

Engineering World Health: Infant Respiratory Monitor
Preliminary Product Design Specifications
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Function: The function of the device being designed is to supply populations in the third-world with a cheap early warning or alarm system that will reduce the number of deaths attributed to Sudden Infant Death Syndrome (SIDS). The causes of the phenomenon are not well understood at this point in time. In most cases however, it is assumed that early warning of respiratory arrest will give caretakers enough time to resuscitate the affected infant.

Client Requirements:

1. Device must be simple enough to assemble in country
2. Device must be low cost (<\$150)
3. Device should *consistently* warn if breathing ceases for a specific number of seconds
4. Implementation in the third-world is paramount

Design Requirements:

1. Physical and Operational Characteristics

- a. *Performance Requirements:* Continuous monitoring both during the day and at night.
- b. *Safety:* The device cannot introduce any harmful electrical interference to the patient or anyone operating the device. Furthermore, the device must be approved for use by the proper committees and hospital staff members.
- c. *Accuracy and Reliability:* The device must *consistently* sound an alarm after a specified period of respiratory arrest.
- d. *Life in Service:* There is no specific life in service characteristic for this device, but it likely needs to be reliably used for multiple years.
- e. *Shelf Life:* The device will likely be wall powered and the only shelf life concern is lead replacement with every new patient.
- f. *Operating Environment:* Preliminary iterations will be provided to mobile hospital units in Haiti.
- g. *Ergonomics:* Infants should be able to sleep comfortably while still wearing the leads of the device
- h. *Size:* The main operating box cannot exceed a cube size of 15cm x 15 cm x 15cm.
- i. *Weight:* Overall weight of the system cannot exceed 3.0 kg.
- j. *Materials:* Device will be made out of various active and passive circuit components varying upon which design option is selected. Materials cannot create electrical interference that would jeopardize patient or operator safety.
- k. *Aesthetics, Appearance, and Finish:* Device should not be exotically colored and follow standard operating room style.

2. Production Characteristics:

- a. *Quantity:* One
- b. *Target Product Cost:* \$100-\$300

3. Miscellaneous:

- a. *Standard and Specification:* Built to legal standards. Must be approved by proper hospital committees and staff to comply with HIPPA and patient disclosure or release. Needs to receive FDA approval.
- b. *Customer:* Engineering World Health
- c. *Patient-Related Concerns:* The device will need to receive proper sterilization between uses as laid out in operating room protocol.
- d. *Competition:* Multiple similar devices are on the consumer market including products by RespiSense, AngelCare, and Snuzza.