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Mindful Breathing: Final Report for breathSense

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Executive Summary

This report outlines the design and development of the breathSense device aimed at enhancing mindful breathing through synchronized vibrations. The project was driven by the research of the project's sponsor, Dr. Negar Fani, who has found that vibration feedback synced to a patient's breath can improve the effectiveness of mindful breathing, particularly in individuals experiencing dissociative symptoms and post-traumatic stress disorder. Dr. Fani's research also suggests that the general audience of meditators could benefit from this device. The current system employed by Dr. Fani's lab (FaniLab) uses a separate vibration output and breath sensor, with a MATLAB script and microcontrollers to execute signal processing. The current system is difficult to use, only feasible in the lab setting, and prone to errors such as missed breaths and vibration output delay. The design opportunity for this project lies in creating an integrated package to solve these issues and target use for the FaniLab's ongoing clinical trials and initial exploration as a consumer device.

This project's objective is to design and develop a meditation aid device for inexperienced or intermediate meditators to use in a clinical setting and their preferred meditation setting. This device tracks the user's exhale and outputs a synchronized vibration response on the sternum to amplify the subtle signal of the breath to support a mind-body connection. The technical challenges necessary to overcome included accurately detecting breath in real time, minimizing the delay of vibration response, and making setup simple for the user. Five different sensor technologies –accelerometer, strain gauge, acoustic sensor, an RF package, and pressure sensor – were considered for initial testing. Performance specifications focused on delivering accurate breath-synced vibrations, ease of use, and adaptability to different body types. The device aimed to - and successfully achieved to - reliably track the user's breath without calibration or tuning and output the vibration response during exhalation. Additionally, the device was required to have minimal setup and provide external monitoring for the lab setting. To best achieve a feasible, effective system which met the stated performance specifications, the strain gauge was selected for use in the design.

Integrated into a wearable device around the chest, the strain gauge accurately captures the relative respiratory volume by measuring the change in chest expansion/contraction. As the user inhales and exhales, the chest expands and contracts and increasing/decreasing tensile stress in the strain gauge strap. The associated mechanical strain causes a change in resistance of the strain gauge, which can then be correlated to detect inhalation or exhalation. The integrated wearable device had several proposed form factors, including a Running Vest, Backpack, and Racerback, based on initial prototype testing and evaluation with the FaniLab, the Racerback design is selected for use in the final design. Presented is a fully integrated and functioning final prototype, a discussion of feasibility and experimental testing.

Nomenclature & Glossary

Nomenclature	Definition
ESP (or ESP32)	Microcontroller
ERM	Eccentric Rotating Mass
Expiration	The exhale of breath.
FaniLab	Dr. Negar Fani's research laboratory
Inpiration	The inhale of breath.
LED	Light Emitting Diode
LRA	Linear Resonant Actuator
Relative Respiration Volume	A relative, unitless, measure of respiration volume used to quantify the layman term "depth of breath".
Respiration Rate	The number of breaths taken every minute, breaths per minute.
Respiration Volume	Volume of air moved by or associated with the lungs at a given point.
RF	Radio Frequency
Sternum	The breastbone, the long flat bone in the center of the chest.
Xiphoid	Lowest part of the sternum located just above the diaphragm.
Value-Chain Actors	Anyone involved in product lifecycle activities without having direct contact with the product

Introduction and Background

Breath-focused mindfulness is a well-studied technique with many benefits to the practitioners' mental health [1]. This technique takes many forms, but the key element is drawing awareness to the breath. Mindfulness-based treatments can also be effective for survivors of psychological trauma like posttraumatic stress disorder (PTSD) [2]. However, survivors of psychological trauma who develop symptoms of disassociation can face barriers to engaging with breath-focused mindfulness [3]. In a study conducted by the sponsor for this project, Dr. Negar Fani, it was found that providing an external stimulus in the form of vibration on the sternum synched to the patient's breath yielded greater improvements to metrics relevant to characterizing dissociative symptoms when compared to traditional mindfulness intervention without the breath synched vibration component [3]. In addition to being an effective intervention method, Dr. Fani believes that the public may also benefit from this form of external stimulation during mindfulness practice and to reduce stress.

For her current research purposes, Dr. Fani uses a Woojer (a wearable subwoofer) for vibration output paired with a soft pressure sensor that detects chest expansion and triggers the vibration during exhalation. However, this system is difficult to set up, requires a third-party vendor's controls to calibrate, and is prone to errors such as missed breaths or vibration response delay. To address these limitations, the team has developed breathSense, a reliable device that synchronizes vibrations with the user's exhale to enhance mind-body connection. While tailored to Dr. Fani's research needs, the device is also designed with future market adaptability in mind.

Existing Products, Prior Art & Applicable Patents

Many products on the commercial market aim to improve meditation outcomes through guided mediation or physically draw focus to the breath. Figure 1 captures many of the relevant product categories to this project.



Figure 1: Current Mindful Aid Devices Sorted by Breath Synched and Vibration Response

While several commercial products, such as the BreathSync, Breathing Buddha, and moonbird, aim to assist users with mindfulness through external stimuli like light or physical expansion, these devices require the user to synchronize their breath with the external stimulus [4,5,6]. Existing products that provide vibrational feedback, such as the Apollo Wearable and Spire Stone, guide breathing through vibration but do not synchronize the vibration to the user's inhale or exhale [7,8]. Additionally, no patents have been found which describe a synchronized vibration response to the user's breathing pattern. Of interest to this project are patents describing non-intrusive respiration volume sensing technology, but no patents have been found which limit the current design.

