Boston University
Electrical & Computer Engineering
EC464 Capstone Senior Design Project

Hardware Report

LungDetect

Submitted to

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by

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LungDetect User Manual

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1 System Overview and Installation

1.1 Overview block diagram

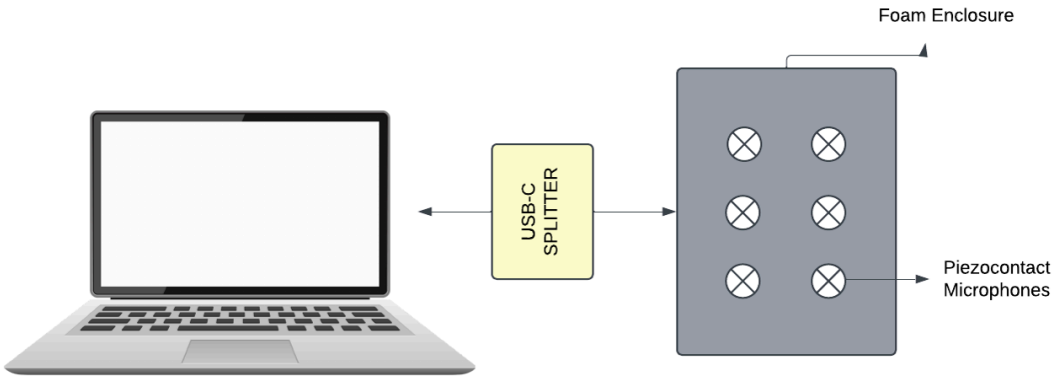

Figure 1: Diagram showing the dataflow of the hardware setup.

1.2 User interface:

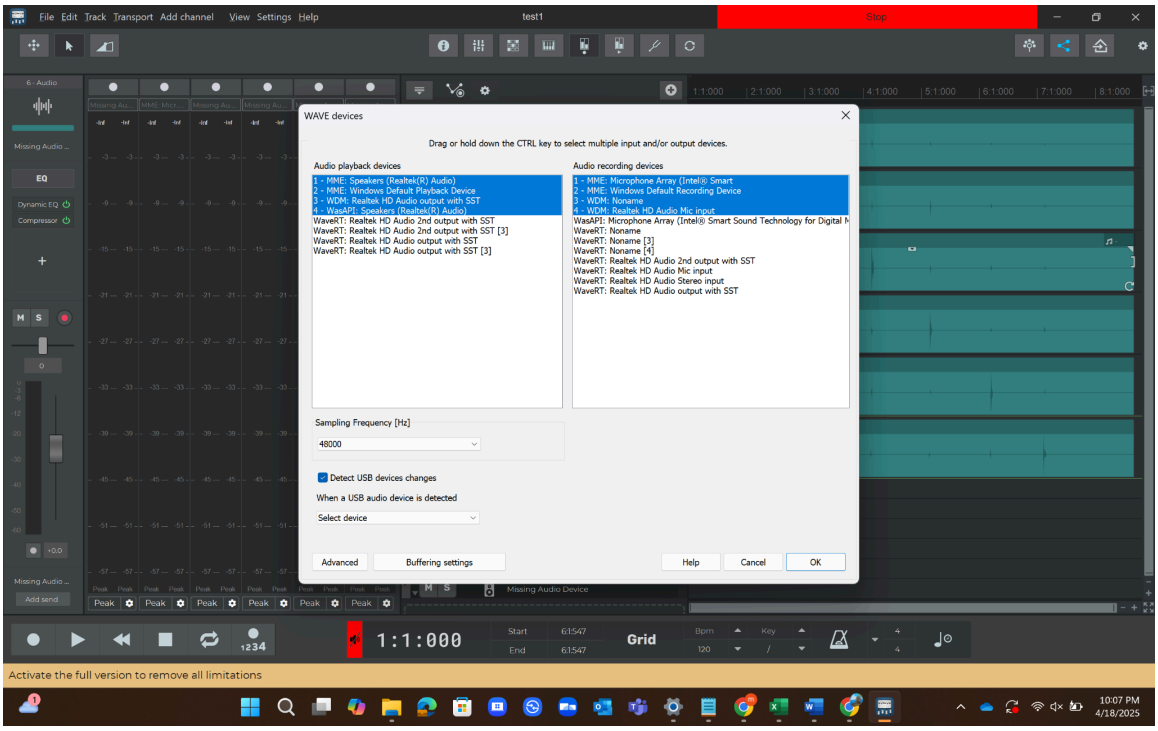

Figure 2: Screenshot of n-Track Studio 10 and its "Audio Devices" settings.
To select multiple inputs and outputs, hold "CTRL" while selecting the microphones registered by the USB hub in order.

