Wireless Heart Rate Detection Device for Neonatal Resuscitation in the Delivery Room

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Wireless Heart Rate Detection Device for Neonatal Resuscitation in the Delivery Room

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Abstract

Accurate and rapid assessment of neonatal heart rate is critical for timely intervention during resuscitation in the delivery room. The IttyBeaty, a wireless heart rate detection device was designed to meet the unique needs of neonates, specifically preterm, newly born infants and expand access to care. This device demonstrated significant improvements in speed and accuracy when compared to existing devices. Dynamic threshold and slope, fixed-size smoothing window, and early moving average (EMA) were implemented into the IttyBeaty software to ensure fast and real-time signal acquisition and filtering. The AD8232 heart rate sensor designed by Sparkfun is sensitive to motion artifacts, creating a noisy signal and inaccurate heart rate detection. To improve accuracy in the heart rate detection, minimization of intervals between beats were added to create a debouncing effect, outlier values were rejected, and rolling average was used to calculate stable signals. Additionally, a warning was displayed on the OLED display if the leads were displaced. When the IttyBeaty was compared to the "gold standard" electrocardiogram (ECG), which takes on average ten to thirty seconds to obtain a stable heart rate, the IttyBeaty achieved an initial measurement and stabilized reading in approximately two and nine seconds, respectively. Statistical analysis revealed that the IttyBeaty was significantly more accurate than two predicate devices, the PulseSensor and the NeoBeat with p-values of 0.00040 and 0.00740 respectively. However, there was no statistically significant difference in the accuracy of the IttyBeaty when compared to the Apple Watch and the FP10 sensor, which both had p-values of 0.20. Analysis also revealed the IttyBeaty was significantly more efficient than all four devices it was compared to. These findings showcase the IttyBeaty as a promising device for rapid and accurate neonatal heart rate assessment as it offers multiple advantages for clinical implementation during neonatal resuscitation.

Keywords: Neonatal heart rate, neonatal resuscitation, delivery room, electrocardiogram

Introduction

Approximately 10% of all newborns require breathing assistance immediately after birth and as many as 1% receive chest compressions or epinephrine due to perceived persistently low heart rate once breathing assistance is provided[1,2]. Once a newborn is delivered, heart rate is assessed to determine whether breathing is adequate[1]. If the heart rate is less than 100 beats per minute (bpm) steps are taken to ensure breathing is effective. If the heart rate remains less than 60 bpm, after optimization of breathing assistance, chest compressions are initiated and intravenous access is obtained to administer epinephrine. In the United States and Canada neonatal mortality has decreased to approximately 4 in 1000 births compared to the 20 in 1000 births in the 1960s[2], in part due to the implementation of the Neonatal Resuscitation Program (NRP) in 1987[3]. Preterm newborns, between 25 weeks and 36 weeks gestation, are more likely to need respiratory assistance at birth than those born full term due to immature lungs and complicated cardiorespiratory transition babies[4].

Assessment of heart rate is key to determining whether breathing is adequate, and NRP guidelines recommend various methods for assessing heart rate including palpating the base of the umbilical cord, auscultating for heart sounds via stethoscope, pulse rate detection via pulse oximetry, and electrocardiogram (ECG) for assessing heart rate in the delivery room[1]. Each of these devices leave room for human error leading to overestimation or underestimation of heart rate, delaying care, or resulting in unwarranted interventions. Additionally, a particular challenge is monitoring a newborn infant's heart rate during delayed cord clamping when the baby remains attached to the mother via the umbilical cord to the placenta. Many infants are born by Cesarean section, and ECG and pulse oximetry leads are not sterile and cannot be placed until after cord clamping. With increased interest in delaying cord clamping by at least two minutes for both preterm and full-term infants, having a wireless device that could quickly and accurately assess the heart rate of an infant as small as one pound (454 grams) would be extremely useful and marketable. The goal of this project was to create a small, wireless device that is sterilizable and can quickly and accurately report the heart rate of newly born infants.

The first aim was to develop an algorithm that collects infant heart rate data and transforms information into visual, auditory and/or stored display. Data collected from the device must be transferred to a displayable and interactive interface in order for next course-of-actions to be determined. This data can be visually categorized by color-coding mechanisms to assess resuscitation. Additionally, we aimed to transmit data into an auditory signal to assess resuscitation and store and collect this data on a visual display/monitor in order for easy care-application in delivery room environments.