Codes & Standards

There are a wide variety of codes and standards that this device will need to comply with for mass market adoption due to direct human interaction, classification as consumer electronics, use of wireless signals, and inclusion of lithium-based batteries.

A full list of these standards for the United States is provided below:

- Consumer Electronics: UL IEC 62368-1 – Covers electrical and thermal safety, mechanical safety, radiation and chemical safety, and user interface and controls. [9]
- Wireless Signals: FCC Part 15 – Regulations for electromagnetic interference (EMI). [10]
- Haptic Feedback: ISO 9241-960 Ergonomics of human-system interaction – Guidance on tactile and haptic interactions, ensuring that the haptic feedback is safe and user-friendly. [11]
- Skin contact: ISO 10993 – If the device has prolonged skin contact, development must ensure that materials used are biocompatible to prevent skin irritation. [12]
- Battery safety: IEC 62133 – Safety requirements for portable sealed secondary cells and batteries, particularly for lithium-ion batteries commonly used in wearable electronics. UN38.3 regulation covers the testing requirements for lithium batteries during transportation to ensure they are safe to ship. [13]
- Product labeling and user instructions: Development must ensure that the device has appropriate labeling, including safety warnings, proper usage instructions, and compliance marks [14]

Stakeholder & Market Research

The key identified stakeholders for the project are Dr. Fani, FaniLab's research participants, and a potential future market of inexperienced public mediators. Dr. Fani served as the primary point of contact, offering guidance and finalizing project requirements. For the product to be successful the needs of the inexperienced meditators and research patients ("Satisfy Group" in Figure 2) had to be met.

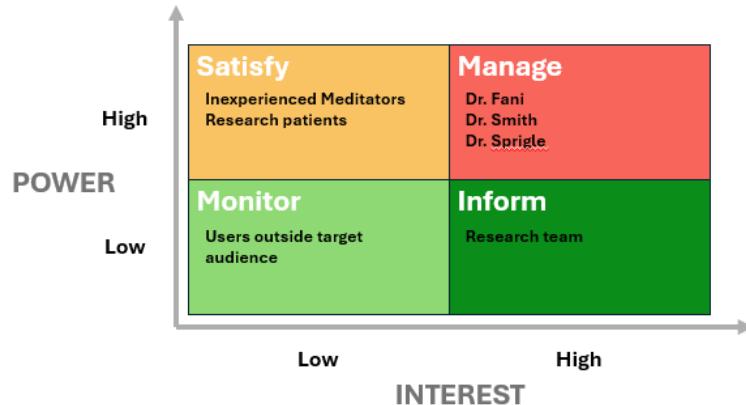


Figure 2: Stakeholder 2x2 Chart

Initial interviews with Dr. Fani and lab manager, Allie Guelfo, at Emory University helped shape the project's key criteria and specifications (Tables 1 and A2, Figure 3). Regular updates to the FaniLab ensured alignment with their goals and the development of an effective device. In addition to sponsor feedback and insight, the team has conducted a quantitative study to determine the likes and dislikes of the existing device with FaniLab's participants (details of the survey are presented in B.1). Initial feedback demonstrated that users are comfortable wearing a strap below the sternum, using it outside clinical settings, and engaging with the device multiple times daily and weekly. Subsystem (electronics and form factor) user testing has been utilized throughout development to make informed decisions on viability of the design as well as comfort. Further user testing was conducted with a fully assembled prototype, detailed in "Feasibility Assessment".

Table 1: Project Objective & Criteria

Project Objective: To design and develop a meditation aid device for inexperienced or intermediate meditators to use in their daily lives and to be used in a research setting. This device will track the user's breath and output a synchronized vibration response on the sternum to amplify the subtle signal of the breath to support a mind-body connection.

- Delivers breath-synced vibrations to assist meditators with breath mindfulness
- Vibrates on the sternum in sync with the user's breath
- Designed for a general audience, with inexperienced mindful meditators as first adopter audience
- Accommodate 5th to 95th anthropometrics for adults (age 18 and above)
- Minimalistic design for ease of use in public spaces
- Works consistently without need for tuning or careful positioning
- Can be used independently
- Comfortable to use when sitting, standing, or laying down
- Can connect in some way to externally monitor respiration sensor and vibration output in the context of clinical trials
- Operates without any external connection
- Offers control of vibration strength and feel
- 5-year lifespan when used in design conditions
- COGS: <\$150

Figure 3: Engineering Specifications Completed (detailed sheet presented in Table A-2).

OPERATION	ENERGY	ERGONOMICS
<ul style="list-style-type: none"> ✓ Worn without assistance ✓ No training necessary ✓ No external wiring ✓ Vibration delay <250ms ✓ Sample every 5ms 	<ul style="list-style-type: none"> ✓ Continuous use >180 mins ✓ Rechargeable with USB-C ✓ Battery charged >85% in <2hrs ✓ Battery of 1200mAh ✓ Replaceable battery ✓ Temperature < 60°C 	<ul style="list-style-type: none"> ✓ Force of vibration >5N ✓ 0mm separation between vibration and chest ✓ >9.5cm of strap stretch for expansion ✓ No perceivable pinch points/rubbing ✓ Comfortable wearing for >30 mins ✓ 5th-95th percentile anthropometrics ✓ Weight target 350-500g ✓ Vibration strength >1.6Grms
INPUTS & OUTPUTS	QUALITY CONTROL	COSTS
<ul style="list-style-type: none"> ✓ Receives breath signal ✓ Delivers synced vibrations ✓ Vibration strength 0-100% ✓ Control over vibration feel ✓ Output breath waveform ✓ Vibration waveform ✓ Power on/off & monitoring 	<ul style="list-style-type: none"> ✓ Calibration capability ✓ 5+ year lifespan with battery maintenance 	<ul style="list-style-type: none"> ✓ Less than \$150