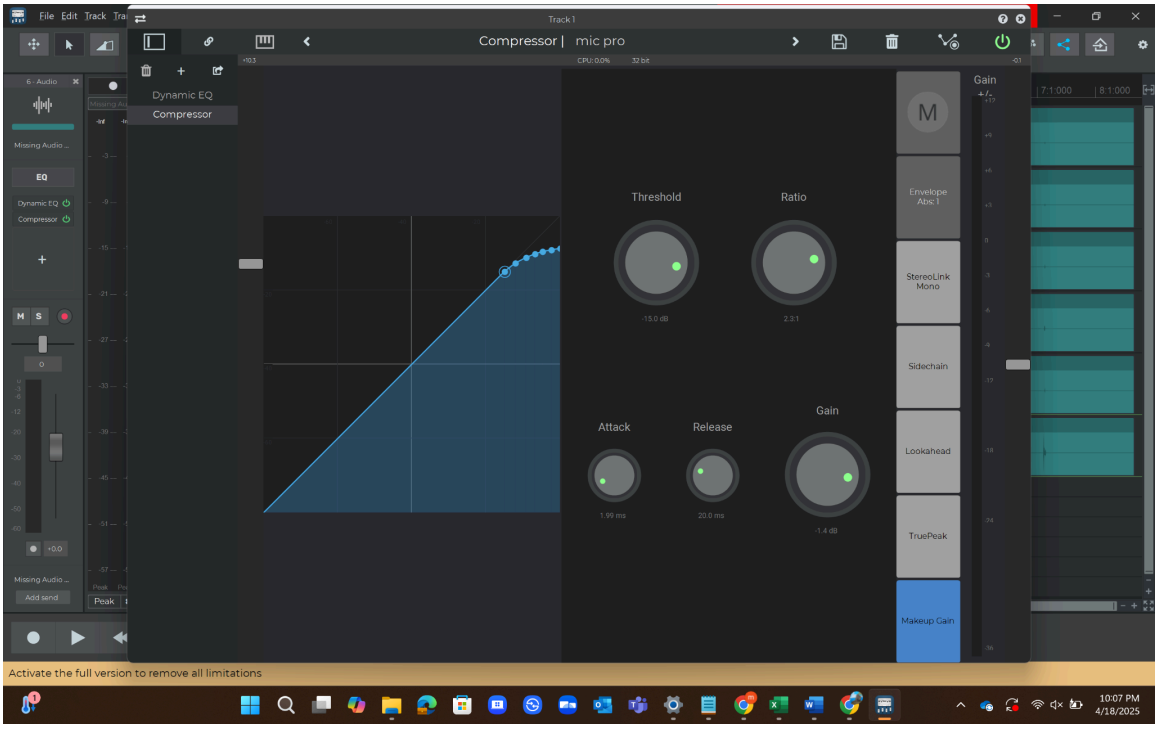

Figure 3: Screenshot of n-Track Studio 10 and its compressor settings. Customized settings can be saved as a preset for easy loading. Input gain: +10 dB, threshold: -15 dB, ratio: 2.3:1, attack: 2 ms, release: 20 ms, signal gain: -1.4 dB. To apply post-processing effects, click on the "+" on the left side under the track information.

