Clinical Research Device and App to Measure Oral Feeding Adaptable In Preterm Infants

Team: [Redacted], [Redacted], [Redacted], [Redacted]
Faculty Mentors: [Redacted] and [Redacted]

Thesis
Can the proposed clinical research device and app collect identical data to the current standard cardiopulmonary monitor and methodology in a faster, time efficient manner?

Purpose
Globally there are over 15 million preterm infants born annually, representing approximately 11% of the total number of births worldwide [1]. 80% of these infants will struggle with achieving safe and efficient oral feeding without proper therapeutic intervention [2]. Currently, clinicians observe the infant feeding, noting behavioral changes (i.e. lips turning blue, coughing, vomiting, etc) and quantity of milk consumed to inform clinical decisions on changes in feeding practice [3], [4]. This archaic methodology is inconsistent, unstandardized, subjective between clinicians, and is globally experienced [5], [6]. Consequently, infants’ feeding protocols vary per physician and improper interventions could be used depending on the experience of the observer. Subsequently, the lack of a uniform and consistent marker of oral feeding adaptability negatively impacts the preterm infants by causing vomiting, coughing, and negative feeding associations as well as increasing the risk of readmission or delaying discharge ultimately leading to more parental stress and large hospital bills [6]. To address this, a clinical research device will be built to explore if it can serve as a clinician’s tool to provide an objective and consistent measurement of oral feeding adaptability.

Objective
The overall objective of this proposal is to develop a clinical research device and app to measure oral feeding adaptability in preterm infants. After development, the device will be tested for safety and effectiveness while the app will be tested for ease of use and logic paths.

- **Objective #1.** Design and print iterations of electronics to capture physiological signals (heart rate, HR; respiratory rate, RR; oxygen saturation, SpO₂; and respiratory waveforms RWV) using Eagle.
- **Objective #2.** Design and print iterations of housing units to hold electronics.
- **Objective #3.** Test electronics and housing units for fit and safety.
- **Objective #4.** Design software/app to clean data and control electronics.
- **Objective #5.** Test and iterate software/app with feedback from faculty mentors and teammates.

Approach
To develop the device, Healthy Pi v4 from Protocentral will serve as a hardware and software foundation [7]. The PCB design from Healthy Pi v4 will be redesigned, modified, and printed and the additional components are mounted, the shell encasing of the device will be designed in SolidWorks and 3D printed.
Additional software designed in Python will be used to collect, filter, and calculate the oral feeding adaptability score using sample entropy.

**Electronics.** The electronics design is derived from Healthy Pi v4 and modified to meet the necessary electrode ports to be compatible with existing electrodes. These electrodes include electrocardiogram (ECG) and oxygen saturation. The primary priority for this project is the ECG used to measure transthoracic impedance through impedance pneumography (IP) and create the respiratory waveform of interest for sample entropy calculations.

The primary two modifications required on the Healthy Pi are the conversion of the (1) 3-lead audio jack to the 12-pin port used by standard commercially available Philips electrodes and (2) power supply to the power port from discontinued modules (Fig. 1). The current oxygen saturation 9-pin DB8 is compatible with existing standard Philips/Masimo connectors. Modifications will be made on the schematic using Eagle from AutoCAD.

**Figure 1.** Healthy Pi v4’s signal acquisition board is marked with components to be modified. Modifications include conversion of (a) 3-lead audio jack to 12-pin port and (b) power supply. (c) Standard 9-pin DB8 port standard connector that does not require modification.

**Housing.** The housing must hold the electronics and have ports available for power, electrode plugs, and user input (i.e. power on). To increase adoption in the limited NICU space, the encasing must be compatible with existing module racks. For the context of the device proposed, the device will be designed to be compatible with module racks from Philips (Fig. 2a). In addition, to mimic what is familiar to the end-users (NICU clinicians) the module will be designed similarly to Philips modules (Fig. 2b).

