Early Detection of Pressure Injuries in Small Infants Requiring the Use of CPAP Ventilation

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Abstract

There are roughly 400,000 premature infants born annually in the United States, majority of which have an underdeveloped respiratory system lacking enough surfactant to keep the lungs fully expanded. This condition is treated with continuous positive airway pressure (CPAP) ventilation to assist breathing. About 25% of infants using CPAP experience tissue injury and ulceration due to prolonged mask pressure, which leads to additional adverse events such as bacterial colonization, sepsis, and death, as well as hospital costs. Health care professionals perform routine checks evaluating visible pressure injury, but non-visible injury can be present. To address this issue, a novel sensor film using Ag/AgCl conductive paste was developed to work in conjunction with current infant CPAP masks. The sensor measures the tissue impedance as a predictive injury indicator and an integrated controller/alarm system altering health care professionals for direct intervention. Based on customer input, the sensor film is designed as a disposable plug-and-play component while the arduino based controller system is designed for repeated use, thereby fitting into current hospital purchase and clinical practice paradigms. The integrated device design and controller algorithm has been fully prototyped as a proof-of-concept and the full device has been analyzed under verification and validation testing.

Introduction

Prolonged pressure of the mask, which can be observed as early as 1-3 days on the underlying skin tissue, can cause pressure injury, including ulceration[1]. Pressure injuries occur in 25% of the premature infant population annually in the United States, which equates to 100,000 premature infants[2]. The most susceptible area for pressure injury is on the nasal bridge; however, facial size can affect pressure loads, causing the area beneath the nostrils and the area to the sides of the nostrils to also be highly susceptible to pressure injuries, as well. Pressure injury in the premature infant population can lead to an open wound, bacterial colonization, infection, sepsis, and even death. Routine visible checks are performed by healthcare professionals as per protocol; however, this practice is not sufficient as every facility has different protocols and non-visible pressure injuries cannot be detected by the natural eye. This project aims to develop a novel sensor film that is able to detect pressure injury through impedance measurements in the underlying tissue of where the mask lays. At the point of detection, an alarm system would notify health care professionals to attend to the premature infant experiencing the pressure injury.

Design Inputs

1. The device must measure the change in impedance of the skin.
2. The device must be available in various sizes for different size patients.
3. The device must incorporate an alarm system when complications occur
4. The device must function for clinically relevant periods of time
5. The device must meet relevant/applicable regulatory standards.
6. This device must meet all electrical safety standards

Design Solution

The final design is composed of two adjoining assemblies: one being reusable and the other being single use (Figure 1). The single use part contains the screen printed electrode sensing array on a polyester film, the 3D stabilization component, and the male connector pin. The reusable permanent housing unit for the hardware consists of the female pin connector, which leads to the arduinos, power supply, breadboard, and audible alarm.

The single use male connector connects to the permanent female connector, which runs to the hardware that interprets and analyzes the impedance measurements. The 6 wires from the female connector each represent an electrode. The electrodes are equidistant from one another, therefore allowing a code to read the impedance and phase angle between each neighboring electrode pair.

The algorithm that was implemented to alert if the device detects impending tissue damage is shown (Figure 2).

