Refinement of Electronic Stethoscope

Product Design Specifications

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Problem Statement:
In every surgical procedure, anesthesiologists need to listen to the patient breathing sounds while they are asleep to ensure the safety of the patient. Manual stethoscopes, which have been used for years, are sufficient but cause discomfort to the listener and do not provide a wide range of activities to be done simultaneously. There are a few electronic stethoscopes in the market today, but it is too large and expensive for practical purposes. In order to improve upon the existing device, an efficient power system must be found that can maximize the life span of the device. Ideally, changes should be made for a small wireless system, as well as a main receiver with a speaker for multiple listeners and a wireless headset for private listening.

Client Requirements:

- One high-quality microphone
- Microphones should be attachable using standard medical adhesive
- The size of the stethoscope head should be no larger than the regular ones used
- Option for headphone or speaker listening
- Main receiver should be as small as possible without effecting sound quality
- Should be able to detect frequencies of the patient breathing
- Battery powered to last ideally 15 hours
- Cost efficient
- Must be able to withstand long term storage at room temperature
- Cleanable with disinfectant wipes

Design Requirements:

1. Performance Requirements: Must accurately convey breathing at correct frequencies and appropriate amplification. Must be able to easily and quickly switch between headphone and speaker listening functions. The device also should not cause the physician trouble due to its size.
2. 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. This includes not interfering with signals of other operating machines in the room.
3. Accuracy and Reliability: See Performance Requirements. The frequency and amplification must be accurate enough to detect problems in the patients' breathing pattern.

4. 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 15 hours.
5. Shelf Life: The prototype should not degrade over time in storage for at least 10 years.
6. Operating Environment: The device must be able to operate reliably in a hospital operating room. The device should not come into contact with blood or liquids during procedures, but if it does for a short period of time it must be ensured that the patient or physician will not be hurt.
7. Ergonomics: The receiving station with speakers and the transmitter should not have loose components or any physical components that could cause harm, and the volume adjustment for the speakers should be easy to use. The two microphones should comfortably, yet securely, attach to the patients' neck. The device interface and its connection should not obstruct or obscure the use of the stethoscope.
8. 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. The transmitter should be able to attach directly to the physician or patient.
9. Weight: Must be easily to carry to different rooms by the physician.
10. 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.
11. Appearance: The device should be aesthetically pleasing, with a smooth, clean finish. All wires should be properly concealed within their respective devices.

User Specifications

1. Intended Use: The client will not be using the device for diagnostic purposes. It will be used to monitor a patient's breathing during surgical procedures and as a result, only needs to be able to detect a breathing frequencies.
2. 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 highest frequency reached should be 2000 Hz.
3. Sound Quality: The sound quality should be sufficient enough to determine that the respiratory system is functioning normally. This means filtering out interference from other operating room machinery. The client also noted that since it was not being used for diagnostic purposes, sound quality as clear as that found in a traditional stethoscope is not necessary.
4. 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 sounds of the other operating equipment present. The device should not be too loud to disrupt any conversation in the room, but also needs to be heard over other machinery.
5. 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.

Product Characteristics

1. Quantity: One fully functional prototype is required at this time.
2. Target Product Cost: The target manufacturing cost for the product is no more than $200.00, which includes microphones, receiver, speakers, tubing and headphones.

Miscellaneous

1. 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. Customer: The product should follow the client's requirements for the headphone and speaker interface, while ideally having two wireless microphones.
2. Patient Related Concerns: The device will come in direct contact with the patient. Therefore, the device must be safe for the patient's skin and not cause harm in any way to the patient's overall health. Regular adhesive used by the physician will ensure that the patient is not harmed.
3. 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 and bulkiness.