The second aim was to incorporate device visual cues to indicate need for resuscitation based on detected heart rate. We aimed to design a device display which flashes red, yellow, or green depending on heart rate measurement. Red indicates need for resuscitation due to severely depressed heart rate (<60 BPM), yellow indicates moderately depressed heart rate (60-100 BPM), and green indicates heart rate within healthy range (100-160 BPM). We aimed to have a continuous display of the heart rate measurement as a function of time, and the associated color on the screen accordingly change with any changes in heart rate measurement.

The final aim was to designate a material that is safe for both premature and full term babies. We aimed to design a device that is biocompatible with the epidermis and of preterm and full term babies. As a neonate's skin is fragile, it is imperative to use a material that will not irritate or damage the skin. Additionally, a newborn infant is covered with amniotic fluid and a HR detection device would ideally adhere loosely to both wet and dried skin. We also aimed to use materials that are sterilizable to disinfect the device for every new use. Using materials that are sterilizable in our device will be safe for use in a sterile surgical field and will reduce the overall waste generated in a hospital system.

Results

Assessment of Device Accuracy

To assess device accuracy, the average difference in the initial and stabilized heart rate measurements of the IttyBeaty was compared against those of four other devices: the Pulse Sensor, the NeoBeat, the FP10 sensor, and the Apple Watch. For the purposes of this project, "Accuracy" is defined as the ability for the device to remain as close as possible to its own initial reading. As such, a device with a lower average difference between its initial reading and its stabilized reading is deemed as more accurate in this context.

After completing a one-tailed paired t-test, with the IttyBeaty being compared to each device, the p-values for this device compared to the Pulse Sensor, the NeoBeat, the FP10, and the Apple Watch were found to be 0.00040, 0.0074, 0.20, and 0.20, respectively. Using a significance level of 0.05, it was determined that the results were statistically significant for the Pulse Sensor and the NeoBeat, and the null hypotheses for these two devices were rejected.

Assessment of Device Efficiency

To assess the device efficiency, time was used as the primary measurement. Specifically, time (seconds) was recorded for how long each device took to obtain an initial heart rate and the time it took for the device to obtain a stabilized heart rate. In this context, we defined a stabilized reading as one that displayed the HR+/-1 bpm for a minimum of five seconds. We then compared the average time it took for the IttyBeaty to obtain an initial reading and the time it took to obtain a stabilized reading against the four other predicate devices. The device that took the shortest time to stabilize was deemed to be the most efficient by our definition. The goal of measuring the initial heart rate measurement was to determine how quickly each device algorithm took to run a primary assessment on the subject.

After completing a one-tailed paired t-test, with IttyBeaty being compared to each device, the p-values for this device's average initial assessment time compared to the Pulse Sensor, the NeoBeat, the FP10, and the Apple Watch were found to be 0.0188, 0.0002, $8.31*10^{-7}$, and $3.07*10^{-9}$, respectively. The p-values for this device's average stabilized assessment time compared to the Pulse Sensor, the NeoBeat, the FP10, and the Apple Watch were found to be 0.025, 0.00111, 0.034, and 0.00029, respectively. Using a significance level of 0.05, it was determined that the results were statistically significant across all devices for both initial and stabilized times, and the null hypotheses were rejected.

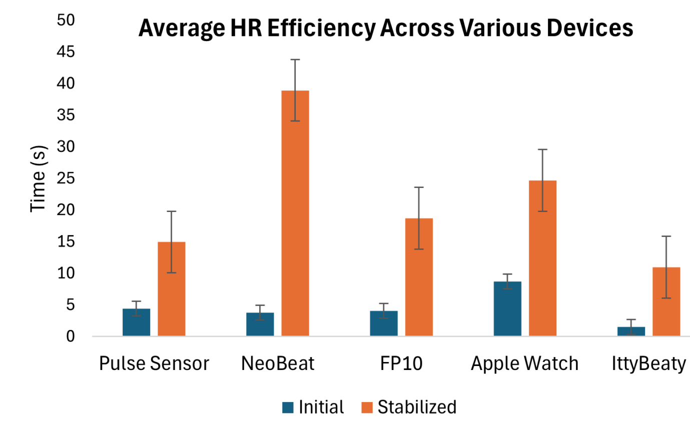

Fig. 1. Initial and stabilized HR time measurements across devices compared to IttyBeaty.