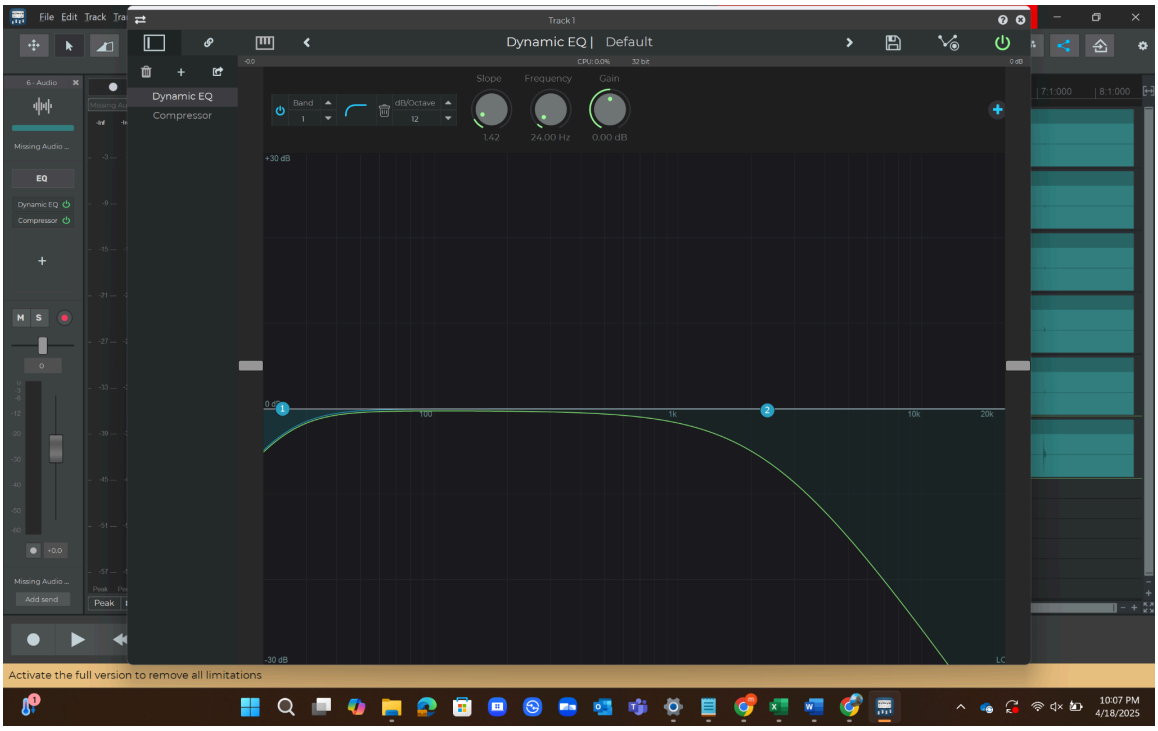

Figure *4: Screenshot of n-Track Studio 10 and its dynamic equalization (EQ) settings. Customized settings can be saved as a preset for easy loading.*

High-pass filter at 24 Hz, slope = 1.42, gain = 0 dB, 12 dB/octave
Low-pass filter at 2300 Hz, slope = 1.00, gain = 0 dB, 12 dB/octave
To apply post-processing effects, click on the "+" on the left side under the track information.