The potential United States consumer market for the breathSense product has a sizable total addressable market (TAM) consisting of beginner to intermediate meditators who may benefit from some form of aid (such as feedback) while they practice. According to the National Health Interview Survey in 2022, 17.3% of US adults practice meditation (roughly 45 million people) [15]. While some in this group may not need a device to enhance their practice, many may be open to trying it. In addition to early-stage meditators, another significant target market for this device is recovery patients of conditions such as PTSD, which affects about 3.5% of adults in the US; such populations could benefit from a product, such as breathSense, for intervention. When assessing the Serviceable Available Market (SAM), households with an income between \$35,000 and \$49,999 are expected to be the minimum group able to afford a device priced under \$150. This eliminates approximately 23.3% of American households from the Total Addressable Market (TAM) estimation [16]. While this device does not have a direct competitor that possesses the same functionality, overlap with meditation apps and other meditation devices would reduce market share. This leaves the breathSense product with a Serviceable Obtainable Market (SOM) of approximately 15% to 30% market share in this sector of meditation aid products. Using the TAM/SAM/SOM framework, it is projected that, at its peak, this device could achieve sales in the low to mid seven-figure unit range, indicating the product's sizeable impact on people across the United States.

Project Criteria, Customer Requirements & Engineering Design Specifications

The sponsor sought a solution requiring minimal setup and external assistance, while also allowing for external monitoring in clinical trial environments. A successful product required a ready-for-research solution that provides breath-synced vibrations to support mindful meditation (Table 1). While the specific metrics captured by the sensor were flexible – reported only for FaniLab to validate correct operation during studies – the core requirement was to ensure that the device can synchronize with the user's exhale.

Key physical parameters established from the stakeholder interviews and market research, were further condensed into a specification sheet (Figure 3). A maximum vibration delay parameter was derived from the human reaction time to ensure synchronous feedback, with a 5ms sample rate to provide sufficient data for the signal processing algorithm. The device's target weight was 350-500g to ensure it remained light and comfortable for prolonged use. Additionally, based on modern vibrotactile feedback devices and first-hand testing performed by the team and Dr. Fani, the device must operate at a vibration strength greater than 0.8Grms. Power is to be supplied by a 1200mAh rechargeable Li-Ion battery intended to provide enough energy for 6 sessions of 30 minutes (based on current clinical testing requirements). The device must also be comfortable to wear for 30 minutes in sitting, standing, or lying positions (as defined by user testing), with no pinch points or rubbing perceived by the user. For adequate vibration feedback, there shall be no separation between the chest and the vibration source in all postures, and 5 N of force must be maintained holding the vibration source to the sternum (based on internal testing of vibration perception). Additionally, the design must accommodate the 5th percentile female to 95th percentile male, with adjustable straps to fit this full range of anthropometric data. The product's desired lifetime is 5 years, with the replaceable battery being the primary constraint. The team aimed to keep the cost under \$150, making it more affordable than Dr. Fani's current device. Other specifications are discussed throughout the report, including the engineering analysis and experiments.

Concept Selection & Design Iteration

To measure relative respiratory volume and to send a vibration to the user's sternum at each exhale, the system must consist of a sensor and a vibrotactile feedback device. To satisfy the breath tracking requirements, five different sensors, based on their common usage in clinical research for similar purposes, were identified for investigation – an accelerometer, strain gauge, acoustic sensor, piezoresistive pressure sensor, and radio frequency sensor. Another important consideration was the device's final form factor, which determines how users will interact with the system. Initial form factors considered included a chest strap, a vest-like garment, a necklace with “pendant”, and a two-piece system where the user holds a vibrating “stone” to their sternum with contactless breath measurement. Additional components of the system include a microcontroller to manage communication between devices, a power source, and user feedback (e.g. power status and sensor connectivity).

Five initial designs were developed using a morphological chart (Figure A-2) to meet project criteria, including an accelerometer strap, strain gauge strap, acoustic sensor pendant, piezoresistive pressure sensor strap, and RF illumination sensor system. Each design consisted of the same microcontroller, battery, vibration source, power source status mode, and sensor connectivity status mode due to their cross-functional capabilities and high performance. An ESP32 microcontroller was selected for its versatility with various input and output signals, low power requirements, and mid-range cost. A lithium-ion battery was preferred over the disposable battery due to its portability, rechargeable features, and increased voltage stability. The remaining components – vibration source, power source status mode, and sensor connectivity status – were

chosen for their ease of integration and user feedback. Detailed descriptions of these designs can be found in Table A-3.

The design concepts presented each offer distinct strengths and weaknesses relative to the project objectives and criteria. A comparative analysis, using an evaluation matrix (Table A-4), assessed how well each concept met the project requirements, prioritized research needs, wants, and then customer-focused criteria, and selected the strain gauge and accelerometer for more detailed analysis while still analyzing other sensors in parallel. An initial evaluation of the sensing devices, with focus on the accelerometer and strain gauge, verified the selection criteria and feasibility.