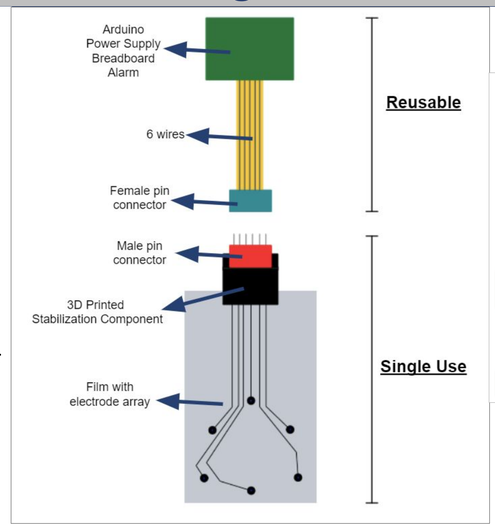

Figure 1. Prototype Components

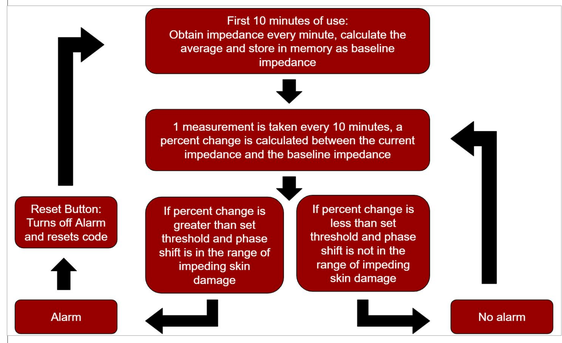

Figure 2. Control Algorithm

Testing

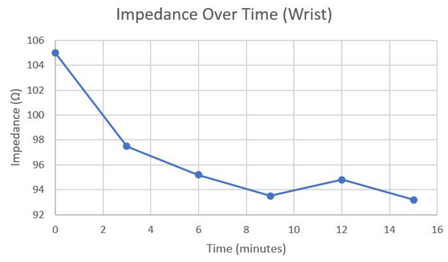

Figure 3. Feasibility Testing of Impedance

METHOD:

1. Measure the impedance on the inner wrist
2. Applied the heating pad to the wrist for 15 minutes and measure the impedance every 3 minutes
3. Measured at 100 mV and 1 kHz

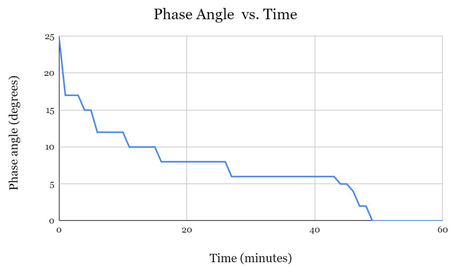

Figure 4. Phase Angle as a Function of Time

Table 1. Verification of Impedance Measurements

Resistor Value	Average Observed	P-value	Pass/Fail
10 Ω	9.97 ± 0.11 Ω	0.575	Pass
100 kΩ	99.50 ± 0.83 kΩ	0.249	Pass
1 MΩ	9.86 ± 0.36 kΩ	0.433	Pass
3 MΩ	2.89 ± 0.33 kΩ	0.497	Pass
5 MΩ	4.87 ± 0.17 MΩ	0.162	Pass

While impedance testing on chicken skin is preliminary, the skin will dry out resulting in a decrease in impedance magnitude corresponding to ischemic skin in small infants.

Conclusions

Premature and small infants that require the use of a CPAP device to aid in breathing are at an increased risk of pressure injury. Currently, there are no devices on the market that support early detection of pressure injury within this respective population in localized areas below the skin. After conducting research, implementing feedback from faculty and healthcare professionals at CHOP, defining user inputs, and testing the feasibility of two design solutions, a novel sensing electrode array was designed, tested, and proven to show a change in skin impedance, thus inferring the reduction of the risk of pressure injury within CPAP mask wearing infants. This device has the potential to detect early, non-visible pressure injuries related to CPAP masks, which would put the patient at a lower risk for pressure injuries that lead to complications ranging from infections to death. In addition, this device has the ability to improve the standard practice of care performed by healthcare professionals by eliminating the need for lifting of the CPAP mask for visible inspection of the respective area. By eliminating this procedure, the infant reduces the risk of becoming systemically unstable, as they will continue their constant ventilation. Based on verification and validation testing, it can be concluded this device is safe and effective in its ability to detect early pressure injuries. Future research should be conducted, however, to improve upon method of alert, fabrication and manufacturing procedures, and material selection.

References

1. Napalitano, N., Stetzer, M., Children's Hospital of Philadelphia, VOC
2. *Nurses eliminate pressure ulcers in premature infants*. (2013). ScienceDaily.

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