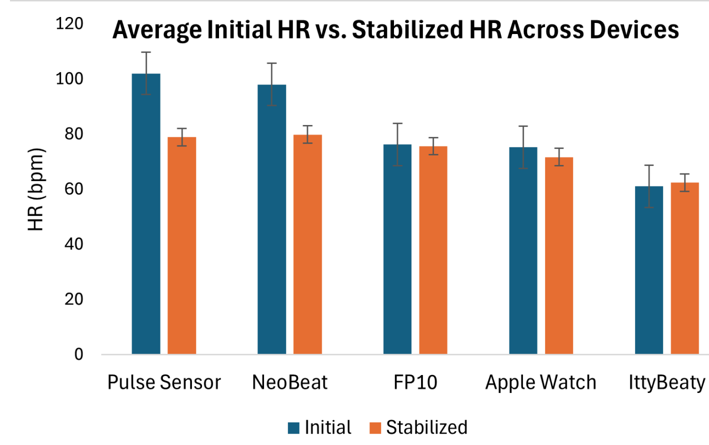

Fig. 2. Initial and stabilized HR measurements across devices compared to IttyBeaty HR measurements.

Discussion

The IttyBeaty performed significantly more efficiently ($\alpha = 0.05$) than all tested devices, resulting in faster initial measurements and average stabilized times when compared to other heart rate measuring devices (Fig. 1). The IttyBeaty presented the initial HR within approximately two seconds, and displayed a stabilized HR within roughly nine seconds. The IttyBeaty is also significantly more accurate ($\alpha = 0.05$) than the Pulse Sensor and the NeoBeat (Fig. 2). On average, the IttyBeaty performs 89.5% and 92.9% more accurately than the NeoBeat and Pulse Sensor respectively. Overall, our device performed well when being tested on adults. From this, it can be gathered that our device efficiently measures HR in a timely manner compared to many existing commercial devices.

This study faced several limitations that impacted the scope and depth of testing. First, Institutional Review Board (IRB) approval for human subject testing was not granted, which prevented in vivo testing on neonates. As a result, the device's performance was only evaluated under simulated conditions with a limited sample size of adults, which does not replicate clinical scenarios. This limitation restricts our ability to validate the system's efficacy and safety in its intended user population.

Second, while miniaturization was a design objective, there were issues with obtaining custom miniaturized components due to the size and the unique physiological needs of the target population. Due to time constraints, the final prototype does not include these miniaturized components, and the device was tested at a larger scale than intended. This affected both form factor and potential integration into neonatal care settings.

Future work for the IttyBeaty includes having a comparative test with the golden standard in labor and delivery, the ECG[1], to confirm its accuracy and testing on neonates. Given the limitations, future iterations should also prioritize early integration of miniaturized components and seek IRB approval earlier in the development timeline to enable clinical testing. Additionally, future iterations of the device would benefit from focusing on the sterility of the device and ability to detect a reading regardless of the contact surface conditions, while keeping neonate skin sensitivity in mind for the application of the device.

Materials and Methods

Study Design and Subjects.

This project was conducted as part of a biomedical engineering undergraduate capstone course at the University of Virginia. The primary objective was to develop and test a novel wireless heart rate monitoring device, the *IttyBeaty*, designed for neonatal use during delivery room resuscitation scenarios. Due to ethical and logistical constraints, heart rate monitoring experiments were conducted on healthy adult volunteers to simulate the physiological signals detectable by the device. Subjects were stratified for sex and gender to ensure a diverse testing population.

Device Construction.

The *IttyBeaty* consists of an electrocardiogram sensor, one lead with three gel electrodes, and an Arduino pro mini. In the future, it will be housed within a compact and miniaturized enclosure with custom circuitry. Electrical components from Sparkfun were utilized for the first iterations of the device, as Sparkfun provides libraries and components applicable for prototyping and research[5]. Components include a serial to USB converter, the AD8232 heart rate monitor, ECG leads, gel pads, and a 0.95" 96x64 Full Color OLED (SSD1331 based) display. These components were soldered together with jumper wires to form stable connections according to Figure 3.

Signal Processing and Algorithm Development.