Sensor Selection

The strain gauge was most effective in clearly discerning inhalation and exhalation in comparison to the other evaluated sensors. The use of a windowed moving average further smoothed the signal and reduced the need for additional external filtering. The accelerometer, acoustic sensor, RF sensor, and pressure sensor were not chosen to be further studied. Specifically, the accelerometer lacked adequate sensitivity and was susceptible to interference from body movement. The acoustic sensor in the stethoscope tubing only captured background noise. The radio frequency sensor lacked precision as the measurements were only accurate when aggregated on the time scale of minutes instead of milliseconds as required by the project criteria. Further, the lack of directivity of the beam made the device susceptible to tracking motion outside the user. The pressure sensor demonstrated discernible waveform outputs, however, during packaging and prototyping it was determined infeasible. For these reasons, the strain gauge was selected.

Form Factor Selection & Development

Sensor selection narrowed down form factors being considered to only those compatible with a strain gauge. Initial ideation led to a chest-strap form factor, with electronics integrated into a single housing unit, due to its ability to deliver an effective vibration response to the sternum with independent use. Discussions with the FaniLab led to a shift from the chest-strap design to a vest-like one due to concerns about comfort, placement, and sensing capabilities. The strain gauge is intended to be positioned around the xiphoid to capture maximal chest expansion – with vertical adjustment features to accommodate chest or stomach breathing. The vibrotactile feedback unit – or vibration puck – must sit higher at the sternum, with independent adjustment for secure placement – as defined in Figure 3. To create a more effective and comfortable system for women, the team drew inspiration from running vests, backpack straps, and sports bras, leading to two design options: a "Backpack" vest and a "Racerback" vest with X-shaped back straps (Figures 4-5).

The Backpack and Racerback styles allow the system to more effectively sense breath and output a vibrational response. Both designs capture the relative respiratory volume through the strain gauge located near the xiphoid, while a vibrational response is output at the top of the sternum. The modularity of the device not only increases comfortability, but also mitigates vibrational interference to the strain gauge and allows for more accurate readings. Based on sponsor feedback, the Racerback was selected as the final form factor. Additional discussion on

ergonomics and how this design meets the specifications is detailed in the “Industrial Design” section, and a final design is presented in “Final Solution”.



Figure 4: Vest-like Form Factor with Separate Sensing and Vibration Modules (Backpack left, Racerback right)



Figure 5: Racerback Form Factor – Early Prototype

Electronics Development

The strain gauge, paired with a Wheatstone bridge breakout board, accurately captures changes in strain as resistance values which are read as corresponding voltage signals by the ESP32 via I2C. The ESP32 communicates over USB-C for the lab monitoring system through serial monitor outputs, allowing the lab to track the breath profile. Initially, an ERM was selected due to challenges with converting DC to AC power for the LRA. However, sponsor feedback highlighted the need for increased strength in vibrotactile feedback. Stronger ERMs were unavailable and running multiple ERMs concurrently did not significantly enhance vibration force through the housing, thus a LRA was implemented. A driver board was identified, making power management for the LRA a trivial problem and simultaneously offering a range of vibration modes as well as control over amplitude, thus fulfilling the desired specification. To power the electronics, a 1200mAh 3.7V LiPo battery was chosen for its compatibility with the ESP32's built-in power management and charging,

meeting the required runtime and charge specifications. To conserve power and to alert the user of battery status an on/off switch and 3-color LED were also implemented. Figure 8 shows a revised version of how the components interface with one another from a functional standpoint. Further testing and finalization of the electronics resulted in the wiring diagram in Figure 9.

