

Engineering World Health: Infant Respiratory Monitor
Preliminary Product Design Specifications

Chris Besaw, Steve Young, Don Weier, Ben Smith

Function:

The purpose of this device will be to prevent Sudden Infant Death Syndrome (SIDS) in third world countries by providing a reliable detection mechanism that alerts nearby caretakers. The monitor should sound its alarm after breathing ceases for more than 20 seconds. This will allow the caretaker to properly resuscitate the infant.

Client Requirements:

- 1) Device must cost under \$20.
- 2) Device must be *highly* reliable and consistently alert caretakers when breathing has stopped for more than 20 seconds.
- 3) Device must be simple and easy to operate with minimal training.
- 4) Device should be suitable for use in third-world countries.

1. 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.

b. Safety: The device cannot interfere with healthy electrical signals in the infant. Or 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 prevent a choking hazard. 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 detection apparatus.

d. Life in Service: The device must be able to withstand reasonable wear due to use. It must be designed to minimize the risk of broken parts.

e. Shelf Life: 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.
- g. Ergonomics:* The device should not interfere with comfortable sleep.
- h. Size:* The device should have a maximum size of 10x10x10 cm.
- i. Power Source:* The device will be battery powered and should maximize power efficiency.
- j. Weight:* The device must be lightweight, not exceeding 3.0 kg.
- k. Materials:* The device will include basic circuitry including microprocessors, amplifiers, and wiring.
- l. Aesthetics, Appearance, and Finish:* The device should fit in a hospital setting

Product Characteristics:

- a. *Quantity:* One
- b. *Target Product Cost:* \$10 - \$20.

Miscellaneous

- a. *Standard and Specification:* Device must meet medical device and legal standards. Must comply with HIPPA and patient disclosure standards and must receive FDA approval.
- b. *Customer:* Engineering World Health
- c. *Patient-Related Concerns:* Device components in contact with the infant must receive sterilization between uses. Must not pose risk of shock or infant entanglement.
- d. *Competition:* Devices on the market include the products made by Babysense, Respisense, AngleCare, and Snuz.