A Medical Device For Predicting and Preventing Infant Apnea

Technology Summary
Research clinicians and engineers working at the Wyss Institute for Biologically Inspired Engineering at Harvard University and the University of Massachusetts Medical School have developed a unique and proprietary integrated system that may be effective in predicting and preventing the onset of neonatal apnea in low birth-weight infants. The system makes use of the concept of Stochastic Resonance by applying a gentle vibration to the infant through the surface of a mattress.

One in nine live births in the United States is preterm (<37 weeks post conception) and these high risk births require specialized monitoring and treatment in neonatal intensive care units (NICU). Cardio-respiratory events are common in preterm infants, with severity ranging from presumably benign periodic apnea with mild oxygen desaturations and cardiac decelerations to severe life-threatening apnea that requires mechanical ventilation. Studies have also linked intermittent hypoxia with a number of acute and long-term complications, including multi-organ dysfunction, retinopathy, developmental delays, and neuropsychiatric disorders. Apnea of prematurity is a major factor in prolonging hospitalization as well as raising concerns for subsequent risk of apparent life-threatening events and sudden infant death syndrome (SIDS) at home. Despite the existence of non-pharmacological interventions for apnea of prematurity (such as vigorous manual stimulation and repositioning of the infant), there is a strong need for a reliable medical device that stabilizes breathing patterns and prevents intermittent hypoxia and bradycardia episodes in preterm infants.

Our system is designed to monitor the infant’s heart rate, breathing patterns, and other physiological signals, and then use proprietary algorithms to identify unique patterns that are predictors of the onset of breathing disruption or cessation. Once an anticipated apnea event is identified, the system activates a precisely tuned gentle SR vibration in the mattress to prevent the onset of the event without interrupting the sleep pattern of the infant.

The integrated system includes:
- Synchronized acquisition of multiple key physiologic signals
- Signal processing algorithms that provide early onset predictions of apneic events
- A therapeutic mattress which applies a gentle, sub-threshold, stochastic resonance vibration to treat apnea without changing sleep state

This integrated system is currently undergoing clinical studies at two leading research and teaching hospitals.

Stochastic Resonance (SR)
is a phenomenon found in biological systems that improves performance when a low-level stimulus is applied. In this application, the breathing of an infant improves by applying a sub-threshold SR vibration.
Benefits and Impact
Positive preliminary preclinical results suggest that this system is effective at reducing both the number and severity of apneic events, as well reducing the incidence, duration and severity of oxygen desaturations for infants in critical care settings. Other potential benefits include:

- Reduced chance for acute, long-term, and potentially life long complications associated with apnea
- Reduced length of stay in hospital intensive care unit
- Reduced need for specialized monitoring and treatment (reduced costs)
- Reduced workload on clinical staff
- Early warning of impending apneic events
- Reduced incidence of alarms, resulting in reduced risk for alarm fatigue
- Reduced need for emergency bedside treatment, resulting in reduced risk of infection

Product Vision
This technology could one day be deployed as an FDA-approved medical device which is fully integrated and enclosed within an infant-sized mattress. Non-contact sensors embedded within the mattress monitor the infant’s cardio-respiratory signals without attaching leads to the infant. These signals are then fed into an on-board processor inside the mattress. Algorithms running on this processor use the signals to predict apneic events and control the vibrational stimulation applied to the infant in attempt to prevent apneic events from occurring.

After discharge, the mattress could potentially be sent home with the family to prevent apnea in a home environment, send apnea alarms to a parent’s mobile device, and potentially alleviate concerns for sudden infant death syndrome (SIDS) at home.

Commercial Opportunity
Each year in the United States, one in nine births, or about 500,000, are premature. Estimates exceed 15 million premature births worldwide. These premature infants all require some form of neonatal intervention, and their combined health care costs are over $25 billion annually in the United States alone. Approximately ten percent of these premature infants are at much higher risk due to very low birth weights and require extended stays in the neonatal intensive care unit (NICU). Each day of NICU care (not including surgeries) costs in excess of $4000 in the United States and it is not unusual for the total cost of one infant in the NICU to exceed $1 million. Future research studies will determine if effective apnea prevention may significantly shorten the length of stay, thereby reducing health care costs for these patients. Initial target markets are likely the NICUs of advanced care hospitals, of which there are 2000 in the United States. Future versions of the technology could target the home market or markets in developing countries.

Intellectual Property
The Wyss has developed extensive broad patent and intellectual property portfolio covering the system, the algorithms, the software, the signal processing, and the therapeutic interventions.

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