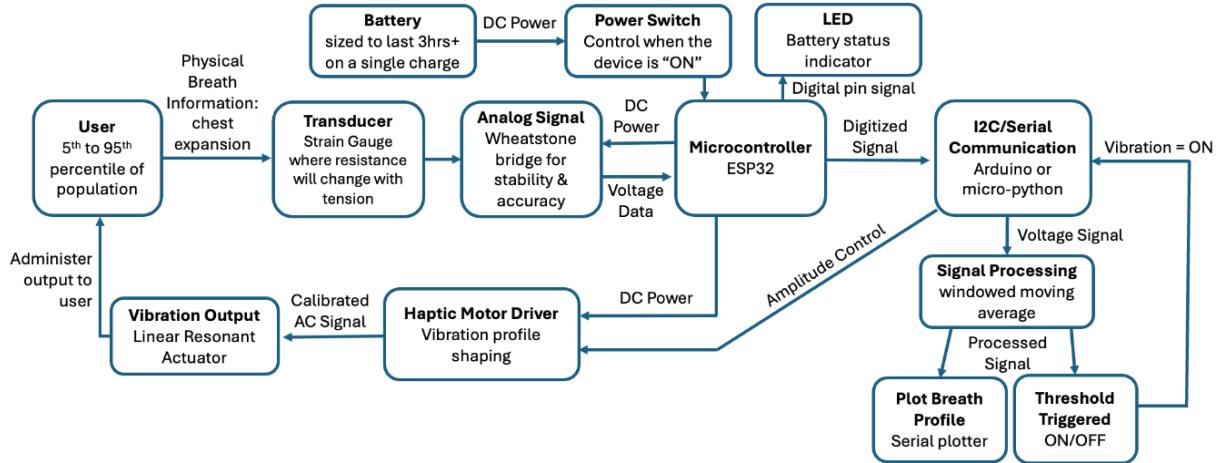


Figure 8: Revised Functional Block Diagram of Electronics

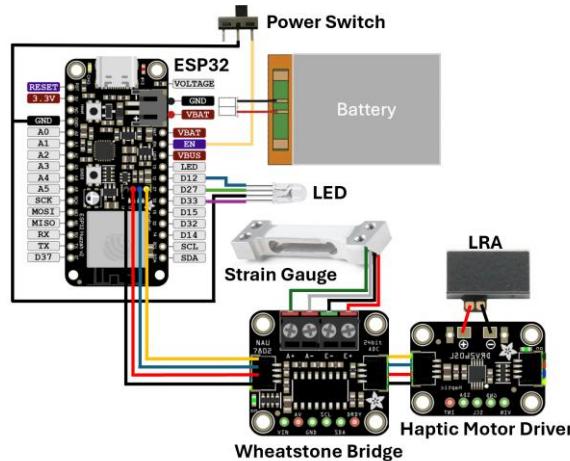


Figure 9: Electrical Wiring Diagram

Packaging Development

Packaging of the sensing and vibration subsystems have undergone various iterations of development. The left figure in Figure 10 depicts an early version of the housing unit in which the strain gauge experiences deformation translated through the D-rings attached to the strap. Both a Wheatstone bridge and microcontroller are fixed in place to the housing with standoffs. This early prototype, however, lacks a battery, battery status indicator, and power switch. The final prototype addresses these omissions yet reduces the housing unit size to minimize the rigid material on the strap. Additionally, it streamlines the overall form factor and user interface by simplifying the buckle, adjusters, and housing unit into a single unit (Figure 10, right).

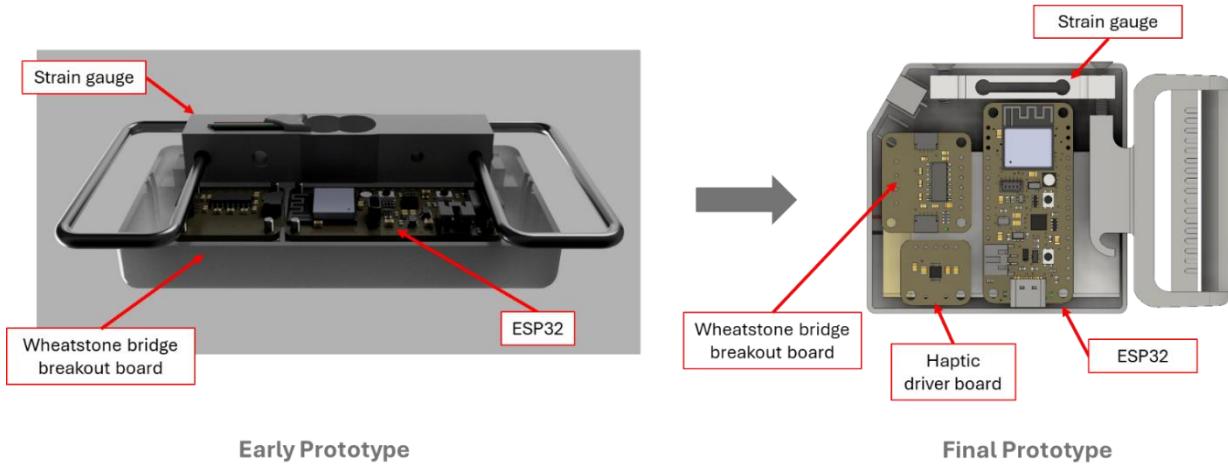


Figure 10: Early vs Final Prototype of Electronic Housing Unit

The vibration puck has also undergone simplification in its design. Initial designs included an Eccentric Rotating Mass (ERM) and its haptic driver board (Figure 11, left). However, final designs switched from an ERM to a Linear Resonant Motor (LRA) – as previously discussed – and moved the haptic driver board to the electronic housing unit (Figure 10 & 11, right).

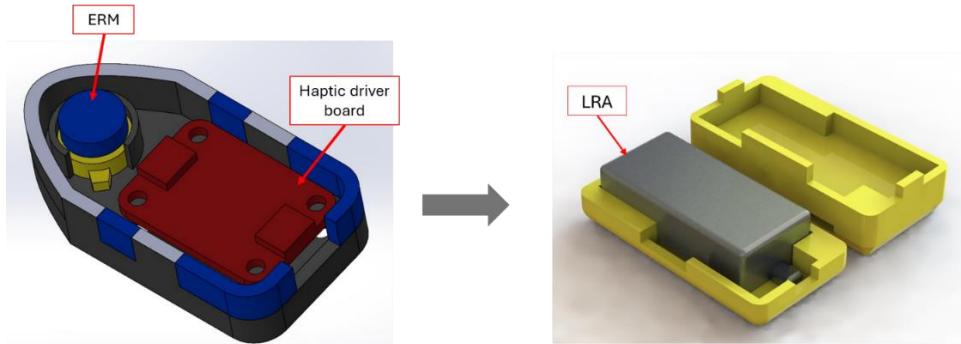


Figure 11: Early vs Final Prototype of Vibration Puck

Industrial Design

For a general market audience, the device must appear safe and unobtrusive to ensure users feel comfortable wearing it. Any distraction caused by the device can interfere with mindful breathing and the device's intended function. Thus, frequent readjustment, discomfort or appearance concerns must be avoided. For the consumer market, the device must be appealing such that the user feels confident wearing it regularly. The device is designed to accommodate the 5th percentile female to 95th percentile male anthropometrics, as shown in Table 4. An adequate amount of elastic material has been used to accommodate up to 9.5 cm of chest expansion [17,18,19]. Adjustable straps were utilized to maintain constant contact of the vibration puck to the sternum and to achieve an adequate holding force (~5 N) for vibration to be felt consistently based on internal testing.

