputting a valid HR.

Comparison of the HR accuracy (fhPPG and PO) with the gold standard (ECG) utilised three methods: (a) Positive Percent Agreement (PPA) which is the percentage of time the test device generated a valid HR within 10% of the paired ECG HR,[21] (b) modified Bland-Altman plots to correct for multiple measurements and its limits of agreement (LOA),[22,23] and (c) Root Mean Square Error (RMSE) calculated between paired HRs (fhPPG vs ECG, and PO vs ECG). HR output time for each device is the time taken from completion of its attachment to the display of a HR.

Analyses were performed using GraphPad Prism 7.01 (GraphPad). Continuous variables were tested for normality using the Kolmogorov-Smirnov test. Data were presented as mean (SD),

TABLE 1 Patient demographics and baseline variables during NICU and elective caesarean section (ECS). Values are absolute numbers or median and interquartile range (IQR)

Demographic or Variable	NICU n = 34	ECS n = 18
Gestational age (wk)	31 + 2 (28 + 5-35 + 5)	39 + 0 (38 + 6-39 + 3)
Age (d)	23 (10-39)	Birth
Birthweight (g)	1460 (1019-2288)	3335 (2833-3561)
Male sex, n (%)	16 (47)	7 (39)
Ethnicity, n (%)		
White	32 (94)	14 (77)
Mixed white/ Middle Eastern	1 (3)	–
Mixed white/ Afro-Caribbean	–	1 (6)
Asian	–	1 (6)
Black	1 (3)	2 (11)
Resuscitation during study	–	2 (positive pressure mask ventilation)

median (range) or median (IQR) where appropriate. Non-parametric data were compared using the Wilcoxon signed-rank test, and between-groups were compared using Friedman's test with Dunn's correction for multiple comparisons. The study was registered at Clinicaltrials.gov NCT 02701920.

3 | RESULTS

A convenience sample of 60 infants was recruited (NICU = 40, ECS = 20) when researchers were available. Six infants were excluded from the NICU phase and two from the ECS phase due to ECG data not being stored or corrupted leading to data loss and misalignment. The patient demographics can be seen in Table 1.

3.1 | Success rate

During the NICU phase, the median ECG success rate was 100% (IQR, 100-100, n = 12 967), PO was 100% (IQR, 99.1-100, n = 12 688) and fhPPG was 98.7% (IQR, 93.9-100, n = 11 501). During the ECS phase, the median ECG success rate was 96.2% (IQR, 91.9-100, n = 2039), PO was 98.1% (IQR, 89.5-100, n = 1903) and fhPPG was 94.1% (IQR, 84.1-98.4, n = 1805).

3.2 | Accuracy of devices

During the NICU phase, the median PPAs were similar for fhPPG (99.6%; IQR 99.0-100, n = 11 353) and PO (99.4%; IQR 99.0-100, n = 12 249). During the ECS phase, the median PPAs were again similar for fhPPG (98.6%; IQR 96.4-100, n = 1584) and PO (98.7%; IQR

97.2-100, n = 1684). Device comparison with the gold standard was also determined using both Bland-Altman plots (Table 2) and RMSE (Table 2 and Figure 1).

Linear regression of all pooled paired HRs demonstrated PO and fhPPG had similar goodness-of-fit with both having an R^2 = .89 (Figure 2). In five babies, the ECG measured a HR <100 bpm. For these, there were 23 paired values with the PO of which two reported a HR >100 bpm and for the fhPPG there were 13 paired values with two reporting a HR >100 bpm, and on both occasions the fhPPG output was identified as a poor signal triggering a warning to the user.

3.3 | Algorithm simulation

Simulated PPG data were applied as described across a range of HRs and with varying rates of change as defined by JIS T (Figure 3). The fhPPG algorithm demonstrated excellent correlation with the simulated HR (Figure 4).

3.4 | Heart rate output time

Median time for HR output was similar for all three devices during the ECS phase. For ECG, this was 24.5s (IQR 14.2-31.2), fhPPG 35.5s (IQR 16.7-53.7) and PO 24.5s (IQR 13.5-53.5) with no statistical significance between any of the devices.

4 | DISCUSSION

We aimed to establish the accuracy and reliability of a new wireless, cap mounted HR monitoring device (fhPPG) in the neonatal setting and compare this to the HR obtained from PO. The fhPPG device provided accurate and reliable HR data compared to current predicate devices generating a median RMSE of 2.8 bpm compared to 3.3 bpm for PO in the NICU. In the ECS phase at birth, median RMSE values of 4.1 bpm and 3.7 bpm were obtained for the fhPPG and PO devices, respectively. Time to output a HR after placement in the delivery room was similar across all three devices.

