**Engineering World Health: Infant Respiratory Monitor**
**Preliminary Product Design Specifications**
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**Function:**
The device shall function as an early warning and detection system of infant central apnea in developing countries by providing a reliable detection mechanism that alerts nearby caretakers of an adverse event. The monitor should trigger its alarm after breathing ceases for more than 20 seconds. This will allow the caretaker to determine the proper course of action to resuscitate the infant.

**Client Requirements:**
1) The monitor must cost under $30
2) The monitor must be reliable and consistently alert caretakers when breathing has stopped for more than 20 seconds.
3) The monitor must be easy to operate with minimal training.
4) The monitor must be tamper-proof with no user serviceable parts (excluding battery)
5) The monitor should be suitable for use in newly industrialized and developing nations.

**Physical and Operational Characteristics:**

a. *Performance Requirements:*

The device must be capable of monitoring an infant's breathing pattern and alerting nearby caretakers if there is a 20 second or more cessation in respiration. (There is difference between breathing and respiration: Respiration is a process where the body breaks down the oxygen, so that the cells in the body can use it.)

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b. *Safety:*

- The device cannot interfere with healthy bioelectrical electrical signals in the infant and present a shock risk to an operator.
- Any external wiring must not present a strangulation risk.
- There should be no small, easily breakable parts that can present a choking hazard.
- The alarm shall not be above levels which damage the infant's hearing ability
- The device must meet all regulatory demands outlined by government or other agencies

c. *Accuracy and Reliability:*

- The device must have reliable accuracy, and cannot allow for a false negative in the monitor.
- The design must minimize the occurrence of false positives to maintain user confidence in the monitor

d. *Life in Service:*

- Excluding the monitor's battery and lead system, the monitor shall function for at least 5-10 years.
- The monitor must be able to withstand reasonable wear due to use.
- The monitor must be designed to minimize the risk of broken parts.

e. *Shelf Life:*

- Excluding the monitor's battery and lead system, the monitor shall function for at least 5-10 years regardless of usage frequency.
- The device will require batteries that should be easily replaced.

f. *Operating Environment:*

- The device should be designed to function in a mobile hospital setting
- The monitor shall be able to tolerate temperature ranges of 0 - 41 °C
- The monitor enclosure shall prevent the buildup of ambient particulate on the inner electronic components
- The monitor enclosure shall prevent the encroachment of moisture within its housing

g. *Ergonomics:*

- The device should not interfere with comfortable sleep.
- The monitor electrode system shall be designed to ensure consistent placement location on the infant's body

h. *Size:*

- The device should have a maximum size of 10×10×5 cm.
- The monitor's electrode band shall be designed according to anthropometric data from infants under 1 year of age

i. *Power Source:*

- The device will be battery-powered and should maximize power efficiency
- The device shall operate continuously for 24 hours on a single fully-charged battery
- The batteries shall be rechargeable, allowing for pairs of batteries to be cycled for use in the same monitor without disruption of daily monitor usage

j. *Weight:*

- The device must be lightweight, not exceeding 1.0 kg but weigh more than 200 g

k. *Materials:*

- The device shall consist of a printed-circuit board including both passive elements and active integrated circuits, as well as a microprocessor.
- The electronic components will reside within a plastic enclosure with holes machined for external connections to electrodes
- The monitor housing will contain one buzzer/speaker
- The housing must be sterilizable

l. *Aesthetics, Appearance, and Finish:*

- The device appearance should align with other devices found in a hospital setting
- The monitor's controls shall be easily understood and operated by individuals from all cultures, races, and dialects

m. *Product Characteristics:*

- Quantity: Two
- Target Product Cost: $10 - $30

*n. Miscellaneous:*

Standard and Specification:

- The monitor must comply with HIPPA, AAMI, and patient disclosure standards

Patient-Related Concerns:

- Device components in contact with the infant must receive sterilization between uses.
- Must not pose risk of shock or infant entanglement.

Competition:

- Devices on the market include the products made by Babysense, Respisense, CloudMonitor, AngleCare, and Snuza

Customer: **Engineering World Health or Similar NGO**