BMEDesign: Product Design Specification

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Project title: ListenBetter: Stethoscope with noise canceling headphones (and amplification option)

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Function

This device improves auscultation by turning a standard acoustic stethoscope into an electronic listening system. A small microphone placed in the tubing of the stethoscope captures heart and lung sounds and converts them to an electrical signal. The signal is then amplified using an operational amplifier and filtered through a band pass filter to make key sounds clearer. The processed audio is delivered to headphones with noise reduction through active noise canceling technology and insulating material to cut outside noise. The goal is clear, more reliable sounds in quiet and loud settings, with better comfort and less ear canal irritation. Optional features include adjustable gain and simple sound enhancement modes to support users with hearing differences and to keep readings consistent.

Client requirements

- The client requests for the stethoscope to reliably listen from helicopters, ambulances, etc.
- The client requests a stethoscope should likely be over-the-ears
- The client requests noise cancellation.
- The client requests to have a double headed option so that two people (such as two medical students) can listen to the same sounds at the same time.The client requests a stethoscope that should be able to be used inside of loud areas including

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**
        i. The device is required to maintain stable performance in environments with ambient noise levels up to approximately 110 decibels, including helicopters, ambulances, and industrial emergency settings.
        ii. Active noise cancellation (ANC) must specifically address frequency bands that interfere with auscultation, particularly those between 100 and 1000 hertz.
        iii. Expected usage is 4–8 hours per shift, with frequent donning and removal during emergency responses. Therefore, durability of ear seals and headband hinges is essential to withstand hundreds of daily cycles without wear affecting acoustic performance.
        iv. The double-headed system must allow two users to listen simultaneously with no more than 3% signal loss or latency between outputs, ensuring medical students and providers hear identical sounds in training scenarios.

b. Safety

i. While the safe limit of constant exposure to audio is at intensities <70 dB, many headphones can reach intensities of up to about 100 dB. For loud environments, the headphones should reach a similar level so that just for short periods of time, medical professionals can hear the clearest sounds possible. The stethoscope should come with product warnings, though, about the dangers of exposure to such intensities for long periods of time. [1]

ii. Power should remain ≤ 5 V DC with battery isolation and short-circuit protection, eliminating the risk of electrical shock even under failure conditions. Overcurrent protection will be integrated into the charging system.

iii. The stethoscope will qualify as a Class II medical device under FDA standards, requiring compliance with electrical safety (IEC 60601-1), and relevant labeling requirements [2].

iv.

c. Accuracy and Reliability

i. Typical noise cancelling headphones reduce outside noise by 20-25 dB, so the goal is for the stethoscope to also reduce outside noise by a value that is within this range [3] . The value headphones end up reducing noise by should be repeatable every time within 5 dB.

ii. The auscultation system should reproduce sounds from 20 to 1000 Hz, which includes both heart (20 to 150 Hz) and lung (100 to 1000 Hz) frequencies. A tolerance of plus or minus 5 percent is needed to maintain sound quality for diagnosis.

iii. Noise cancellation should reduce sound from 20 to 25 dB at the frequencies of 300 to 800 Hz. These are the frequencies from helicopters and ambulances are most common. With this level of noise reduction, medical staff can better hear.

iv. Reliability must exceed 95% uptime during 8-hour shifts. Testing protocols should simulate at least 500 on and off cycles over the product's lifetime. The design must address potential failure modes, including microphone drift, earcup seal degradation, and Bluetooth interference in wireless configurations.

d. Life in Service

i. The system should last at least 2-3 years of clinical use assuming 250 working days per year.

ii. Replaceable or rechargeable batteries must support >500 full charge cycles without significant loss of capacity.

e. Shelf Life

i. In storage, the stethoscope should be able to fully perform for 2 years.

ii. The lithium-ion batteries should exceed 30% charge for a majority of its life span to preserve battery life.

iii. The stethoscope should be stored ideally in a room temperature (20 °C) environment.

f. Operating Environment

i. The stethoscope must function in temperatures ranging from 0–40 °C covering cold ambulance deployments and hot, enclosed helicopter cabins.

ii. The device must tolerate up to 90% non-condensing relative humidity, as paramedics work in humid or rainy environments. Moisture ingress protection should meet IPX4 or higher to prevent sweat, blood, or cleaning fluids from damaging electronics.

iii. Hospitals/clinics

iv. Crowded areas (sporting events, concerts, etc.)

v. Physicians with hearing impediments

g. Ergonomics

i. Over ear headphone design must allow for healthcare professionals to have their hearing aids in place.