TABLE 2 Bland-Altman limits of agreement (LOA), bias (fhPPG HR-ECG HR) and Root Mean Square of the Error (RMSE) expressed as medians from patient level data

Measure	NICU (n = 34)		ECS (n = 18)	
	fhPPG	PO	fhPPG	PO
LOA (bpm)	−5.6, 4.9	−6.3, 6.2	−8.7, 7.7	−7.6, 7.1
Bias (bpm)	−0.6	−0.3	−0.5	−0.1
RMSE (bpm)	2.8	3.3	4.1	3.7

Abbreviations: ECS, elective caesarean section; fhPPG, forehead wireless cap PPG device; NICU, neonatal intensive care unit; PO, pulse oximeter.

All devices provided similar success rates when outputting a HR. During the NICU phase, the fhPPG device had fewer data points because of the requirement to remove and replace the device for safety checks as required by the ethics panel. The high ECG success rate reflects the use of electrodes that were already in place for normal neonatal care and, unlike the fhPPG device, were not removed and re-sited for safety and acquisition time purposes.

Accuracy, as measured by PPA, Bland-Altman and RMSE demonstrated the fhPPG device was similar to the PO in both settings. The measures of variance for each of these measures were within clinically acceptable limits, both optical devices providing accurate data when compared to the ECG that detects electrical activity. This requires the algorithms to respond in a timely fashion to rapid changes in HR, a key requirement of any device in these settings. For PO in the NICU, Singh et al (2008) had demonstrated the Bland-Altman LOA of ±12 bpm.[24] In our study, the PO performed much better in the NICU and ECS groups. For the new fhPPG device, accuracy in the NICU has improved to approximately ±5 bpm from the previous iteration with LOAs of up to ±12 bpm.[13] This improved accuracy remained for the fhPPG device during the ECS phase with LOAs of approximately ±8 bpm. PO has been studied in the delivery room across a range of gestational ages. Kamlin et al's [8] study was mostly mature infants, with a mean gestational age of 35 weeks, and the majority (65%) did not require any intervention. The Bland-Altman demonstrated a mean difference of −2 bpm and LOA of ±26 bpm. The results for both PO and fhPPG in the present study were significantly better although the groups were not entirely comparable with only infants ≥37 weeks gestation recruited at birth in the ECS group. The additional measures of HR accuracy also add confidence that the fhPPG device performs as well as current devices with a PPA of approximately 99%, in the NICU and ECS phase, and an RMSE 3-4 bpm. Furthermore, both the PO and fhPPG devices produced high correlations with an R^2 = .89 for goodness-of-fit compared to ECG HR. For the ECS phase, these data are reassuring given the vigorous nature of the babies at birth and the significant motion artefact introduced.

It is essential that any newborn HR monitoring device is able to detect low rates, particularly those below 100 bpm. The majority of babies in this study were stable with limited HR variability so limiting the number of HRs <100 bpm. Use of the JIS methodology allowed us to test the software algorithm to rapidly changing simulated HRs across the typical newborn range. The fhPPG algorithm was able to track the HRs quickly and accurately with an R^2 = .994. This strong correlation supports the accuracy of the device's software based on simulation data, but the whole system requires real-world evaluation with infants undergoing resuscitation or stabilisation.

The secondary aim of this study was to explore the acquisition time of the new device, as it is essential for fast delivery of information to the attending team to allow correct management of the baby. Output of the HR at birth for all devices was similar although more babies in the study would be required to confirm this persisted

FIGURE 1 Violin plots of the Root Mean Square of the Error (RMSE, median and interquartile range) for the wireless cap (fhPPG) device and the pulse oximeter (PO) in the neonatal intensive care unit (NICU, n = 34) and at birth in the elective caesarean section (ECS) phase (n = 18)

