Product Design Specifications—Refinement of Electronic Stethoscope

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Problem Statement:

Anesthesiologists need to listen to patients' heart and breath sounds during anesthesia care. Manual stethoscopes are commonly used but only allow for one listener and are uncomfortable for extended wear. An electronic stethoscope was developed which utilizes a speaker and microphone system, but it is too large for practical purposes. In order to improve upon the existing device, a more suitable power supply must be found. Ideally, changes should also be made to allow for a dual microphone system with Wi-Fi capabilities, as well as a main receiver with a speaker and a headphone jack for private listening.

Client Requirements:

- One high-quality microphone; ideally two wireless microphones
- Microphones should be attachable using standard medical adhesive
- Option for headphone or speaker listening
- Universal headphone jack
- Main receiver should fit in someone's hand
- Cleanable with disinfectant wipes
- Battery powered
- Cost efficient
    - ~ $300.00
- Must be able to withstand long term storage at room temperature

Design Requirements:

1) Design Requirements
    a. *Performance Requirements:* Must accurately convey heart and lung sounds at correct frequencies and appropriate amplification. Must be able to easily and quickly switch between headphone and speaker listening functions.
    b. *Safety:* The device must not endanger or contaminate the patient on which it is being used in any way or cause danger to the person who is operating it.
    c. *Accuracy and Reliability:* See Performance Requirements. The frequency and amplification must be accurate enough to detect problems in the patients' cardiovascular system.
    d. *Life in Service:* The device must not degrade or become unreliable for up to 10 years of usage, assuming correct precautions in cleaning and protection of electronics are taken by the owner. Battery life should be at least 12 hours.
    e. *Shelf Life:* The prototype should not degrade over time in storage for at least 10 years.

f. *Operating Environment:* The device must be able to operate reliably in a hospital operating room. The device may be exposed to blood or other bodily fluids throughout the course of a procedure, but should not be exposed to large amounts of liquid for an extended period of time.
g. *Ergonomics:* The receiving station with speakers should not have rough edges or any loose components, and the volume adjustment for the speakers should be easy to use. Microphones should comfortably, yet securely, attach to the patients' chest. The device interface and its connection should not obstruct or obscure the use of the stethoscope.
h. *Size:* The receiver with the speaker should be no larger than the size of a hand and the microphones should be of comparable size to a stethoscope head.
i. *Weight:* No quantitative limit, but must be easily portable by one person.
j. *Materials:* The materials used should be safe for use around humans. They should meet standards for surgical use, such as being non-abrasive, non- toxic, non-radioactive, non-flammable, and non-corrosive. The materials should be easily disinfected by use of cleaning wipes.
k. *Aesthetics, Appearance, and Finish:* The device should be aesthetically pleasing, with a smooth, clean finish. All wires should be properly concealed within the receiver housing.

2) User Specifications
   a. *Intended Use*: The client will not be using the device for diagnostic purposes. It will be used to monitor a patient's heartbeat during surgical procedures and as a result only needs to be able to detect a heartbeat and not determine abnormalities.
   b. *Frequency Range*: Because the device will not be used to diagnose heart abnormalities, the prototype does not need to detect frequencies below 100 Hz. In order to limit interference from other devices in the operating room, the high frequency cut off should be close to 2,000 Hz.
   c. *Sound Quality*: The sound quality should be sufficient enough to determine that the heart is beating and the respiratory system is functioning normally. This means filtering out interference from other operating room machinery. The client would prefer if the sound reproduced is similar to what is heard from a traditional stethoscope but also commented that it would be interesting to hear new sounds generated by our device. The client also noted that since it was not being used for diagnostic purposes, sound quality as good as that found in a traditional stethoscope is not necessary.
   d. *Volume*: Since the device will be used in a standard operating room, the biggest concern with volume level is whether it can be heard over the ambient sounds of the other operating equipment present. As the operating room is not a very large room, sound projection is not an issue; if the device can be heard over other operating room equipment, it will be loud enough for the room size.
   e. *Power*: The main receiver and speaker box portion of the prototype can be powered via a wall outlet. The individual microphones should be battery powered.
   f. *Additional*: The client requested that the main box of the prototype should have a way to be attached to the instrument cart currently used in the operating room. He

suggested attaching brackets to the side of the device and securing it to the instrument cart.

3) Product Characteristics
    a. *Quantity:* One fully functional prototype is required at this time.
    b. *Target Product Cost:* The target manufacturing cost for the product is no more than $300.00, which includes microphones, receiver, speakers, and headphones.

4) Miscellaneous
    a. *Standards and Specifications:* The device as a whole will need FDA approval because it is a medical device that has the possibility to be used on humans. The device will adhere to client specifications.
    b. *Customer:* The product should follow the client's requirements for the headphone and speaker interface, while ideally having two wireless microphones.
    c. *Patient Related Concerns:* The device will come in direct contact with the patient. Therefore, the device must be sure not to: cause damage to the patient's skin, infect or poison the patient in any way, or leave debris after use. The device should not endanger the operator.
    d. *Competition:* There are currently a handful of similar devices on the market. However, none are optimal for our client's needs due to their excessive cost.