Needs Assessment for *Infant Stimulus for Apnea of Prematurity* project, Dr. [redacted] and the physicians of the Neonatal Intensive Care Unit (NICU) at The University of Tennessee Graduate School of Medicine

Date of Approval: [redacted]

Document Created, Organized, and Upkept by Biofeedback Solutions

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Purpose of Document

The purpose of this document is to explicitly enumerate the needs for the *Infant Stimulus for Apnea of Prematurity* project. The needs of this project, as heard from our stakeholders, are stated and described, and their applications explained in this document. This document also contains a gap analysis, comparing the current system to the one that Biofeedback Solutions is proposing.

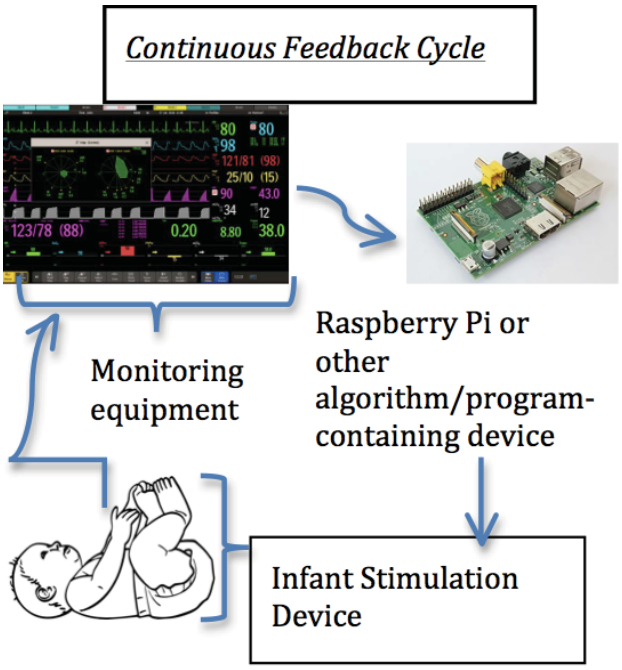
It is also understood that, due to the dynamic nature of engineering itself, and this project specifically, these needs may adjust and evolve over time. This is due to currently unforeseen issues that Biofeedback Solutions may encounter, future constraints that may be placed on the design process (such as monetary or time constraints), and modifications to the proposed solution(s) as the project progresses.

Each time one of these scenarios occurs, this document shall be updated as necessary, as the team members and/or stakeholders see fit. The review rate of this document shall be set to once monthly, or more often if necessary.

Based on meetings with project stakeholders, Dr. Chris Stephens and Dr. Mark Gaylord at the UT GSM, the justification for the key needs selected is the discussion of said needs with our stakeholders. Throughout the course of multiple meetings, our stakeholders have identified their *key needs* (or those that are *essential*) versus their *wants*, which have governed the prioritization of our device's design input. These discussions, and the *key needs* and *wants* that have manifested as a result of them, are described in this document.

Overview

The system to be built by Biofeedback Solutions, in collaboration with the Graduate School of Medicine, is essentially described as a feedback loop. This feedback loop is best and most simply envisioned by the graphic below.



Starting at the infant:

1. The first 'sub-assembly' of our device will be an array of novel sensing equipment that will monitor an output from the infant. This equipment will replace biosignal monitoring equipment currently in use in the NICU, as per the doctors' requests stating that this equipment's sub-standard response times need to be improved upon.

2. The monitoring equipment designed by our group will send its output data to a microcomputer of sorts, where this data will be analyzed to determine whether or not apnea is occurring. If so, the microcomputer will send an ON signal to the stimulation device. This apnea detection must occur rapidly (less than 20 seconds into an apneic episode).

3. The stimulation device will initiate stimulation upon receipt of the signal from the microcomputer. This stimulation will not be harmful to the infant, or infringe upon current equipment present in the infant's environment. It will also be designed to be as re-usable as possible.

4. The monitoring equipment will continuously monitor the infant, sending data to the microcomputer that can detect when apnea has ceased, in which case the microcomputer will cease sending the ON signal to the stimulation device.

Description of Stakeholders and their roles:

Dr. [redacted] medical-engineering liaison, and our main point of contact within the Graduate School of Medicine. Given Dr. [redacted] medical and engineering backgrounds, he will act to represent the needs and desires of the NICU physicians and nurses (our customers and target audience for the completion of this project) throughout

the duration of this project, as these stakeholders are not as readily available to meet and discuss the project. He will be depended upon to provide said guidance in the best interest of the GSM NICU, while having the understanding of our group's ability, timeline, and overall project scope. Dr. [redacted] is the core facilitator of meetings between the physician/nursing stakeholders and our group.