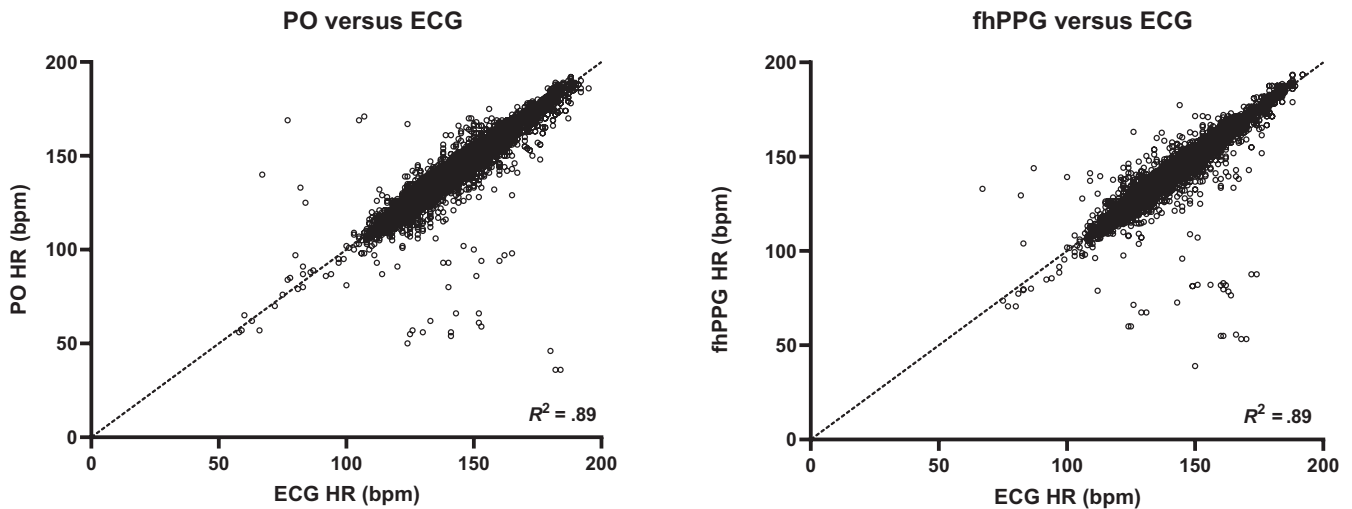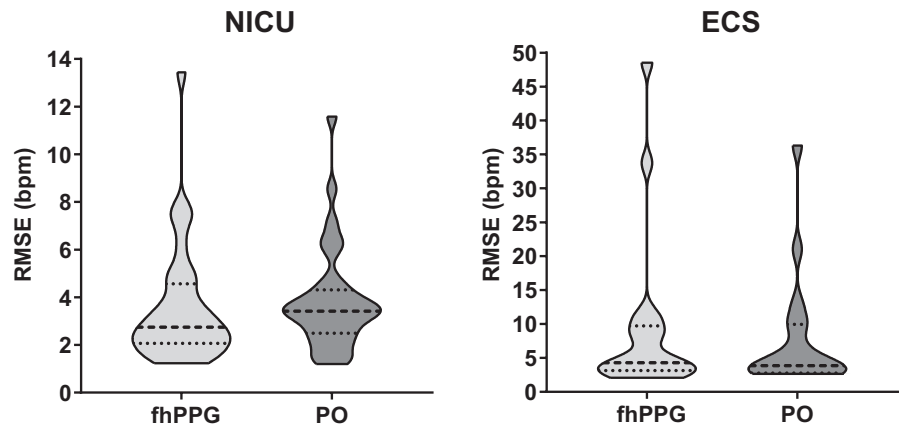**FIGURE 2** Linear regression of heart rate between pulse oximetry (PO) vs ECG (n = 13 935) and wireless cap (fhPPG) vs ECG (n = 12 939). Each data plot represents paired HR values between the devices

