

ClearPulse: Stethoscope with noise canceling headphones (and amplification option)

Preliminary Report

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Section 305

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Abstract

EMT workers cannot accurately obtain heart and lung readings in cacophonous environments with their current stethoscope devices. This project aims to create an inexpensive alternative digital stethoscope with noise cancelling and amplification capabilities. Current digital stethoscopes cost too much for the average EMT worker to justify purchasing. Our proposed design is to incorporate a difference amplifier, bandpass filter, and an ESP32 microcontroller in order to process the physiological signals into an audio output. The components all will follow IEC 60601-1, minimizing electrical hazard risks in a medical device environment. The testing focuses on ensuring the audio output through the stethoscope will be clear enough to be read in hospital environments. In the future, this device will allow for improved clarity on heart and lung sound acquisition, allowing EMT workers to assess patients more efficiently and provide care.

Introduction

Overview, Context and Motivation

In a 2019 study on auscultation, researchers found a mere 20% of graduating medical students were able to accurately identify cardiac sounds- a critical skill of any physician [1]. This lack of skill extends beyond just training and testing, but into the field. Another study compared findings from manual auscultation to echocardiography, a noninvasive heart screening tool, in heart disease screenings of children in Fiji. Clinicians diagnosed 349 children with a murmur, when only 29 were confirmed to have an abnormality through echocardiography [2]. Clearly, a gap exists in auscultation ability that either extends from the user's skill or the technology used, and a solution is necessary in such a high-stakes field as medicine. Suffice to say, in both instances referenced, providers had been trained in auscultory techniques at the level of medical doctors, meaning this is likely an issue of the technology. In unique instances however, the gap may come from both the technology and the provider's ability, as this relates to hearing loss.

Healthcare providers are exposed to high noise levels and as a result of this, may develop hearing loss, in numbers of up to 64%, one study finds [3]. This is especially true for those working in environments such as ambulances and helicopters, where noise levels can easily and regularly exceed safety standards [4]. For this prehospital provider population, paramedics in moving ambulances (*without* sirens on) have also been found to have nearly a 90% accuracy drop in their ability to detect simply the presence of breath sounds [5]. However, along with this, several case studies of medical students with hearing loss revealed significant auscultation difficulties that were drastically improved after electronic amplification [6]. In total, this paints a picture of a drastically needed improvement or widened availability of improved stethoscope technology, in an industry which exposes workers to already unfavorable environments for these types of evaluation techniques.

Competing Designs

Given the very prolific nature of this problem in the healthcare industry, it's a given that alternative products already exist to attempt to address this gap, and have succeeded. An example of one of these such alternatives is the EKO CORE 500 Digital Stethoscope, which provides a rated 40x noise amplification, active noise cancellation, an integrated ECG, bluetooth connectivity, and a battery life of up to 60 hours [7]. A similar product exists, the Eko CORE Digital Attachment, which can simply be inserted into a manual stethoscope, rather than replacing the entire body, and provides similar features, save for the ECG [8]. Another major producer, Littman, manufactures the 3M Littman CORE Digital Stethoscope, offering up to 40x amplification, in-app wave visualization, and active noise cancellation with more comfortable eartips [9]. Relevant patents include those for the EKO CORE Digital Attachment, which is already a manufactured product, but somewhat similar to our chosen design, and for this reason, the patent is important to examine [10]. Additionally, two older patented designs which focused on an active noise cancellation approach via multiple microphones on the chestpiece of the stethoscope were conceptually related to our goal and involved unique, relevant approaches to tackle the problem at hand [11], [12]. Another patent from Honeywell aims to achieve a different goal, but involves the same method competing designs could take advantage of: earmuffs with significant passive noise cancellation, with earbuds/speakers wired into input noise that can filter out unwanted signals [13].



Figure [1]: 3M Littman Core Digital Stethoscope [9]



Figure [2]: EKO CORE 500 Digital Stethoscope [7]

Problem Statement

Traditional stethoscopes can be difficult to use effectively in noisy or high-vibration environments, including hospitals, helicopters, and ambulances. Environmental noise and poor acoustic conditions can interfere with healthcare providers' ability to accurately hear and distinguish heart and lung sounds, potentially compromising the reliability of auscultation. Providers with hearing loss may also experience these same difficulties. Additionally, prolonged use of traditional stethoscope ear pieces can lead to discomfort or ear canal irritation.

Our team will address these limitations by designing and fabricating a stethoscope system that incorporates noise amplification with optional passive noise isolation of over-the-ear headphones or active noise cancellation. The system will improve the clarity of heart and lung sounds across a broad range of environmental conditions while prioritizing comfort and ease of use. The final design must be durable, cost-effective, and manufacturable, with potential for commercial development through WARF or other outside organizations.

Background

Background Research

Overall, the majority of research has been primarily focused into the circuitry and electronic components of the amplification and noise reduction process. The main topics researched include filters, amplifiers and microcontrollers.

For filters, the main concern was determining the sound frequencies of heart, lung, and typical ambulance environment. The main frequency components of the heart sound signal are in the range of 20-100 Hz. If the frequency was < 30 Hz, then it belongs to the category of the abnormal heart sound, as third and fourth heart sounds and the diastolic murmur of mitral stenosis. The murmur with the highest frequency noise is aortic regurgitation, the dominant frequencies around 400 Hz. Other sounds and murmurs have the major frequencies between 100 and 400 Hz [8]. Lung frequencies are reported primarily within a range of 100-1000 Hz, with abnormal sounds such as crackles and wheezes appearing outside of this range [9]. For the sake of the design filtering, frequencies between the ranges of 100-1000 Hz must be accounted for both accurate heartbeat and lung readings. Amplification is crucial for the design as physiological sounds output low amplitude signals. A research study was done where an electrical stethoscope was constructed using a two-stage amplification and filtering system. The total gain from the circuit was 3.0, substantially increasing the heart and lung soundwaves, allowing the user to get a more accurate reading. [10]

For the design, a microcontroller is necessary to transmit the analog signal into digital in order to process the signal. The ESP32 is commonly used in biomedical engineering projects due to its low cost, low power, and simple use, compared to competing microcontrollers. The ESP32 is unique due to its built-in bluetooth and Wi-Fi capabilities. The dual core processor allows the microcontroller to handle multiple tasks simultaneously, such as processing and filtering through audio. The compactness and technical specifications of the ESP32 makes the microcontroller a strong candidate for the stethoscope project. [11]

Standards and Regulations

Due to the contact with the human body, closely with the heart and lungs, all standards for typical electronic medical devices must be followed. First, IEC 60601-1, focusing on the foundational requirements regarding safety and performance of electrical medical equipment [12]. The stethoscope contains a power source, audio amplification circuitry, and other components that pose a risk of electrical shock hazard. Closely related, IEC 60601-1-2, which requires that the risks from foreseeable electromagnetic disturbances be taken into consideration during the risk management process analysis, must be followed [13]. Since the stethoscope will be amplifying heart and lung sounds, it's imperative no external electric or electromagnetic noise affects the device. The device should minimize interference while maintaining reliable sound acquisition when operating in environments surrounded by electronic medical devices. ISO 14971 provides a framework to identify and control risks in medical devices [14]. Risks involved

in the stethoscope pertain to inadequate amplification, electrical malfunction, failure to filter between body and ambient noise, and excessive audio output.