Table 4: Anthropometric Data for 5th Female to 95th Male Percentiles [18]

Measurement Type	Anthropometric Data (inches)	
	5 th Percentile Female	95 th Percentile Male
Waist → Waist Over Should	33.35	45.00
Chest Circumference	32.44	47.52
Chest Breadth	9.49	12.60
Waist Circumference	27.95	44.53
Waist → Chest Height	12.48	17.24

The racerback form is modeled after existing products to give a sense of familiarity to the design, such as running vests and sports bras. To meet the specification of single-user operation without training or assistance, the device is designed to be donned and doffed similarly to a running vest, life jacket, or safety vest. User interaction with electronics (power switch and LED) are modeled after typical consumer electronics. The aesthetics of the device takes inspiration from existing wearable technology. Figure 12 shows a mood board of aesthetic inspiration.



Figure 12: Aesthetic Design Inspiration

The device's visual hierarchy is organized to focus the user's attention where needed. The vibration puck and xiphoid strap buckle are unique with bright coloring, priming the user to expect the vibration response from the puck. Other components are kept in greys and blacks to be aesthetically unobtrusive. Soft, rounded corners were also incorporated wherever possible to convey approachability and ensure comfort, making the device suitable for various postures and prolonged wear.

The intended use context of the device in a lab setting means that the device would be primarily worn as an outerwear clothing piece. However, to maximize versatility, the design accommodates both under- and outerwear use for private and lab context. The specific choices that emphasize this design language are thin supporting straps over the shoulder, flexible stretch bands, and thin and small sliding adjustable straps.

Feasibility Assessment

Electronic Housings: Material Strength & Failure

To understand the feasibility of the design, the electronic housing plastic parts must be validated to withstand expected loading from users to a margin of safety greater than 1. To accomplish this, FEA and destructive testing were employed. A Static Structural Finite Element Analysis (FEA) failure test was conducted in ANSYS to evaluate the electronic housing under simultaneous maximum static loads applied at all interface points, with Von Mises stress used as the evaluation criterion. The electronic housing material selected for analysis was Bambu Labs PLA with a material strength of 76 MPa [20]. An applied load of 25lbf at both hook points and the top and bottom faces of the prototype were applied to ensure that the device would not fail when being adjusted or compressed by hand. Under these conditions, the housing successfully passed the maximum load case with a safety factor of at least 1.5 relative to the material's yield strength (Figure 13).

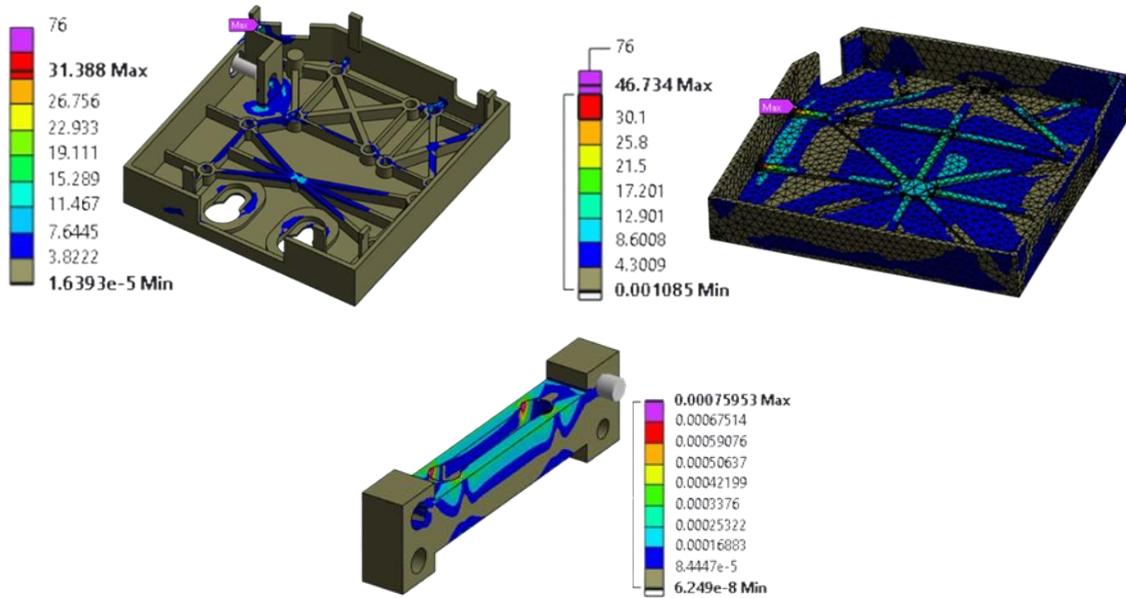


Figure 13: Von Mises stress of reported for Electronic Housing and Strain reported for Strain Gauge

For additional robustness, these results were verified through destructive physical testing of 4 prototypes. The results of these tests and a material strength discussion are reported in Appendix C.1 and C.2, showing that the parts are extremely robust against expected loading. The tests were used to develop and reinforce the part, so the minimum load rating of 32lbf reported is likely to be higher if further testing is investigated.