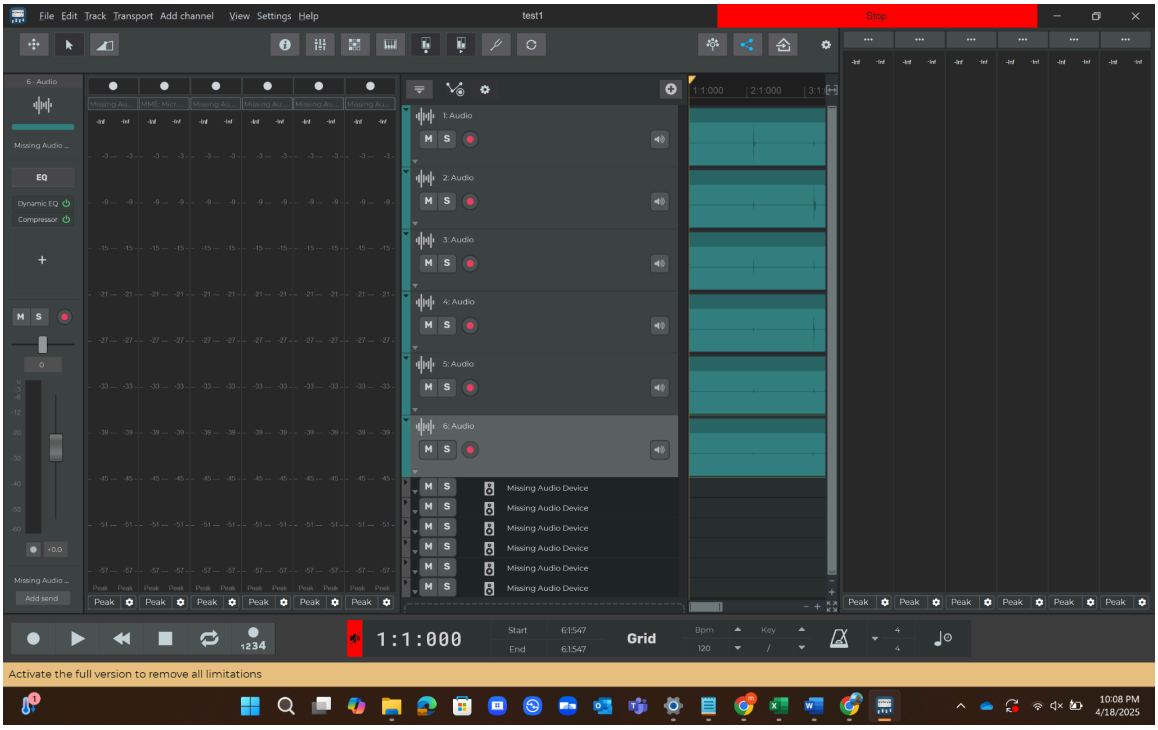

Figure 5: Screenshot of n-Track Studio 10 and its input volume (left side) and output volume (right side) monitors. Use the input volume monitors for testing microphone recording capabilities, and use the output volume monitors for testing audio signal playback.

1.3 Physical Description

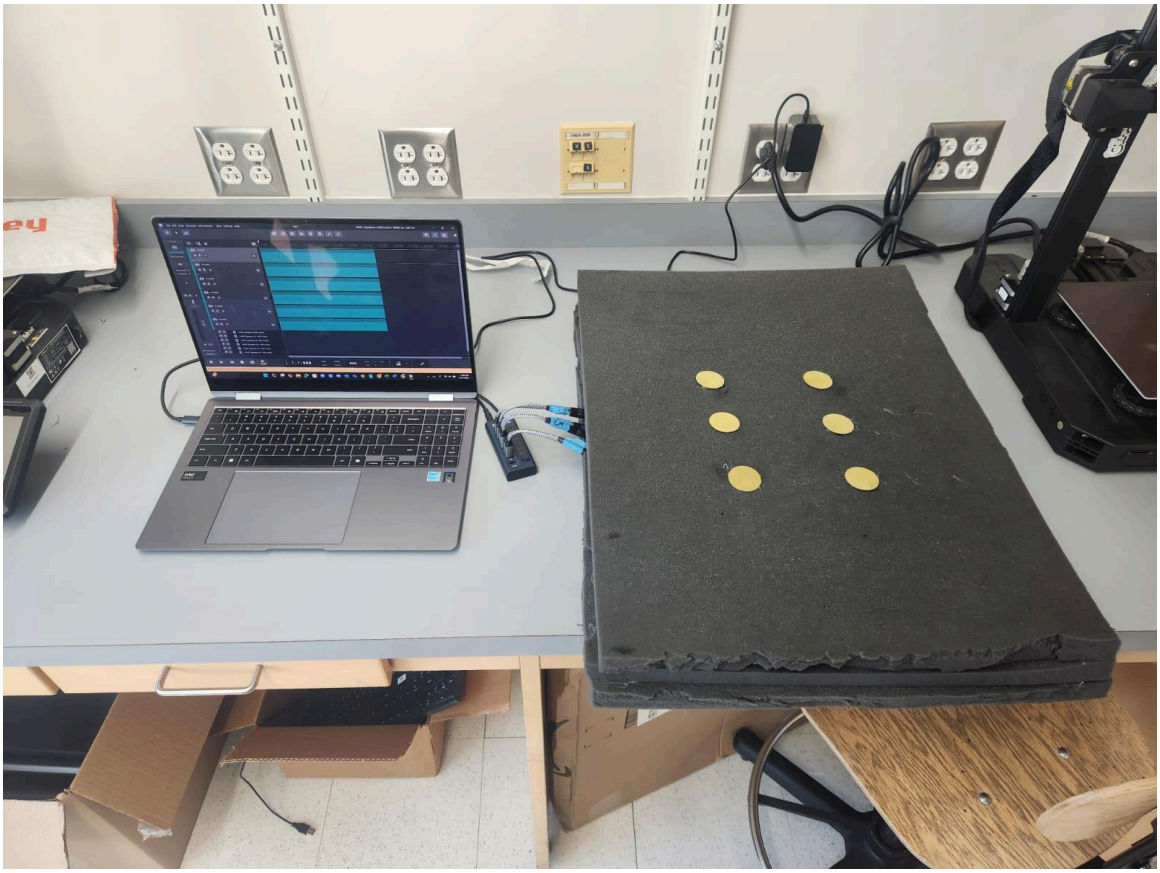

Figure 6: Photograph of the device active and ready to record on n-Track.