Client Information

The client for this design project is Dr. Lenard Markman, a retired family medicine physician with over 35 years of experience. Furthermore, he was the former president of WI association of Osteopathic Physicians and Surgeons [15]. Dr Markman had many conversations with EMT workers discussing the difficulty of obtaining accurate heartbeat readings in noisy environments, which led to the creation of this design project.

Design Specifications

As discussed in Appendix A, the following are criteria the ClearPulse product specifications must meet. For general characteristics, the product must be reusable and easily transportable in space limited environments. The product must have noise cancellation of the ambient noise and amplification of the heartbeat readings. The project has a budget of \$100. The major priority is for the device to be inexpensive, allowing EMT workers the ability to purchase within a \$50-70 price range. Further information of the product specifications can be found in appendix A.

Preliminary Designs

Fully Detachable Model

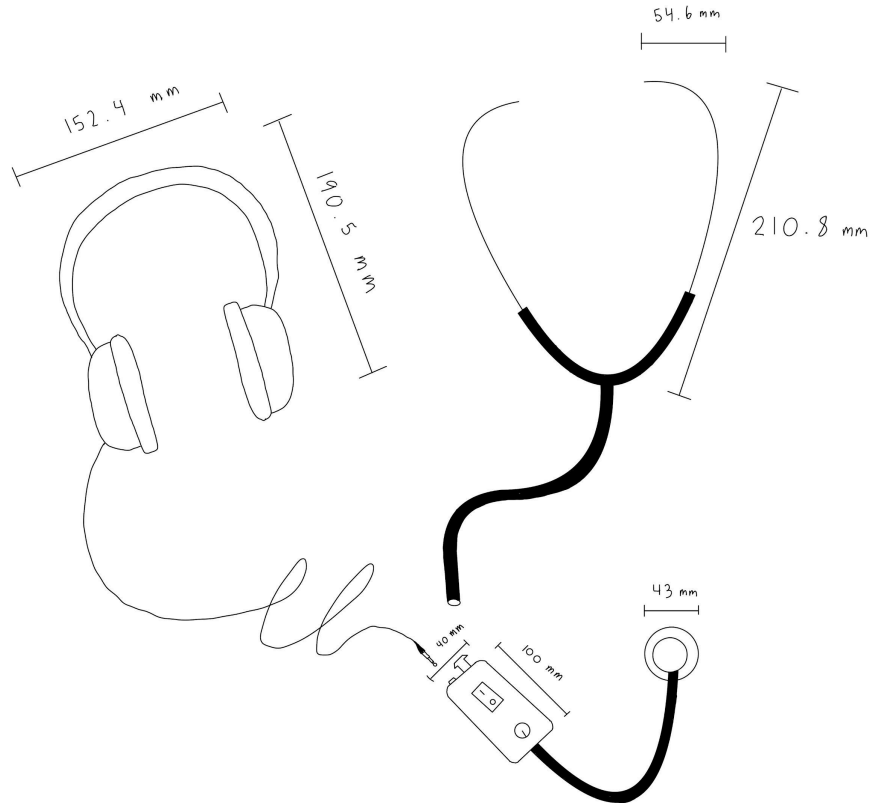


Figure [3]: *Fully Detachable Model Sketch*

The fully detachable model consists of a traditional stethoscope chestpiece and tubing connected to an electrical component that amplifies the heart and lung sounds and converts them to electrical signals, which can be connected to the user's headphones that have active noise-cancelling ability via a headphone jack. A traditional stethoscope headset can also be connected to the device, and amplification settings can be adjusted on the device. To use, the user will put on the headphones or stethoscope headset, turn on the device to the desired settings, and place the chestpiece on the patient to hear auscultation.

Headset Design



Figure [4]: Headset Design CAD Representation [16]

The headset design connects the traditional stethoscope chestpiece and tubing to an electrical component that amplifies the heart and lung sounds and converts them to electrical signals, which is wired to a headset that has active noise-cancelling ability. The earcups of the headset are designed to block out and reduce sound. To use, the user will put on the headset, turn on the device, and place the chestpiece on the patient to hear auscultation.

Fully Passive Design

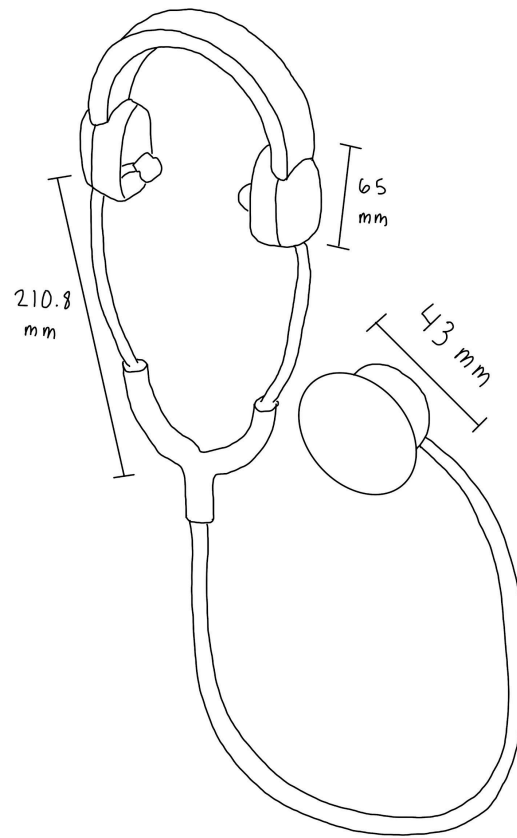


Figure [5]: *Fully Passive Design Sketch*

The fully passive design implements noise-reducing earmuffs and fits them over a traditional stethoscope. The design implements a dense ear cup and foam ear cushions to block out ambient noise with low frequencies. It has no sound amplification and relies on the stethoscopes osculation to hear the heart and lung sounds. To use, the user will put on their stethoscope, then the earmuffs, and place the chestpiece on the patient to hear auscultation.