The device collects analog data from the ECG sensor and transmits it via a FTDI basic breakout to a custom Arduino-based software application. Signal filtering and processing were implemented using a dynamic threshold and slope algorithm that adapts in real-time to remove noise and enhance peak detection accuracy. The software calculates both initial and stabilized heart rate values, where stabilized heart rate is defined as the average of readings fluctuating within ±1 bpm for a minimum of five continuous seconds. Initially, with the original test code from SparkFun[5], obtaining an initial heart rate was slow and highly inaccurate. To combat this, early moving average (EMA) and a fixed-size smoothing window were implemented. EMA

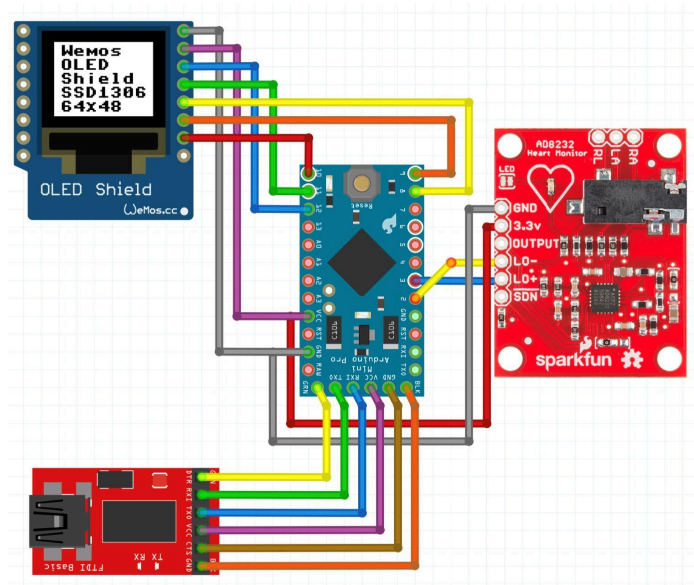

Fig. 3. Circuitry diagram with OLED display, SparkFun's AD8232, and FTDI Basic Board.

works by smoothing the raw ECG data over a specific sampling window and averaging the values of each peak to provide a value. This processing technique allowed for there to be less short-term variation in the data and reduced the high-frequency noise before and while the algorithm analyzed the data. Output from the algorithm is communicated to a user interface featuring a visual heart rate display and an OLED-based color-coded resuscitation indicator: red for HR <60 bpm, yellow for HR 60–100 bpm, and green for HR 100–160 bpm. To minimize the sensitivity to motion of the AD8232 sensor, outlier values– values exceeding 210 bpm and values less than 0 bpm – were rejected as null. Additionally, to create a debouncing effect, the intervals between beats were minimized. Adding the debouncing effect was effective as it reduced the devices ability to register multiple erroneous beats, which could otherwise lead to incorrect heart rate output on the OLED display and potentially misguide health care providers when in use.

Comparative Testing Protocol.

To benchmark the IttyBeaty's performance, four commercially available heart rate monitors were used for comparison: the Pulse Sensor, NeoBeat, Apple Watch, and FP10 sensor. For each device, heart rate was recorded under resting conditions. Two metrics were measured:

1. Initial Reading Time – time (in seconds) from device activation to first heart rate display.
2. Stabilized Reading Time – time (in seconds) to achieve and maintain a consistent heart rate within ±1 bpm for at least five seconds.

Each subject was tested sequentially with all five devices, including the IttyBeaty, under the same environmental conditions. Data were collected in duplicate for reliability.

Statistical Significance.

A one-tailed paired t-test was used to compare the initial and stabilized heart rate readings of the IttyBeaty against those of the other four devices. Statistical significance was determined for each device compared to the IttyBeaty at an alpha level of 0.05. Heart rate accuracy was defined as the absolute difference between the initial and stabilized readings for each device, meaning each device was assessed for its ability to remain as close to its initial reading as possible. Heart rate efficiency was defined as the amount of time taken for the device to obtain an initial reading and the amount of time taken for the device to obtain a stabilized reading.

End Matter

Author Contributions and Notes

All authors designed and performed research, A.M.T., and A.J.C., wrote software, J.A.C.P., and A.M.T. constructed the device, M.S.G. and A.J.C. analyzed data; and all authors wrote the paper.
The authors declare no conflict of interest.

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