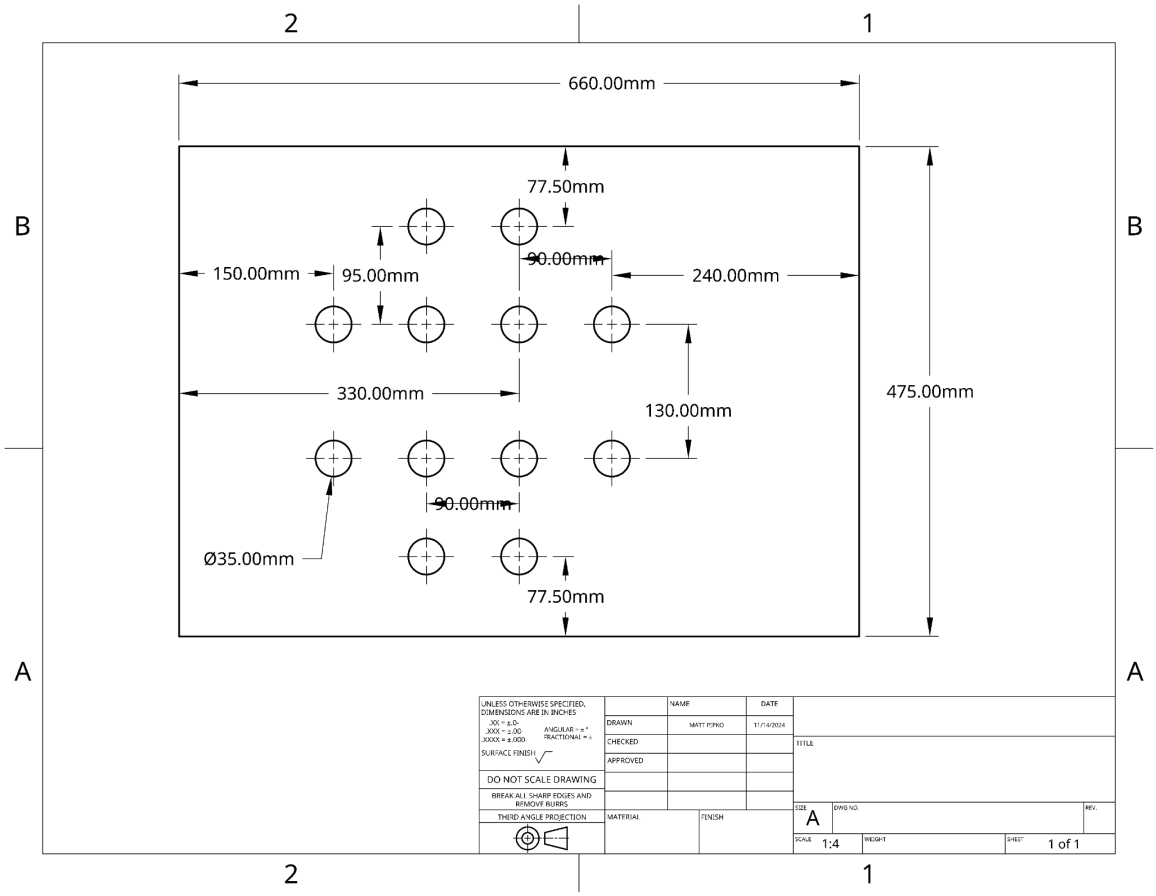

Figure 7: Initial drawing of the foam enclosure with the initial 12-microphone design that was then repurposed for the 6 channel design.

1.4 Installation, setup, and support

First, connect the microphones from the foam to the USB splitter to be inserted into the computer.

Making sure all the connections are secure and correct, open up n-Track's "Audio Device" settings and make sure to select a channel and corresponding speaker for each microphone.