Design Matrix

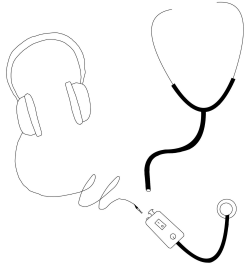
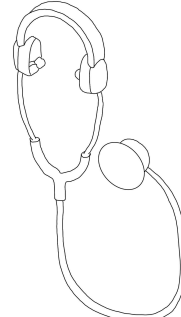
Design	Fully Detachable		Headset Design		Fully Passive	
						
Criteria (weight)	Raw	Weighted	Raw	Weighted	Raw	Weighted
Amplification (25)	4/5	20	2.5/5	12.5	0/5	0
Noise Reduction (25)	3.5/5	17.5	2.5/5	12.5	4.5/5	22.5
Cost (20)	1.5/5	6	3.5/5	14	4/5	16
Ergonomics (15)	4/5	12	1.5/5	4.5	1.5/5	4.5
Durability (10)	3.5/5	7	2.5/5	5	4/5	8
Regulatory Compliance (5)	1.5/5	1.5	3/5	3	4/5	4
Total (100)		64		51.5		56

Figure [6]: Design matrix outlining the three preliminary design ideas for the stethoscope with noise canceling headphones and their respective scores. The green-highlighted categories indicate the highest scores of the three designs in the specific category. Scores are out of 5 points; displayed as Raw Score | Weighted Score.

Amplification: Amplification was selected as one of the key criteria for our project and, as a result, was given a weight of 25/100. This criterion was weighted equally with noise reduction because both amplification and noise reduction directly contribute to ClearPulse's primary goal of improving auscultation in noisy environments. Amplification considers the ability of each design to amplify key frequencies to assist in the auscultation of heart and lung sounds, particularly in high-noise environments. The amplification must provide sufficient volume and clarity such that clinically relevant sounds are easy to hear without introducing excessive noise, distortion, or feedback. The fully detachable design scored the highest with a raw score of 4/5 because it allows for signal-specific in-line amplification as well as general amplification through compatible headphones. The prior semester design scored a 2.5/5 because it allows for

signal-specific in-line amplification but does not provide general amplification. Finally, the fully passive design scored a 0/5 because it does not rely on electronics and therefore does not provide any form of amplification.

Noise Reduction: The category of noise reduction measures how well each design will be able to limit ambient noise, including ambulance sirens, road noise, and helicopter blades. This category is weighted heavily since reducing ambient noise is key for EMTs to hear the bodily sounds coming through their stethoscopes in noisy environments. The Fully Detachable design was scored a 3.5/5 since its noise reduction abilities rely on the quality of headphones owned by the user, which provides for a wide range of noise reduction possibilities. The prior semester design scored a 2.5/5 since 3D-printed headphones are not as efficient as most headphones on the market at limiting ambient noise. The Fully Passive design scored highest in this category with a 4.5/5 since construction headsets reduce ambient noise by 20-30 decibels, a mark that is effective and more consistent than the other designs.

Cost: Cost was evaluated at a 20 percent weight, as it carries significant importance with our unique design goals. The desires expressed by our client, which are reflected in the budget allotted to our team, is that the product be a low-cost, simple alternative to many of the expensive, technologically complex, digital stethoscopes currently on the market. A main factor taken into account is whether the design would be possible to manufacture cheaply and deployed across markets to be an accessible alternative to current options. The fully detachable option scored lowest in this criteria at 1.5/5, as due to the nature of the design (stethoscope attached to external headset), the cost of the headset may vary greatly, and end up being rather expensive/cost-inefficient. The prior semester design lands in the middle, with a rating of 3.5/5. This design is more cost-efficient, in that the majority of the parts can be 3D printed/cheaply assembled, given that the design includes a headset. The design that scores best in the cost category is the fully passive design, with 4/5. This was scored highest because we plan to have very few electronic components in this option, relying on noise reduction from the physical properties of the headset, rather than electronic cancellation.

Ergonomics: Ergonomics was considered as a culmination of comfortability and ease of use. EMT workers and other stethoscope users have commented on how uncomfortable using inexpensive stethoscopes can be. This was the major reasoning behind the 15 percent weight. Thus, the designs focusing on a headphone earpiece rather than the traditional ear plugs were scored much higher in this regard. The fully detachable design scored the highest, with a rating of 4/5, due to its ability to change between a headset and the typical stethoscope depending on the user's desires. The other two designs both scored a 1.5/5, due to the inability of switching ear headpieces and their inability to be efficient in the workplace (i.e the detachable design can be broken down into many parts for ease of transportation). The ability to be efficient ties directly

into the ease of use criteria, which is also why the detachable design is scored much higher than the other designs.

Durability: The different environments in which the design will be used could vary from the doctor's office to high-stress environments in ambulances. As such, the durability category measures how well each design is able to withstand the forces of daily use and rigorous environments. However, as this is not a main focal point of the project, it is not weighted as heavily as other categories that signify a satisfactory product. The fully detachable design was scored a 3.5/5 as it is compact and sturdy, sufficiently strong enough to withstand most impacts from rough handling, though possibly weaker in the connection jacks. The prior semester design scored a 2.5/5, as the fully connected stethoscope and headphones would be more susceptible to failure as a whole if a part was damaged. The fully passive design scored the highest with 4/5, being structurally sound with few parts that could be heavily impaired by rough use.

Regulatory Compliance: Regulatory compliance describes the ease with which the product can meet regulatory requirements, standards, and not infringe on existing patents for stethoscope related noise-cancelling technology. As a Class II medical device, being able to prove substantial equivalence to existing legally marketed devices via 510(k) circumvents a lengthy and resource intensive Premarket Approval Process. Additionally, the device must meet the following standards:

1. IEC 60601-1 (Medical Electrical Equipment Safety): This is the foundational safety standard that the device must pass [1]. It dictates basic safety and essential performance, ensuring the stethoscope's power supply and electronics do not present electrical shock hazards to the user or patient.
2. IEC 60601-1-2 (Electromagnetic Compatibility): The device must be tested to ensure it operates correctly in a hospital's complex electromagnetic environment without emitting interference that could disrupt other critical care equipment [17].
3. ISO 10993 (Biocompatibility): Materials comprising the chest piece (which contacts the patient) and the earpieces (which contact the clinician) must be evaluated for skin sensitization, irritation, and cytotoxicity [18].

Finally, the recent Eko Devices (2020) patent [US11741931B2 / US20220301537A1](#), which describes an electronic stethoscope device designed to integrate into conventional stethoscope tubing to digitize auscultated sounds is a potential issue for our project, as there are overlapping concepts [19]. Further investigation is needed to identify the delimitations established by patent law on what features our product can maintain and adopt without violating patent claims, ensuring that our design space remains both legally compliant and technically differentiated. This particularly affects the fully detachable concept, which is why it was given a 1.5/5. The other concepts have no major regulatory compliance issues, which is why they were rated equally at 4.5/5.