**Figure 2.** (a) Example of a module rack from Philips health monitor. This rack is used to provide power to modules like (b) and to collect their respective physiological data. (b) Example of a Philips ECG module that has been discontinued [8].
**Software.** Additional software is required to transition data from the electrodes to the processor in the PCB and later transferred to a Raspberry Pi where additional software is needed for filtering and processing the respiratory waveforms. These codes will be created in Python and automatically implemented on the command terminal upon powering up. The filters include a cardiogenic and motion artifact filter which then streamlines the data to be processed by the sample entropy calculation code. The data will be displayed to the user via an auxiliary screen or an app. The workflow of data collection to pre-processing, processing and display is illustrated in Fig. 3.

![Workflow diagram](image)

**Figure 3.** Workflow of the proposed system for data collection to pre-processing (i.e. filtering data), processing (calculating sample entropy), and displaying the score to the end-user.

The sample entropy calculation and filters have already been created. The cardiogenic filter and motion artifact filter have been previously designed using a 6th order Butterworth filter and instantaneous frequency calculated from the Hilbert transform. Thus further work for these filters is creating a streamlined code that implements the filters and subsequently the sample entropy algorithm.

**App.** Lastly an app has been designed and will be updated throughout this proposal to act as the controller for the device and software (Fig. 4). Practice data will be used to test data input and device control. The data accuracy and time to input data compared to the standard method will be compared.

![App interface](image)

**Figure 4.** Examples of current oral feeding adaptability app user interface.
Responsibility
The following is the breakdown of responsibility for the completion of the project and how the team member will work with faculty mentors [Redacted] (clinical advising) and [Redacted] (engineering advising) to accomplish the objectives of the project.

- [Redacted]. [Redacted] will work with [Redacted] to test the app by inputting practice data. She will provide iterative feedback on app design and device use. After the app is complete, she will write standard operating procedures (SOPs) for future clinical researchers to utilize apps and devices.
- [Redacted]. [Redacted] will primarily work on software components of the project. He will update and refine motion artifact filter for cleaning and preprocessing data as well as work with [Redacted]’s research personnel to update the app using [Redacted]’s feedback.
- [Redacted]. [Redacted] will design the housing box and print iterations. Through testing, she will incorporate feedback for changes using [Redacted]’s input and guidance from [Redacted] and [Redacted].
- [Redacted]. [Redacted] will Redesign the PCB on Eagle, coordinate printing, solder additional components and test electrical components for continuity and shortening. [Redacted] will then test the device using a patient simulator and compare with the current methods for collecting physiological data.

Timeline
The following gantt chart (Tab. 1) summarizes the timeline of when objectives will be completed between Fall 2022 and Spring 2023. The individual(s) responsible for ensuring its completion are also listed with the objectives.

<table>
<thead>
<tr>
<th>Objective #</th>
<th>Responsible Person</th>
<th>Fall 2022</th>
<th>Winter 2023</th>
<th>Spring 2023</th>
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<td>Objective 1</td>
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<tr>
<td>Objective 2</td>
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**Itemized Budget**

In order to complete the project, the following itemized budget is required (Tab. 2). To use the RS232 board and cable, the UCI Medical Center has allowed the team to borrow a Philips cardiopulmonary health monitor to conduct testing.

**Table 2. Itemized budget for proposal.**

<table>
<thead>
<tr>
<th>Item</th>
<th>Budget</th>
<th>Justification</th>
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<tr>
<td>1. PCB prototype prints from JLC</td>
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<td>Objective #1</td>
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<td>2. Healthy Pi v4.4 from Protocentral</td>
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<td>Objective #1</td>
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<td>3. Rechargeable battery pack</td>
<td>$50</td>
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<td>4. Raspberry Pi 4B+</td>
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<td>5. Neonate patient simulation (Pronk Technologies)</td>
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<td>6. 3D prints from Fabworks and RapidTech</td>
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<td>7. RS232 USB to RJ45 Data cable</td>
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<td>8. RS232 Board for Philips Health monitor</td>
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<td><strong>Total</strong></td>
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**References**