Additional electronic sub-components are off-the-shelf parts and were tested as an integrated subsystem, their feasibility was determined through user testing of the assembled product.

Electronic Housings: Thermal Analysis

A steady state thermal analysis was conducted to evaluate the heat management of the electronic housing due to power generated from the LED, ESP32, and LiPo battery at worst case conditions or

maximum operational current draw over time. The ANSYS simulation demonstrated that the electronic housing surface temperature remained at 31.97°C, well below the 43°C limit (defined in Appendix C.3) [21].

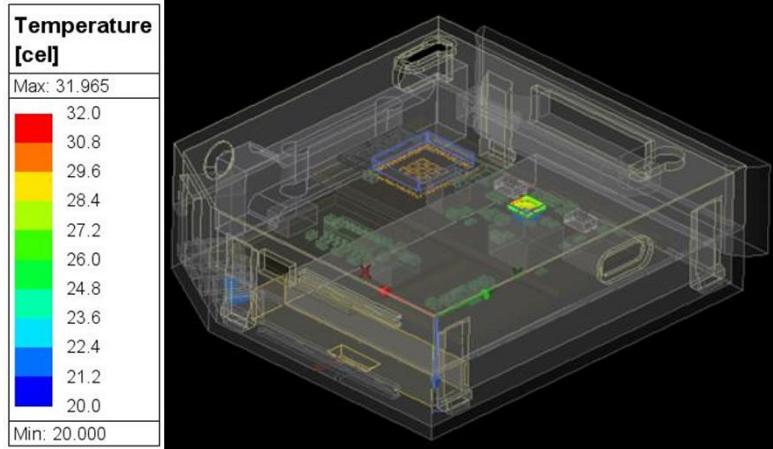


Figure 14: Thermal Analysis of Electronic Housing & Components

System: User Testing

User testing was essential to validate the performance, functionality, and human-interface aspect of the device. Amongst this testing was a device detection and delay test which evaluated the synchronization of the vibration to the user's breath (detailed in Appendix C.3). The average delay between the users' true breath phase change and the response of the device ranged from 150-350ms, approximately reaching the target delay of 250ms which corresponds to the average human reaction time. Additionally, the users rated the device's synchronization performance on average as 7.3/10 (10 being completely in sync). This value is rated lower due to 2 outliers present in female population; these outliers are hypothesized to be due to poor device fitting / oversized clothing. In addition to device delay testing, user comfort and usability were tested, as outlined in Appendix C.4. On average, it took users to don the device for the first time approximately 1 minute. Users rated the device's comfort 8.4/10 (10 being able to sleep with the device on) at initially donning and after 30 minutes of use. User testing revealed ways in which the device could be improved including a smoother, lighter, and quieter vibration and wire/strap management.

Finally, testing was conducted to evaluate the device's compatibility with the FaniLab environment, where no unexpected complications arose. Additionally, lab members participated in user testing and provided insightful feedback to improve the device's design and functionality. Recommendations included expanding the mid-section size range to better accommodate the FaniLab's subject population, increasing the vibration puck size to achieve more dispersed vibrotactile feedback, and integrating a data collection warning into the lab interface. Insights from user trials also highlighted the need to explore special cases of chest versus belly breathing for improved adaptability. While panic breathing was noted during testing, it was deemed outside the project scope as the device is not intended for applications related to panic breathing.

Final Design Solution

The final design solution, presented in Figure 15, is a wearable device that synchronizes with the user's unique breath and provides vibrotactile feedback on the exhale. To use the device, the user simply turns it on, adjusts the xiphoid strap for a snug fit, and positions the vibration puck against the sternum. Once correctly positioned, the device automatically synchronizes with the user's exhale and delivers targeted vibrations. The device can be connected to a computer via USB-C for real-time plotting of the breath and vibration waveform. Further details of the function and development of this final design solution are presented in Figure 16 and “Concept Selection & Iteration”.