Dr. [redacted] is the figurehead of the NICU physicians, who can be described as our customers and target audience for the completion of this project. Dr. [redacted] has provided (and will continue to provide) technical/detailed guidance for our project, given his extensive experience as a NICU physician. Dr. [redacted] may be turned to for answers to questions relating to the infants (say, average blood oxygen content or heart rate during apnea, for example), or the incubators or NICU itself. Biofeedback Solutions understands the nature of the NICU doctors' busy schedules, and will first turn to Dr. [redacted] for these types of questions if possible.

Other NICU physicians and nurses – this group of stakeholders represents our implementation audience. That is, they, along with Drs. [redacted], are the group that has the final say in whether our device is in fact what they're looking for to solve their current problem. These physicians and nurses may not be dealt with directly throughout the duration of our project, but they are the group that is governing our device's specifications and requirements. As such, their interests will be spoken for by Drs. Stephens and Gaylord. If they do in fact come into direct contact with our group, their desires, requirements, opinions, and input are heavily valued, and will be taken into consideration.

Referenced Documents

As mentioned in our *White Paper Proposal*, there are multiple patents and other documents that will be referenced throughout this project. Referencing these documents not only provides guidance on what works and what doesn't, and how, but also what *has* been done and what *hasn't*. Specifically, whether our device will be patentable or not. The following items are of utmost interest to our group (more can be found in our *White Paper Propsal*):

1. US Patent 5,555,891: Vibrotactile stimulator system for detecting and interrupting apnea in infants. Full text found here.
   This patent is extremely well-aligned with our design proposal. It will likely be highly referenced throughout the duration of this project. Furthermore, this patent cites several other patents of interest that will also serve as guidance throughout this project.

2. US Patent 4,694,839: Auxiliary stimulation apparatus for apnea distress. Full text found here.
   Again, this patent is very well-aligned with our design proposal. It discusses a foot or neck vibrotactile device for apnea interruption.

3. Infant's mattress comprises the vibration/stimulation device:
   Findings suggest that nonlinear properties of the immature respiratory control system can be harnessed using afferent stimuli to stabilize eupneic breathing, thereby potentially reducing the incidence of apnea and hypoxia. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2763836/

Needs Elicitation

Biofeedback Solutions contacted Dr. [redacted] via email to schedule time to discuss the requirements for a device to aid in the detection and treatment of apnea of prematurity. Meetings with Dr. [redacted] and the Neonatal Intensive Care Unit doctors followed, in which we asked questions regarding the requirements for the device, as well as general questions about the procedures already in use for the detection and treatment of apnea, giving us a good idea of their current solution. Having had these meetings, the basic design for the device could be created.

The first meeting with only Dr. [redacted] occurred on September 19th at the University of Tennessee Medical Center. During this meeting we were told the primary requirements for the finalized device: the device must measure and respond to apnea very quickly and accurately, it must be reproducible, and it must maintain a low stimulation strength in order to streamline FDA approval processes. Furthermore, we were told how heart monitors are currently used to measure drops in heart rate and blood pressure to signal apnea, but this method has an inherent delay, which needs to be improved upon. At this meeting we were also told how delicate a premature infant's skin is. Therefore, nothing can be stuck to the infant without the use of a hydrogel, or the infant's skin will be severely damaged.

The second meeting with the stakeholders occurred on October 4th, again at the UT Medical Center. For this meeting, Dr. [redacted] was accompanied by two NICU doctors. During this meeting we discussed more specific details concerning the monitors currently used to monitor apnea, as well as other possible monitors that may be used to measure a drop in respiration. In this meeting we were also told about the incubation chambers that

many of the infants live in. The incubation chambers maintain a temperature of about 90 degrees and a 40-80% humidity levels to keep the skin of the infant moist.

These meetings are currently the primary means of communication with the stakeholders, and they guide the direction of the project. Meetings will continue to occur throughout the year to provide Biofeedback Solutions with details for the project, as well as to maintain the stakeholders' interest in and knowledge of the progress of the device.

Needs Description

The following needs were made apparent after meeting with Dr. [redacted] and Dr. [redacted] the UT Graduate School of Medicine.