After checking for the correct microphone settings, some additional audio adjustments must be made before we can begin recording patient breathing.

n-Track set up:
If these post-processing settings have not been set and saved before, then they need to be applied to every track (see figures 4 and 5 for details):

- High-pass filter applied at 24 Hz with no gain.
- Low-pass filter applied at 2300 Hz with no gain.
- Compression with an input gain of +10 dB, a threshold of -15.0 dB, a ratio of 2.3:1, an attack of 2 ms, a release of 20 ms, and a signal gain amplification of -1.4 dB.

See figures 3 and 4 for the visual demonstration of what the effects and settings look like.

2 Operation of the Project

2.1 Operating Mode 1: Normal Operation

2.1.1 Hardware Normal Operations:

- Ideally, the device should be able to record audio from six different microphones simultaneously
- Each microphone can be assigned to its track for data separation
- Audio settings like high-pass filters, noise reduction, gain, etc., should be easily adjustable pre-recording and be reflected in the final file

2.1.2 n-Track Normal operations

- Check the “Audio Devices” settings to ensure that all 6 microphones are connected and plugged in correctly.
- Ensure that each track is assigned to its corresponding microphone in order (channels 0-5 correspond to tracks 1-6).
- If n-Track is opened for the first time, apply the post-processing effects that are shown and described in section 2.2 User Interface and 2.4 Installation, Setup, and Support.
- After successfully connecting and applying the effects to each microphone, open the input volume and output volume meters to monitor how the microphones record, and how the audio is processed after recording respectively.
- When the user is finished recording the audio, they can export each track as an individual .wav file for signal analysis.

2.2 Operating Mode 2: Abnormal Operations

2.2.1: Hardware Abnormal Operations:

- At times, there might be an instance where audio from a specific microphone isn’t being picked up. When this occurs, check connections for any loose cables or for a faulty splitter. If all is correct and secure, then ensure all the correct inputs are mapped in n-Track.
- If n-Track crashes or is unresponsive, reload the session with the same test file. All settings should stay the same. If not, refer to the previous setup documentation to repeat all settings.
- If input levels are low, increase gain and/or check hardware for damage.

2.3 Safety Issues

There aren’t many safety issues associated with this project, especially since it is a non-invasive diagnostic device. However, our biggest concerns regarding the device have to do with contamination and patient data safety.

First, since the device is used within a medical environment and requires skin-to-microphone contact, it is important to ensure that it does not become the cause of the spread of infection. To mitigate this, the external surfaces of the device should be disinfected with an electronic-safe disinfectant. Additionally, a disposable plastic covering would ideally be placed over the device between patients. This feature is yet to be implemented, but it would most likely be done by a material such as medical-grade PVC. This material is transparent, waterproof, and resistant to common medical disinfectants. It is also able to be infused with microbial agents to further prevent the spread of infection. Most importantly, the plastic covering should be thick enough to be durable, but thin enough not to interfere with any audio recording.

As for patient data safety, ensuring privacy is essential to comply with important medical regulatory laws such as HIPAA. To ensure patient privacy, all audio recordings should be encrypted during transmission and storage, with cloud services that comply with relevant data protection laws. Additionally, access to patient data must be restricted to authorized users only, and strong authentication methods should be employed.

3 Technical Background

The hardware portion of the project is made up of multiple components. For one, the device includes six piezoelectric contact microphones for simultaneous recording. By doing this, the system can acquire a comprehensive look at the patient's sound patterns.

As for the device's enclosure, it is made up of polyethylene foam due to its durability, resistance to water, and ability to maintain cleanliness (preventing mold, contamination, etc). This foam acts as the device's housing material, embedding the microphones and preventing their displacement during the diagnostic process.

Data from all six microphones is combined into one, singular USB-C port by the USB-C splitter, streamlining connection and data transmission to the laptop for data analysis. Additionally, the device is powered by external power. This makes sure that the device is uninterrupted during its use.

Once the audio file is recorded and exported as a .wav file by n-Track, it is uploaded to our custom-made software app.