ii. The clamping force of the headband should not exceed 10N since higher values can be attributed to discomfort over long wearing periods.

iii. Weight distribution of headphones should be uniform on the sagittal plane with +/- 5% margin of error so that both ears are balanced to minimize pressure.

h. Size

i. The tubing length between the diaphragm and the headset should ideally fall in the 22–27 inch range.

ii. Earcups should have a minimum diameter of 90 mm to ensure proper ear cushioning.

iii. The stethoscope should be able to collapse into a volume of no larger than 20cm x 20cm x 8cm for portability.

i. Weight

i. To keep the single-headed model easy to carry and comfortable for long periods, aim for a weight under 450 grams.

ii. For the double-headed version, a weight of up to 650 grams is acceptable if the headband spreads the weight evenly.

iii. The weight should be distributed in a manner for comfort and prolonged use.

j. Materials

i. No specific material requirements other than those that keep the product light and cheap to manufacture.

ii. Common material for stethoscopes include steel, aluminum, and polymers such as plastic/rubber. [4]

k. Aesthetics, Appearance, and Finish

i. Over- the-ear

ii. Neutral colors (black, silver, white, etc.) should be used as this device is for strictly professional and educational purposes

iii. Outside texture should be smooth as this device will be used frequently by hands and will often make contact with skin.

2. Production Characteristics

a. Quantity

i. A single successful working prototype is the goal of the project.

ii. It would be ideal if the design is easy to repeat and could be mass produced.

b. Target Product Cost

i. The cost goal is $150 for the noise-cancelling electronic prototype and $100 dollars for replicable models.

ii. The cost may exceed $150 if opted for electronic amplification on top of the noise-cancelling.

3. **Miscellaneous**
    a. **Standards and Specifications**
        i. The device should comply with FDA Class II medical device regulations [5].
        ii. The device should comply with ISO 13485:2016, ensuring quality management standards for safe and consistent medical device design and production [6].
        iii. Noise cancellation performance should be quantified with ANSI/ASA S12.6 testing (noise reduction rating, NRR, in dB) [7].
        iv. Biocompatibility testing for skin contact materials under ISO 10993 [8].
    b. **Customer**
        i. Needs to be worn comfortably for extended periods of time.
        ii. Should allow the user to adjust the volume to their preferences.
        iii. Customer reports irritation from traditional ear-canal stethoscopes and inconsistent readings due to poor placement.
    c. **Patient-related concerns**
        i. Devices must be sterilizable between uses: surfaces must withstand repeated use of alcohol sterilization (>200 cycles) without degradation.
        ii. The stethoscope must ensure no loss in sound quality so that users hear proper diagnostic information.

Competition

iii. Littmann 3200 and ThinkLabs One are both competing electronic stethoscopes. Competitor stethoscopes are priced around $250–500 and focus on amplification but are not optimized for high-noise environments (≥90 dB).
iv. The competing stethoscopes do not feature the over ear headphones that are required for the design.

References:

[1] Hearing Health Foundation, “Keep Listening | What Are Safe Decibels?,” Hearing Health Foundation, 2023. https://hearinghealthfoundation.org/keeplistening/decibels

[2] IEC, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV), 3rd ed., International Electrotechnical Commission, Geneva, Switzerland, 2020.

[3] R. Pak, “Engineering Healthy Silence: Using Noise-Cancelling Headphones to Block Harmful Sound – USC Viterbi School of Engineering,” illumin.usc.edu, Apr. 01, 2024. https://illumin.usc.edu/engineering-healthy-silence-using-noise-cancelling-headphones-to-block-harmful-sound/

[4]“Anatomy of a Stethoscope: Everything You Need to Know,” Stethoscope.com, 2025. https://www.stethoscope.com/blog/anatomy-of-a-stethoscope-everything-you-need-to-know-/?srsltid=AfmBOoqntaAlou-OktmCCxAm_DfGoH6y9GnwZdLJdjCYTZP9Whiqyr13 (accessed Sep. 19, 2025).

[5] U.S. Food and Drug Administration, Medical Devices: Class II (Special Controls), Silver Spring, MD, USA: FDA, 2023. [Online]. Available: https://www.fda.gov/medical-devices

[6] ISO, Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016), International Organization for Standardization, Geneva, Switzerland, 2016.

[7] ANSI/ASA, Methods for Measuring the Real-Ear Attenuation of Hearing Protectors (ANSI/ASA S12.6-2016), American National Standards Institute/Acoustical Society of America, Melville, NY, USA, 2016.

[8] ISO, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018), International Organization for Standardization, Geneva, Switzerland, 2018.