Essential:
Current monitoring times for apnea in the UT NICU do not sound an alarm until greater than twenty seconds of apnea have occurred. One of the essential needs of this project is to develop a system that senses an apneic episode in *less time* than this previously allotted sensing period. The second major need for our project is the device's ability to provide a stimulus to interrupt the infant's apnea once it has been sensed. This can be done in a variety of ways; the main requirement is just that the apnea is ceased. The device must also be re-usable with the exception of the electrodes that attach to the baby's skin. Overall, speed in both sensing and interrupting the apneic episode is the primary need that will be taken into consideration during the completion of this project.

Wants:

A possible design for our device would include a 2-in-1 feature that simultaneously attempts to prevent apnea while still having the ability to correct apnea through stimulus in the event that it occurs. This is somewhat ambitious in nature, but our group is considering the possibility of accomplishing this design during the project's timeframe. A want in every project would be a prototype that is as inexpensive as possible; cost will certainly be taken into account, but it is not the primary motivator in this device's design.

Constraints:

Because the subject affected by our feedback loop (the premature infant) is so delicate, our design process has many constraints that have to be considered. Our device needs to be as non-invasive as possible and provide only the adequate amount of stimulation, and no more, in order to prevent injury to the infant. A premature infant's skin is very delicate, comparable to a wet paper towel (as described by Dr. [redacted]), so all electrodes, monitors,

or stimuli need to be covered in hydrogel or another material to ensure the baby's safety and prevent rubbing. Incubators in the NICU are kept at high humidity and temperature (40-80% , 90° F), meaning our monitors must be adjusted accordingly to account for these conditions. The baby's ability to move must also not be hampered. Final constraints include the disallowance of electrical stimuli and compliance with existing monitoring and treatment equipment in the NICU.

Needs Validation

The needs that have been described herein have been discussed with and approved by Dr. [redacted], who reflects the needs and input of the NICU staff that this device will affect. We have met with Dr. [redacted] once (September 19th) and Dr. [redacted] once (October 4th), and have elicited and reviewed these needs. We have also presented our design proposal to Dr. [redacted] (October 9th) and are in the process of validating the accuracy of the reflection of these needs. As it is sometimes a challenging process to schedule meetings and ensure alignment of stakeholder input, in addition to the fact that our design may change as more information becomes available and device testing occurs, the process of needs validation will be ongoing throughout the design phase of our project (essentially the first half of the project). This document will be updated as the group sees fit when these changes occur. The first revision of this document will occur in the near future as per the recommendations of Dr. [redacted], which were made at a point in time too near the due date of this document to make the modifications. Said recommendations will be discussed at our next meeting, and this document will be revised accordingly.

Gap Analysis

The current system used for detecting apneic episodes in infants is one that uses standard vitals such as heart rate and SAT levels, vitals one would expect from a generalized current generation monitor. The response time of the current system is simply too slow (as heard from NICU physicians), taking around 20 seconds to sound an alarm at which point a nurse must stimulate the infant by hand to end the episode. This system really only satisfies one need of the NICU, and that is the interruption of an apneic episode. Every other need fails to be met by the system, such as lack of needing a nurse to physically touch an infant or quick and accurate response times. To generalize, the need is a feedback loop.

What we propose will ultimately change every method mentioned of detecting apnea and the stimulation process. The most important section we will be addressing is that of the time it takes to detect an apneic episode. The need of the NICU is to have the time for reaction reduced as much as possible, but still be able to not give false-positive readings. For this, our main process is going to be finding the right sensors for the job, and

properly calibrating them such that the monitor we create – as current monitors will not make the cut for the job – will be able to accurately determine if an apneic episode is occurring, in a quick manner.

Regarding the stimulus, unlike the current system, our system will be hands free using a stimulation device such as a motor or other stimulus method we see fit. Thus we will meet the need to not have nurses actually contact the infant.

Cost Comparison

The cost of our device is directly related to our choice of detection equipment and stimuli apparatus. The current least expensive option for detection would be the use of a thermistor for around $200. The most expensive option would be a pulse oximeter that retails for $800. The detector is the most expensive sub-assembly in the project, however, and we have no worries as a group over completing the device under budget. The stimulation device will cost anywhere from $25 to $300 depending on the type of stimulus we use. Low cost stimuli include the use of a fan, cold mist, or baby-sock with vibrating ability. The more expensive option would be designing a programmable bed that would help prevent apnea by moving to a randomly programmed pattern. This option is in our list of wants; its price would be additional to the device design. The microcomputer/microcontroller is the cheapest sub-assembly, costing only around $75 when cords, connections, and interfacing is included. Software programming might also be outsourced at a rate of $10/hour.