Proposed Final Design

We're moving forward with the fully detachable design, as it has the highest overall score of the design matrix, and also since it is perceived to be the best solution that EMT workers would actually incorporate into their practice based on interviews we conducted and previous studies of practitioner preferences [20]. Unlike the other designs, the detachable design is not bulky and unwieldy or rendered useless when it becomes uncharged. The reliability of a hybrid device that works acoustically and also electronically is highly desired.

Circuit Changes

The last team's design had a straightforward circuit design that was unfortunately unable to produce an audible output. The lack of amplification embedded in the circuit resulted in no audible output coming from the speakers. As shown in the schematic of last year's design, a microphone picked up the signal from the stethoscope and converted it into an analog electrical signal. A bandpass filter was then employed to filter for unwanted frequencies.

Last Team's Electric Circuit Design

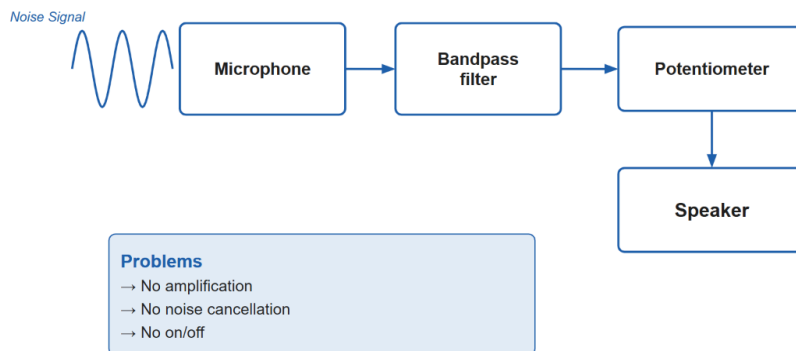


Figure [7]: Last year's electric circuit design and proposed changes

We hope to address the issues of no amplification and no noise cancellation by employing a difference amplifier topology into our circuit design. The difference amplifier will provide a fixed gain while subtracting the ambient noise from the stethoscope signal.

Our Improved Design

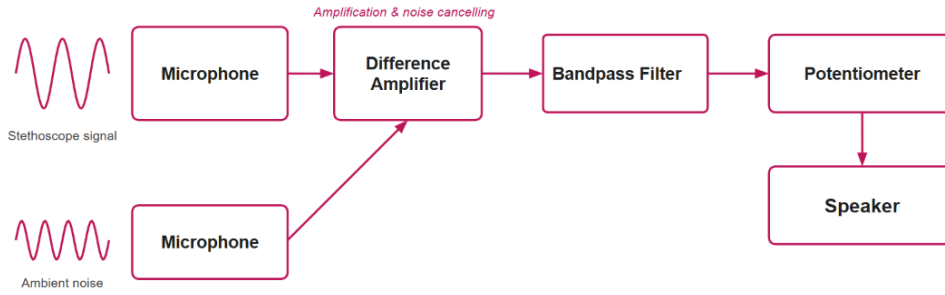


Figure [8]: Our Circuit Topology Improvements

In the new signal chain (Figure 8), two microphones are used instead of one. The primary microphone sits in line with the stethoscope, where it picks up sound coming through the chestpiece tubing. A second reference microphone faces outward on the housing and picks up the ambient noise around the user. Both are PUI Audio POM-2245L-C33-R omnidirectional electret condenser microphones (Appendix B). Their outputs feed the two inputs of the difference amplifier, which is followed by the bandpass filter and a volume potentiometer.

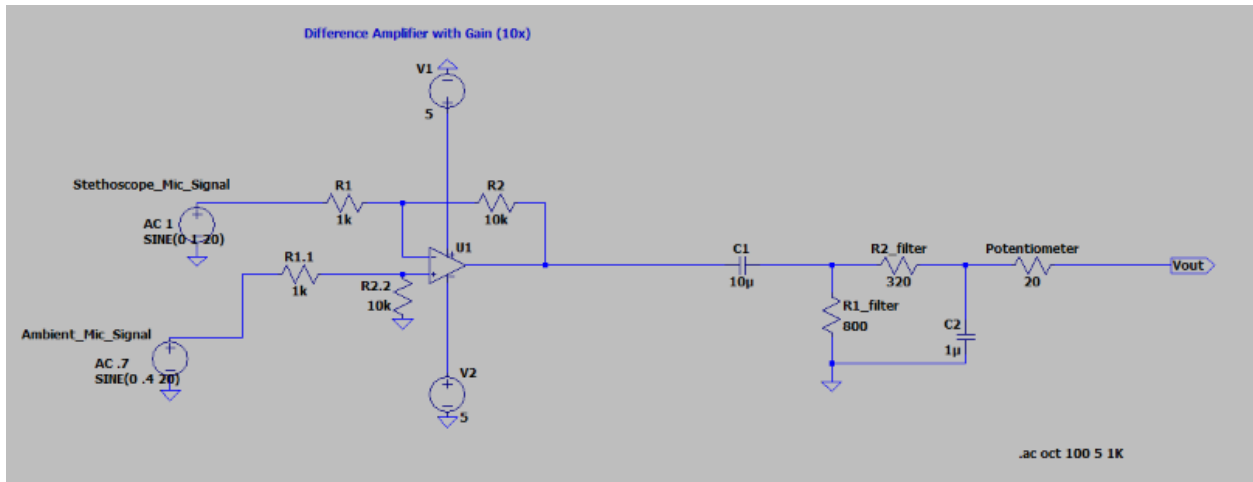


Figure [10]: LTspice model of the difference amplifier ($10\times$ gain), passive bandpass filter, and output potentiometer

Figure 9 shows the difference amplifier. With matched resistor pairs, its output is $V_{out} = (R2/R1)(V_s - V_a)$, where V_s is the stethoscope microphone signal and V_a is the ambient microphone signal. Noise that appears equally on both inputs is subtracted out, while heart and lung sounds, which reach mainly the stethoscope microphone, are amplified. We chose $R1 = 1$

k Ω and R2 = 10 k Ω , giving a differential gain of 10 (20 dB). The amplifier uses a Texas Instruments OPA134 audio op-amp, chosen for its low input noise (8 nV/ $\sqrt{\text{Hz}}$), very low distortion (0.00008% THD+N at 1 kHz), and 100 dB typical common-mode rejection ratio (CMRR) [23].