4 Relevant Engineering Standards

Domain	Standard / Regulation	Relevancy to the project
Patient-contact hardware	IEC 60601-1 (Ed. 3.2) & IEC 60601-1-2 (EMC)	Electrical safety & emissions for medical equipment used or worn by patients. Determines insulation, leakage current, and EMC test limits for the piezo microphones, jack-to-USB-C ADCs, and the powered hub.
	ISO 10993-1 / -5 / -10	Biocompatibility tests for the polyurethane foam and any protective SMS layer that touches the skin.
	NFPA 99 / NFPA 70 (U.S. hospital power)	If the pad is used in a clinical, patient-care area, the hub must plug into a hospital-grade receptacle, and the power strips must be medical-grade.
Electronics & connectivity	USB 2.0 Base Spec & USB Audio Device Class 1.0	Confirms 5V bus-power must be < 500 mA, descriptor tables, mono-audio streaming at 48 kHz. Ensures Windows lists each dongle as an independent MME input.
	FCC 47 CFR Part 15, Class B (or EN 55032 Class B in the EU)	This is applied to the hub + dongles as composite "unintentional radiation." Radiated & conducted emissions for digital devices used in homes/clinics.
	RoHS Directive 2011/65/EU	Restricts Pb, Hg, Cd, Cr VI, PBB, PBDE in solder, cables, piezo ceramics. Needed for CE marking.
Software life-cycle	IEC 62304:2006 + A1:2015	Software development life cycle for medical devices. Classifies risks, mandates unit/integration tests for the Node back-end and Python crackle-analysis scripts if the product is to be sold as a diagnostic.
Quality & risk management	ISO 13485:2016	QMS covering design-history file, supplier controls for the foam, dongles, and firmware.

Domain	Standard / Regulation	Relevancy to the project
	ISO 14971:2019	Hazard identification & risk controls (electrical shock, false-negative crackle detection, data loss).
Cyber-security & privacy	HIPAA (45 CFR Parts 160/164) &/or GDPR (EU 2016/679)	Audio files are Protected Health Information (PHI). This requires all of the files to have encryption at rest, user authentication, audit logs, and patient consent language.
	ISO/IEC 27001:2022	Information-security management system for the cloud VM or on-prem server that stores WAV files and analysis results.
	OWASP ASVS v4 & OWASP Top 10 (2021)	Secure-coding checklist for the Node.js API (e.g., input validation, auth tokens, CORS).
Web & data exchange	RFC 7231 & 7540 (HTTP/1.1 & HTTP/2), RFC 8446 (TLS 1.3)	Governs REST endpoints between React front-end and Node back-end; mandates HTTPS with modern cipher suites.
	ECMA-262 (ECMAScript 2023) & ECMA-404 (JSON)	Language spec for React (browser JS) and the JSON payloads exchanged with the API.
	W3C HTML5, CSS 3, ARIA 1.2 & WCAG 2.1 AA	Accessibility and semantic-markup rules for the React UI, so clinicians and patients with disabilities can use the web dashboard.
Coding conventions	PEP 8 (Python), Google JS Style Guide (or ESLint Airbnb)	Keeps the Python crackle-analysis script and Node/React codebase readable and maintainable..
Audio processing	RIFF/WAV PCM (Microsoft/IBM spec)	Ensures exported 48-kHz mono WAV files are interoperable with the Python analysis pipeline.

5 Cost Breakdown

Matthew Pipko and Shadin Almaiman

Project Costs for Production of Beta Version (Next Unit after Prototype)				
Item	Quantity	Description	Unit Cost	Extended Cost
4 pack of 3.5mm Male Plug to Bare Wire Open End Headset TRRS Cord 4 Pole 1/8" Jack Stereo Audio Cable	2	The cables required to connect the microphones to a 3.5 mm male microphone jack.	$4.97	$9.94
USB C to Aux Audio Dongle Cable Cord (Pack of 2), Type C to 3.5mm Female Headphone Jack Adapter	3	These dongle adapters act as ADCs for the microphones. The piezoelectric microphones have their recorded analog signals converted to digital to be assessed by the software.	$8.99	$26.97
Polyurethane Foam (36" x 24" x 1")	1	Foam acts as the main form of housing for the microphones, as well as the point for the patient to lie on.	$44.99	$44.99
USB-C Splitter	1	Combines six analog microphone inputs into a single USB-C output, allowing the device to transmit multi-channel audio data to a laptop for recording and processing.	$45.69	$45.69
10 pack: Piezo Contact microphones	1	Recording posterior lung sounds from the patient.	$9.99	$9.99
Total Cost				$137.58

The vendors for these parts is Amazon