FIGURE 3 Comparison of the Japanese Industrial Standard (JIS) input signal with the wireless cap (fhPPG) algorithm output rate over simulated heart rate signals ranging from 25 to 250 bpm. Fluctuations are designed to simulate a number of heart rate changes observed in the newborn
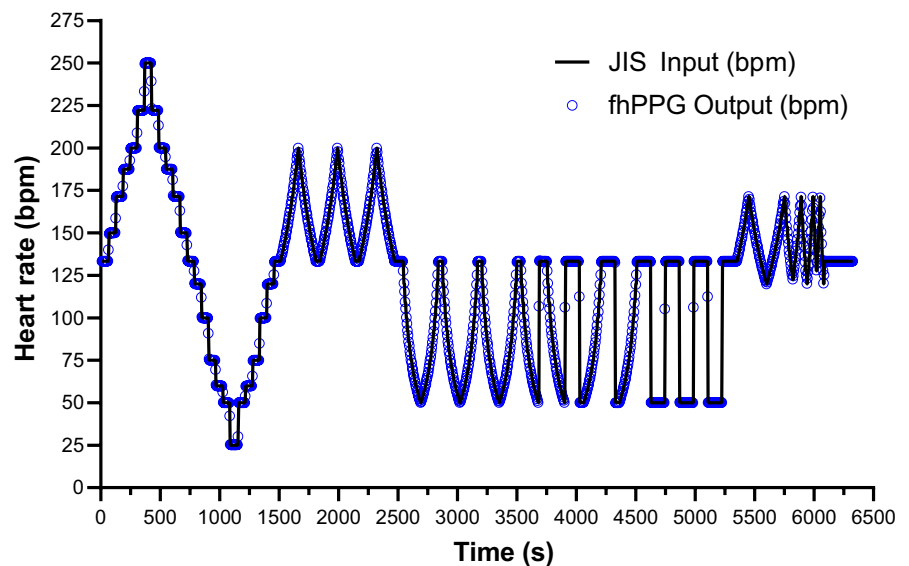
or identify any differences. ECG measures electrical activity and has been shown to acquire a HR quicker than pulse oximeters, possibly reflecting delayed acquisition from early cutaneous perfusion increasing in the first few minutes of life. The fhPPG device uses green light to measure HR, but also has red and infrared light that are optimised for oxygen saturation measurement and used by POs to
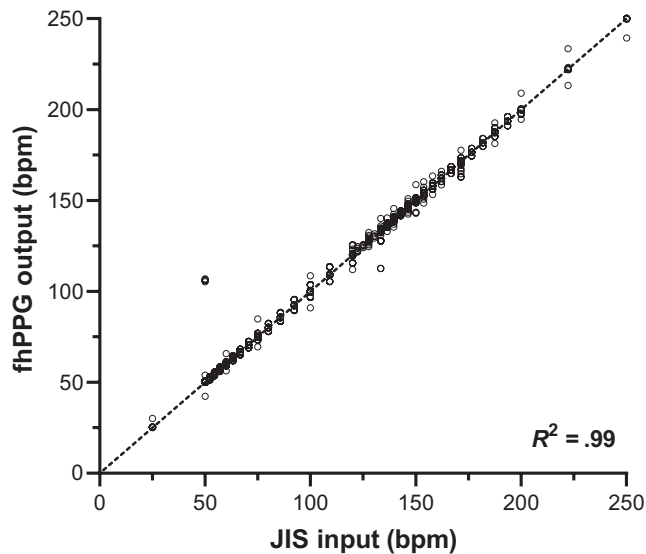
FIGURE 4 Linear regression plot of Japanese Industrial Standard (JIS) input signal (n = 1266) with the wireless cap (fhPPG) algorithm output (n = 1264) rate. Each data plot represents paired HR values between the device and input signal

measure HR. Green light is better suited to detecting pulsatile blood flow [13] so potentially optimising HR estimation particularly during low perfusion states. The sequence of device attachment after birth was fhPPG, ECG and PO, respectively, potentially disadvantaging the fhPPG device as it was placed earlier during the transition period. Whilst fast detection of electrical activity of the heart is useful, when cardiac output is poor or non-existent[5,6] there could be advantages to having a parallel optical sensor that is able to detect blood flow and hence confirm the electrical activity is associated with cardiac output. Any potential benefits of a centrally placed, green light optical sensor, that is fhPPG which detects blood flow from the forehead sharing a common central arterial blood supply to the brain, compared to a peripherally sited transmission mode device, require further evaluation in larger number of patients including preterm infants.

The main limitation of the present study is the low number of HRs below 100, reflecting the nature of the population who were stable NICU patients or ECS term babies born following uncomplicated pregnancies. There were fewer paired ECG and fhPPG values <100 bpm, compared to the PO, due to sensor repositioning as the signal had been identified as poor. We mitigated against low HRs by using the JIS methodology fully exercising the software algorithm to create HR values over the range 25-250 bpm confirming successful algorithm functionality. However, additional studies are required to establish this in compromised newborns, especially those with HRs <100 bpm, where the HR variability changes frequently and a larger number of preterm infants.

5 | CONCLUSION

With the increasing use of DCC, the development of a wireless, continuous HR monitor that aligns with the normal care pathway,

including placement of a cap with attachment for respiratory equipment, could better support transitioning of newborn babies and audit interventions.[25] Confidence in such a device could allow monitoring of the newborn and aid decisions around when to clamp the cord and instigate any stabilisation or additional resuscitation steps. fhPPG operates in reflectance mode allowing detection of a PPG signal on many parts of the body. The forehead allows inclusion in a cap, normally applied to keep the baby warm, and could potentially improve reliability during low perfusion states with a shared carotid artery blood supply to the brain.[13] The wireless design avoids multiple trailing wires that could become accidentally detached during bedside care with DCC. This device provides healthcare professionals with an accurate alternative to current neonatal HR monitoring. Further development of the HR algorithm, addition of oxygen saturation monitoring and evaluation during low perfusion states are underway.

CONFLICT OF INTEREST

Following are shareholders in SurePulse Medical Ltd—Don Sharkey, Barrie Hayes-Gill, John Crowe, James Carpenter and Steve Morgan. James Carpenter is the chief executive officer for SurePulse Medical Ltd. Don Sharkey and Barrie Hayes-Gill are non-executive directors of SurePulse Medical Ltd.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.