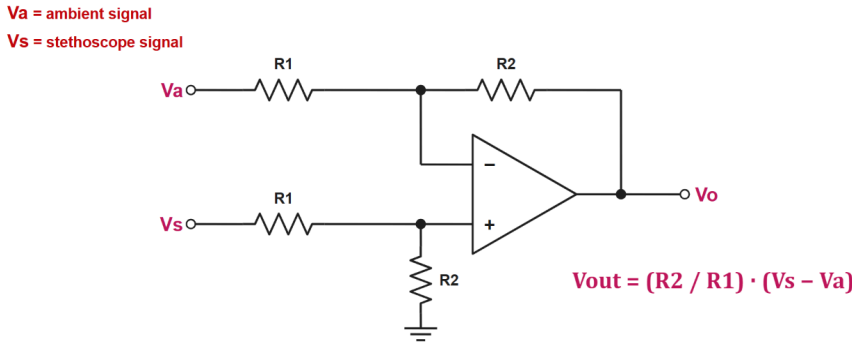


Figure [9]: Difference Amplifier

How much noise is actually cancelled depends on two factors. First, the resistor pairs must be closely matched, because resistor mismatch limits the CMRR of the stage well below the op-amp's own rating. For resistor tolerance t , the worst-case CMRR is approximately $(1 + R2/R1)/(4t)$: about 49 dB with 1% resistors and about 69 dB with 0.1% resistors, so precision resistors will be used. Second, ambient noise reaching the stethoscope microphone has passed through the chestpiece and tubing, so it will be quieter and differently shaped than the noise at the reference microphone. If the two are not matched, subtracting them can add noise instead of removing it. To account for this, we will add an adjustable gain to the ambient channel so it can be calibrated against the stethoscope channel.

Bandpass Filter

The bandpass filter is made of two first-order passive RC stages in series. The high-pass stage ($C1 = 10 \mu\text{F}$, $R1_{\text{filter}} = 800 \Omega$) blocks DC offset and very low-frequency handling noise, and the low-pass stage ($R2_{\text{filter}} = 320 \Omega$, $C2 = 1 \mu\text{F}$) removes higher-frequency noise. Calculated on their own, the two stages have corner frequencies of $f_c = 1/(2\pi RC) = 19.9 \text{ Hz}$ and 497 Hz . In simulation, the corners of the combined filter are 22 Hz and 450 Hz (Figure 11), because the low-pass stage loads the high-pass stage. This passband covers the main heart sound components (20–100 Hz) and most murmurs, including aortic regurgitation near 400 Hz [8]. Much of the engine and road noise in a moving ambulance falls in this same low-frequency range, so the filter alone cannot remove it; that is the job of the difference amplifier and the user's headphones.

The 450 Hz upper corner does cut into the lung sound range, which extends to roughly 1000 Hz [9]. If testing shows that lung sounds are noticeably weakened, replacing $C2$ with a $0.47 \mu\text{F}$

capacitor would raise the calculated upper corner to about 1.06 kHz. Both stages are first order, so they roll off at only 20 dB per decade. If more rejection outside the passband is needed, a second-order active filter can be built with one of the remaining OPA134 op-amps.

Figure [9]: Bode Plot for Bandpass Filter, with corner frequencies of 22 and 440 HZ

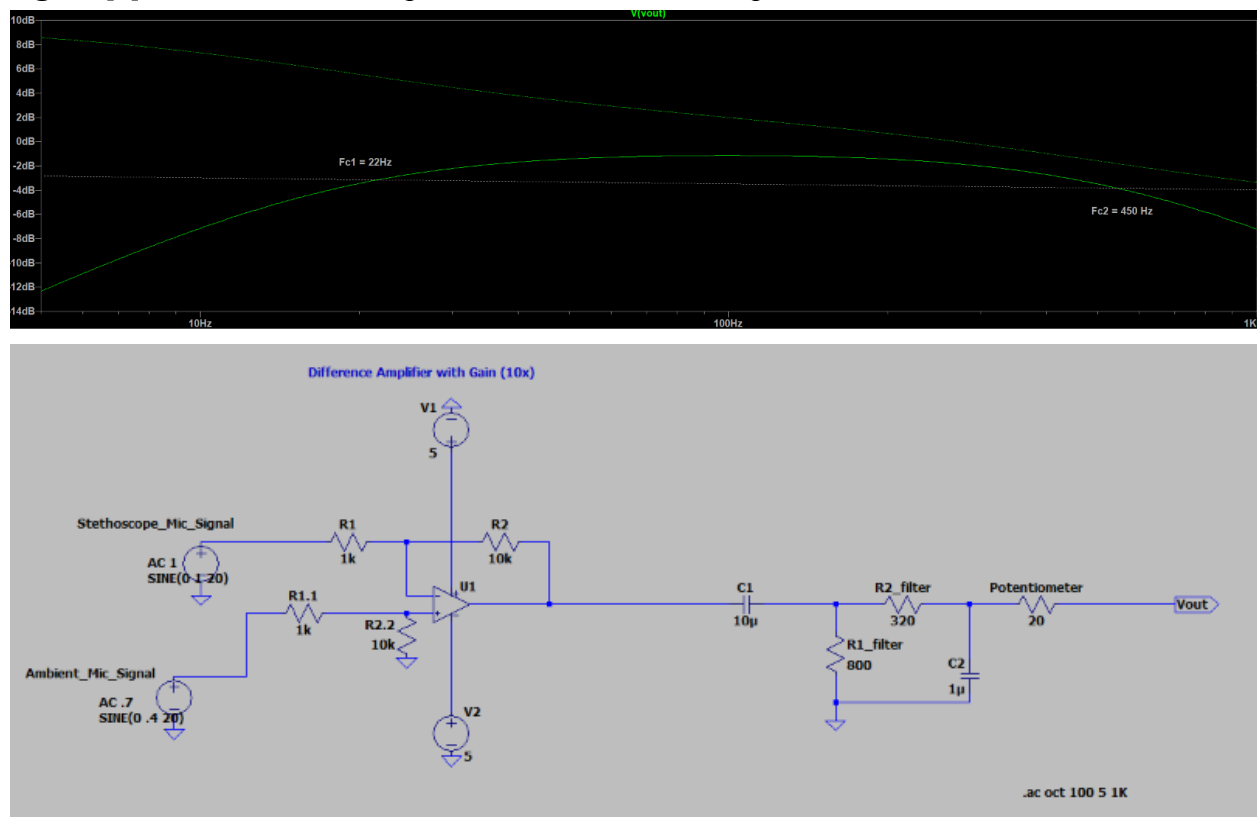


Figure [10]: LTspice model of the difference amplifier ($10\times$ gain), passive bandpass filter, and output potentiometer

Testing and Results

Tests will be done to investigate the effective noise cancelling, amplification, and ergonomics of the device, as these are the most weighted factors considered in our Product Design Specification.

To investigate the effectiveness of our noise-cancelling device, we'll perform a modified version of the Total Insertion Loss Test from the European Telecommunications Standards Institute Standard TS 103 640, "Test Methods and Performance Requirements for Active Noise Cancellation Headsets and Other Earphones, Section 5.1.2". From this testing, a Total Insertion

Loss Function will be calculated, representing the attenuation of an ambient sound field when using an ANC device as a function of frequency, such that $20 \text{ Hz} \leq f \leq 20 \text{ kHz}$.

