

Heart and Breath Sound Amplifier
Preliminary Product Design Specifications
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Function: The function of the device being designed is to increase the functionality of the standard medical acoustic stethoscope in three ways while maintaining the diagnostic capabilities of the original stethoscope design. The three areas of functionality are to be increased are: converting the acoustic sound waves from the stethoscope to a filterable electronic signal, increase the length of the stethoscope so the heartbeat can be heard from further away, and create dual listening capabilities so the sounds from the stethoscope can be heard both in standard headphones as well as a speaker.

Client Requirements:

1. Ability to hear sounds clearly with both headphones and speakers.
2. Device must be able to be transported from one operating room to another.
3. Device cannot introduce harmful electrical interference onto the body of the patient.
4. Amplification process must preserve all diagnostic information that a normal stethoscope can provide.
5. Device needs to stay within a budget of \$100-\$300.

Design Requirements:

1. Physical and Operational Characteristics

- a. *Performance Requirements:* The device can be expected to be used multiple times daily and must perform to medical standards each time. Amplification must be to a minimum of 60 dB and the frequency must not exceed 300 Hz.
- b. *Safety:* The device cannot introduce any harmful electrical interference to the patient or anyone operating the device. This is especially important for electrical devices that have been implanted such as pacemakers. Furthermore, the device must be approved for use by the proper committees and hospital staff members.
- c. *Accuracy and Reliability:* The device needs to provide heart and sound amplification of the same or better diagnostic quality as a medical stethoscope.
- 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 battery operated and the only shelf life concern is battery replacement every three to four months.
- f. *Operating Environment:* The heart and breath sound amplifier will be used in a standard hospital operating room as well as in an educational setting.
- g. *Ergonomics:* The device must allow the anesthesiologist to easily listen to on headphones to the heart and breath sound amplifier and alter medication dosages up to three meters away.
- 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 circuit components including a condenser microphone and a polymer outer housing. The device will utilize a standard stethoscope head and esophageal tube to initially receive sound vibrations.

Materials cannot create electrical interference that would jeopardize patient or operator safety.

- k. *Aesthetics, Appearance, and Finish*: Device needs to be visually appealing. 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 United States 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*: Dr. Scott Springman and the anesthesiology staff of the University of Wisconsin-Madison Hospital
- c. *Patient-Related Concerns*: The device will need to receive proper sterilization between uses as laid out in operating room protocol. If necessary use of device during surgery may need to receive patient approval.
- d. *Competition*: Multiple similar devices are on the market including products by 3M Littmann Stethoscope, Thinklab Digital Stethoscope, and Cardionics EScope. Prices for competition are not within the price range of the client.