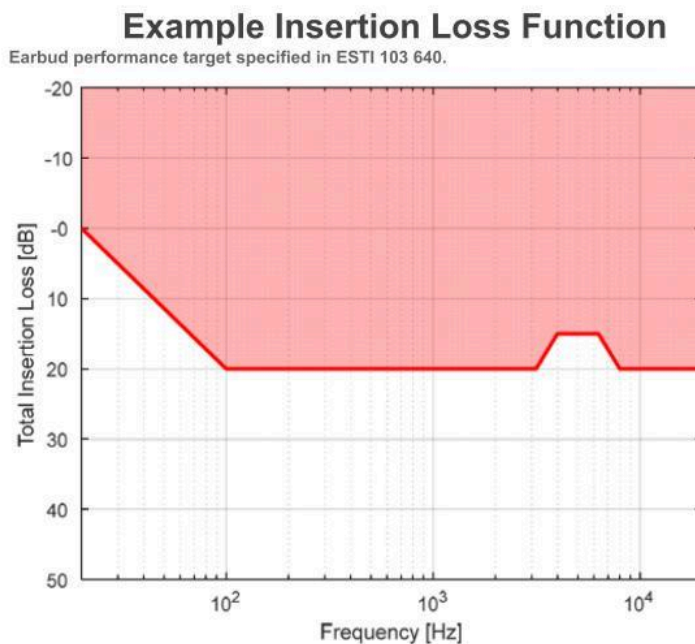


Figure [11]: Example of an insertion loss function - the total insertion loss performance target for insert-type earbuds per ESTI 103 640 standard.

In order to calculate the Total Insertion Loss Function from the testing, established recordings will be played and recorded as specified in table 4.2.4-1, with and without the ANC device in a specified testing environment as outlined in Section 4.4. From those recordings, 4096 point Fast Fourier Transform spectrograms are made representing the intensity of various frequencies over the length of the recording. From the difference of these graphs the Insertion Loss Function is derived.

From the results of this test, we'll be able to quantify the magnitude of our noise reduction at various levels.

Additionally, we want to perform qualitative tests with EMT providers to verify the ergonomics of the device. [describe a test that the EMT's could perform and compare to a regular design, and

select a statistical test to compare the results, describe how that will be useful]

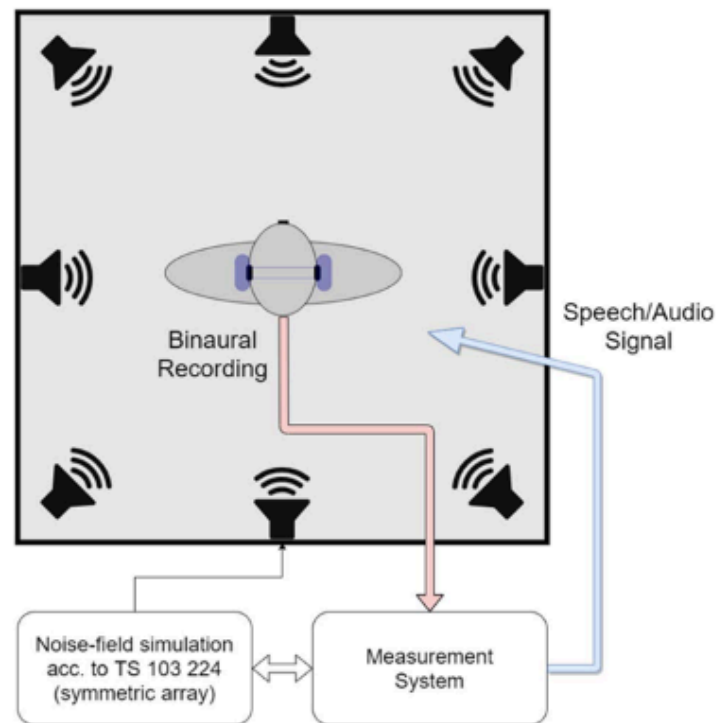


Figure [12]: Loudspeaker arrangement for background noise simulation in the testing environment for Total Loss Insertion testing, as defined in section 4.4 of Test Methods and Performance Requirements for Active Noise Cancellation Headsets and Other Earphones, ETSI TS 103 640 [21].

Discussion

The testing results will determine the feasibility of using our design in a clinical setting. It is vital that the device provides ample noise isolation and amplification in order for healthcare professionals to perform successful auscultation. If we are unable to reach our threshold of a 15 dB reduction in ambient noise levels, we may need to evaluate a new design that attenuates more of the outside noise, as no safe amount of amplification will be able to fully combat this. Additionally, if we meet the ambient noise attenuation threshold, we also need to ensure that our device is able to provide adequate amplification. This threshold was set at 40x in an attempt to be competitive with commercially available designs, but it must not exceed safe listening levels, in which case maintaining safe volume levels will take priority over our target amplification.

In addition to attenuation and amplification, we will need to evaluate the quality of the amplified auscultation signal. Meeting our attenuation and amplification thresholds alone does not guarantee that the device will be effective. The device must also be able to preserve relevant heart and lung sounds while minimizing distortion, feedback, and unwanted noise. If these issues

are present, further adjustments to the microphone, amplification circuitry, or digital signal processing may be necessary.

If and when our design is proven and refined enough for patenting and commercialization, we will need to ensure that it complies with all of the regulations required for a Class II medical device. These include, but are not limited to, device safety and performance testing, labeling requirements, quality system requirements, and other applicable FDA requirements. Electronic stethoscopes are currently classified by the FDA as Class II medical devices, and a 510(k) submission is the applicable premarket pathway for this device type. Additionally, we may need to complete a 510(k) submission to demonstrate substantial equivalence to an existing legally marketed device. In this case, we plan to work with the Wisconsin Alumni Research Foundation (WARF) and appropriate regulatory professionals to ensure that we are meeting all necessary requirements.

Conclusion

In summary, this project aims to provide healthcare professionals with a cost-effective stethoscope that provides amplification and is compatible with noise-cancelling headphones. Many healthcare professionals, especially those who work on ambulances and helicopters, have trouble performing auscultation due to the excessive noise (>100 dB during siren use [22]) present in these environments. The goal of this project is to design a stethoscope that allows for more effective auscultation in noisy environments, leading to better care for patients.

The proposed solution is a hybrid between a standard and a digital stethoscope. This design allows the device to be used as either a standard analog stethoscope or as a digital stethoscope by plugging in any pair of headphones with a 3.5 mm audio jack. In digital mode, the device will provide signal filtering and variable amplification to improve the user's ability to hear auscultated sounds in noisy environments.

Future work would likely involve implementing some form of on-board active noise cancellation (ANC) rather than relying solely on filtering and amplifying the auscultated signal. In our current design, noise cancellation relies on the user already owning noise-cancelling headphones and plugging them into the device. These headphones can be costly, and it should not be an expectation that all healthcare professionals already own them. Implementing ANC directly into the device could make ClearPulse more accessible and provide a more complete solution for use in noisy environments. Additionally, if and when we reach a point where we are ready to take our design to market, there will be a significant amount of work associated with patenting the design and preparing the device for commercialization.

References

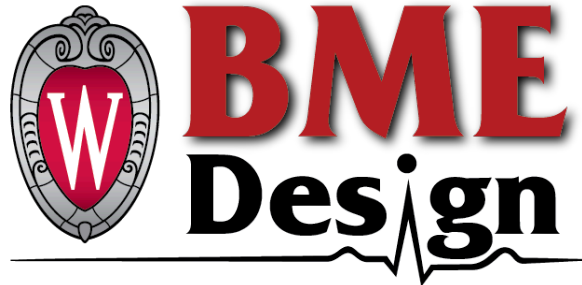
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Appendix

Appendix A: Product Design Specifications



ClearPulse: Stethoscope with noise canceling headphones (and amplification option)

Product Design Specifications

September 17, 2026

Section 305

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Function:

EMT workers have issues with reading heartbeats in noisy environments such as ambulances. The stethoscope device is to be used in these noisy environments, allowing the user to obtain a more accurate heartbeat reading. The stethoscope should be able to amplify the heartbeat vibrations to ensure the reading is clear while also blocking outside noise. The stethoscope will be able to be turned on and off with an easily accessible system to all users. The stethoscope is to be used mainly by EMT workers, who desire to have an inexpensive stethoscope option. Overall, the device will allow for easier heart analysis in cacophonous environments.

Client requirements:

1. The product needs to transmit clear heartbeat readings in a noisy environment.
2. Device should be confined and easily transported.
3. The stethoscope should be able to turn on and off with ease.
4. The stethoscope must have noise cancellation and amplification.
5. The device should be long-lasting and reusable.
6. The stethoscope should be safe for human contact.
7. The product must be inexpensive. Market products are too expensive for the intended consumer. [1]
8. Client encourages applying to WARF for a patent.
9. \$101 budget

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

- i. The device must maintain functional auscultation in environments such as helicopters and ambulances, where ambient noise levels can routinely reach 96 dB [2]
- ii. The noise cancellation system must provide measurable attenuation of ambient noise between 100–1000 Hz without significantly reducing the amplitude of clinically relevant auscultation sounds.
- iii. The device must provide user-controlled amplification of auscultated sounds without introducing distortion that interferes with interpretation of heart or lung sounds.

- iv. The device must allow the user to switch between available operating modes without interrupting auscultation.
- v. The device must maintain sufficiently low audio latency such that auscultation sounds are perceived without noticeable delay.
- vi. The device must prevent acoustic or electronic feedback from interfering with auscultation during normal operation.
- vii. The selected headset should passively reduce ambient noise levels by 15 dB before any additional active noise cancellation (ANC) is enabled.
- viii. The device must provide a maximum amplification of at least $40\times$ at the peak frequency, comparable to the 3M Littmann CORE [3].

b. Safety:

- i. The device must limit audio output to 85 dBA or below during normal operation to reduce the risk of noise-induced hearing damage during prolonged use [4].
- ii. The device must operate at a maximum of 5 V DC and incorporate short-circuit and overcurrent protection to minimize the risk of electrical hazards under normal and failure conditions. For rechargeable batteries, the charging system must include appropriate overcharge and overcurrent protection.

c. Accuracy and Reliability:

- i. The device must provide consistent amplification of auscultation sounds across repeated measurements under identical operating conditions.
- ii. The device must maintain consistent noise-cancellation performance under identical operating conditions, with a maximum allowable variation of 5 dB.
- iii. The device must reproduce clinically relevant heart and lung sounds without significant alteration of their frequency or amplitude characteristics.

d. Life in Service:

- i. The device must withstand daily use for a minimum of 2 years, including use during common EMS shift schedules such as 8-hour and 24-hour shifts [5].

- ii. The device must provide a minimum of 24 hours of continuous operation per charge or set of cells. The device must use either replaceable batteries or a rechargeable battery rated for a minimum of 250 charge cycles.
- iii. All external components of the device must withstand normal handling and use for a minimum of 2 years without loss of function.
- iv. The device must withstand routine cleaning and disinfection without loss of function.

e. Shelf Life:

- i. Our product will contain a charging apparatus, likely either via battery-powered, for an adapter, and lithium-ion batteries, for a rechargeable headset. The storage/life guidelines for both are as follows:
 - 1. Standard AAA batteries are common in many electronic stethoscope designs, and should typically be stored between 10° C and 25° C, without going above 30° C, as well as avoiding extreme humidities [6]. AAA batteries can be expected to last 1-3 years in medium-draw devices.
 - 2. Lithium-ion batteries are present in most modern headphones (a function of our preliminary design), and are typically stored best at 25° C, 50% SOC (State of Charge). In these conditions, battery life can be expected to degrade by ~2% a year, meaning the battery will functionally last 8-10 years [7].
- ii. The overall life of the product should ideally last upwards of 5 years, although given the nature of the environment the product will likely be used in (ED, helicopter, ambulance) and the fast-paced, sometimes hazardous nature of EMS, this span is by no means entirely reliable.

f. Operating Environment:

- i. During operation, this device will likely be exposed to many hazards (as previously mentioned). Assuming our device will be used as often and in the same conditions as a standard manual stethoscope, the main design guidelines come from bodily fluid (such as blood and vomit) and temperature ranges (ideally, should be usable outdoors), and of course, noise levels. In standard hospital settings, including the ICU, the mean dB is 69 dB, in the ambulance, on average, 80 dB, and in the headset of a helicopter EMS pilot, 83 dB on average [8].

g. Ergonomics:

- i. The product should be simple to use, and comfortable for the wearer. The maximum allowable clamping force (force applied to the user's head by a

given headset) should not exceed 8 N, and ideally, be much lower for comfort, around 1.5-2 N [9]. The product should also be easy to use/assemble (if applicable), as a wide variety of healthcare professionals and experience levels will be interacting with this device.

h. Size:

- i. The product should be very portable, able to be brought with an EMT in a go-bag on calls, or on a helicopter with a flight medic. While space is not an extremely limiting factor, size should certainly be considered to maximize portability, especially because it has been shown a larger size of headsets does not significantly reduce noise cancellation [9]. Standard over-ear headsets typically range from 80-90mm in outer diameter (earcup width), which can be a good range to shoot for. Additionally, the inner cup volume should be ~100,000–300,000 cubic millimeters, based on prior designs [10]. Any part of our device which is attached to the stethoscope as a conversion/amplification device should be small, although it is highly unlikely that this size will be a limiting factor in any way, and there are no industry standards for such a measurement.

i. Weight:

- i. There is no industry minimum or maximum weight for stethoscopes, but common stethoscope models on the market tend to weigh in the range of 100g-200g [11]. Noise cancelling headphones have a wider range of weights, reaching from 180g [12] on the lightweight end to 340g [13] on the heavy end. A reasonable range to shoot for on this product is 250g-600g.

j. Materials:

- i. All materials that will be contacting any person must pass ISO 10993-10, which accounts for skin sensitization [14]. Material biocompatibility documentation must follow the risk-based framework in FDA's guidance on ISO 10993-1, Section 6.4.4.3 [15]. For electrical components, they must comply with IEC 60601-1, which checks for general electrical safety [16].

k. Appearance:

- i. Aesthetic design should be benchmarked in comparison to ANC headphones available on the market and to stethoscopes available on the market. The process that should be followed in aesthetic design is outlined

in IEC 62366-1, which includes five steps: define users/environment, identify hazards, identify critical tasks, mitigate, validate [17].

2. Production Characteristics

- a. Quantity:
 - i. The goal is to produce one functioning prototype.
- b. Target Product Cost:
 - i. The client gave a budget of \$101 and requested that the product be accessible to EMTs, and the price was determined through field research to be less than \$100. Other projects have claimed to produce low-cost digital stethoscopes [18] but rarely succeed with noise cancellation and amplification [19].
 - ii. Currently, similar products such as high-quality digital stethoscopes and stethoscope amplifiers range from \$200 [20] to \$449[21].

3. Miscellaneous

- a. Standards and Specifications:
 - i. FDA Classification: Electronic stethoscopes featuring noise cancellation and diagnostic algorithms are typically classified as Class II medical devices in the United States (under Product Code DQD). They require 510(k) clearance to demonstrate substantial equivalence to existing legally marketed devices [22].
 - ii. IEC 60601-1 (Medical Electrical Equipment Safety): This is the foundational safety standard that the device must pass. It dictates basic safety and essential performance, ensuring the stethoscope's power supply and electronics do not present electrical shock hazards to the user or patient [23].
 - iii. IEC 60601-1-2 (Electromagnetic Compatibility): The device must be tested to ensure it operates correctly in a hospital's complex electromagnetic environment without emitting interference that could disrupt other critical care equipment.
 - iv. ISO 10993 (Biocompatibility): Materials comprising the chest piece (which contacts the patient) and the earpieces (which contact the clinician) must be evaluated for skin sensitization, irritation, and cytotoxicity [24].

b. Customer:

- i. Two qualitative interviews were performed to validate the market need for a low-cost noise cancelling stethoscope. A new EMT ambulance worker reported that sometimes hearing can be an issue, but so far most patients have had normal breath sounds. Alternatively, an experienced EMT worker found loud ambulance noise to be a repetitive issue, especially working in ALS (Advanced Life Support), where breath sounds, heart palpitations, and pulse can be very low.
- ii. Likes:
 1. Familiar Acoustic Profile: Clinicians prefer electronic devices that do not sound overly "digital." Research demonstrates that clinicians are highly receptive to electronic stethoscopes whose filtered outputs deliberately mimic the acoustic characteristics of traditional analog stethoscopes, as this bridges the transition to new technology [25].
- iii. Dislikes:
 1. Aggressive Filtering: Over-filtering that removes subtle, high-frequency heart murmurs or low-frequency lung crackles in an attempt to block ambient noise.
 2. Weight and Ergonomics: Heavy digital modules that make the chest piece cumbersome to maneuver across the patient's torso.
 3. Workflow Friction: Devices with short battery lives or cumbersome charging protocols that fail during long shifts.

c. Patient-related concerns:

- i. Infection Control and Cleaning: The stethoscope head comes into direct contact with dozens of patients daily, posing a vector risk for healthcare-associated infections (HAIs). The device does not require total sterilization (autoclaving), but it must be rated for high-level surface disinfection. The electronics, charging ports, and microphones must be sufficiently sealed (e.g., an IP54 or higher rating) to withstand frequent wiping with harsh 70% isopropyl alcohol or bleach wipes without degrading.
- ii. Data Privacy and Security: If the stethoscope records audio or visual (PCG) data and transmits it to a mobile device or cloud server for telehealth purposes, the software ecosystem must adhere strictly to HIPAA (US) and GDPR (EU) regulations. Patient auscultation recordings are considered Protected Health Information (PHI). The data must be encrypted in transit and at rest, and the companion application must

require authenticated access to prevent data from syncing to unsecured personal storage.

d. Competition:

- i. The market is split between legacy acoustic brands retrofitting digital modules and digital-first startups optimizing AI algorithms (Wu et al., 2022).
- ii. Key Competitors:
 1. 3M Littmann CORE: Developed in partnership with Eko Devices, this device attaches a digital noise-canceling and amplifying module to traditional analog tubing, allowing clinicians to toggle between acoustic and digital modes.
 2. Thinklabs One: A highly compact, tubeless digital stethoscope that pairs with standard wired or wireless headphones, offering extreme amplification designed for hearing-impaired clinicians [26].
 3. Mintti Smartho-D2: An AI-enabled electronic stethoscope with advanced noise reduction algorithms tailored specifically for remote cardiopulmonary screening and telehealth [27].
- iii. Relevant Patents:
 1. US11741931B2 / US20220301537A1 (Eko Devices, 2020): Details an electronic stethoscope device designed to integrate into conventional stethoscope tubing to digitize auscultated sounds, featuring active noise cancellation and wireless peripheral transmission [28].
 2. US5909495A (Andrea Electronics Corp, 1997): Covers a pressure gradient microphone situated within a microphone isolator acoustic coupler. It operates via mechanical/acoustical means to cancel background noise, specifically optimized for listening to heart sounds in noisy environments [29].
 3. US5610987A (University of Mississippi, 1996): An early active noise control stethoscope utilizing a digital signal processor and a least mean squared algorithm to digitally subtract ambient noise correlated from secondary environmental sensors [30].

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Appendix B: Expense Spreadsheet

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Category 1- First Design/ Microphones + Amplifier										
M5STACK AUDIO MODULE	ES8388 CODEC Audio Platform Evaluation Expansion Board	M5Stack Technology Co.	M144	Digikey	2221-M144- ND	10/6/26	1	\$7.95	\$7.95	Link
IC OP AMP 1CH 8-PDIP	Audio Amplifier 1 Circuit 8-PDIP	Texas Instruments	OPA134PA	Digikey	OPA134PA- ND	10/6/26	4	\$4.39	\$17.56	Link
MIC COND ANLG OMNI -45DB 0.236"D	Analog Microphone Electret Condenser 2 V ~ 10 V Omnidirectional	PUI Audio	POM-2245L- C33-R	Digikey	668-1390-N D	10/6/26	2	\$2.03	\$4.06	Link