Figure 15: Final Prototype

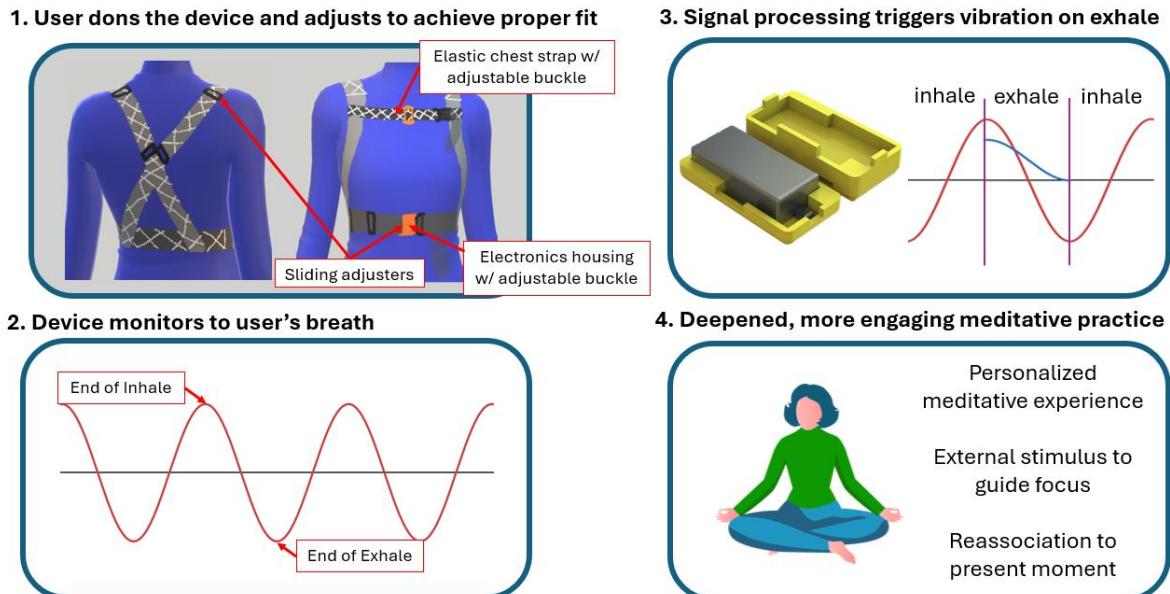


Figure 16: Representation of Final Solution

Risk Assessment, Safety, and Liability

To design a reliable system, potential failure modes and their effects were analyzed. Key concerns included inaccurate breath readings, mechanical and thermal stresses on internal electronics (tension on wires, overcurrent effects, etc.), and wear or fractures in the wearable device.

Mitigation strategies involved enhanced signal processing, industry-standard materials, and thorough physical testing for strength and durability. Human factors, such as comfort, overheating, weight distribution, and strap tension, were addressed through extensive user testing to ensure proper material selection and design functionality. A detailed analysis of failure modes and controls is provided in Tables A-5 through A-9. With regards to safety and liability, typical consumer electronics precautions apply including small parts as a potential hazard to children and being mindful of the connection to a live power source when product is opened or mishandled.

Societal, Environmental, & Sustainability Considerations

Understanding the societal implications of breathSense is crucial for fostering responsible design and usage practices. Potential benefits and challenges associated with the device are outlined.

Table 5: Goal and Scope Section Summary

Objective of Assessment	Design Function	Functional Unit	Lifecycle Stages Considered	Associated Activities
Assess the societal impacts of a mindfulness aid device.	Amplify awareness of the breath by providing synced vibration to a user's exhale.	A racerback vest containing a relative respiratory volume sensing module and vibrational output mechanism.	Use	Customer Use
				Device Maintenance
			End of Life	Recycling and Landfill

Table 6: Inventory Analysis Section Summary

Product Lifecycle Stage	Stakeholder Group	Social Impact Category	Impact Indicators
Use	Consumers	Health and Safety	Number of customer complaints
			Quality of labels and warnings
	Value-Chain Actors	Privacy	Country ranking on data regulations
		Respect of Intellectual Property (IP) Rights	Organization's policy and practice
		Promoting Social Responsibility	Industry code of conduct in the sector
			Membership in societal initiatives
End of Life	Consumers	End-of-Life Responsibility	Strength of national legislation on product disposal/recycling
	Society	Public Commitment to Sustainability Issues	Agreements on sustainability issues
			Presence of mechanisms to review realization of promises

Potential positive societal impacts of the breathSense device include enabling value-chain actors like clinicians to offer a noninvasive intervention to patients experiencing anxiety and/or PTSD-adjacent symptoms. Additionally, it provides consumers with a safe, compliant device to help them find moments of calm during their day to help them reassociate. Potential negative societal impacts are related to the product end-of-life stage. To minimize these negative impacts, it is

necessary to clearly inform consumers of safe disposal/recycling practices with regards to the device via usage of standard symbols and labels.

The team focused on the use and end-of-life stages of the breathSense device, recognizing the growing issue of electronic waste resulting from the rapid turnover of consumer electronics. Consumers, due to their role in product use, and value-chain actors (e.g., researchers and clinicians) due to their interest in the device's impact on patient quality of life, are key stakeholders. Society is also considered a stakeholder at the end-of-life stage, given the global concern over electronic waste. The selected social impact categories and indicators align with the interests of these stakeholders and the device's purpose.

Next Steps & Conclusion

The breathSense device successfully addresses the need for a reliable and user-friendly mindful breathing aid, as identified through sponsor and user feedback. Engineering analyses and user testing have demonstrated its effectiveness in accurately tracking respiratory patterns, providing timely feedback, and overcoming the limitations of the FaniLab's existing device, particularly in terms of accuracy, response time, ease of use, and comfort.

Next steps in prototype development include refining the vibration waveform to create a more natural vibration feel, as well as exploring alternative vibration puck designs (e.g., increasing the puck size to enhance vibration dispersion). Furthermore, with additional time, further testing of chest and belly breathing patterns could facilitate improved signal processing. The team plans to implement the custom vibration waveform and finalize the lab display output before transferring the project to the sponsor. Subsequently, the team will conduct a final visit to Emory to discuss next steps, including patent considerations and product development.

Team Contributions

The team collaborated across key project areas. All members contributed to the expo materials, final presentation/report, and prototype. Specifically, Audrey led deliverable and sponsor management, wrote up patent materials, greatly contributed to the final report and testing slides of the presentation. Pedro designed electronics housing, conducted all destructive testing and structural FEA analysis, conducted material selection study, manufactured all 3D printed components and final prototype assembly. Hanna contributed to the electrical fabrication of the prototype, conducted theoretical battery analysis, contributed to development and revision of the final presentation, and created the product poster for the expo. Jose designed the vibration puck, completed scaled BOM for 500 units, and developed user and device functionality test plans. Additionally, Jose and Audrey conducted user testing and FaniLab compatibility testing. Ethan designed and manufactured racerback form factor, wrote prototype code (including signal processing and vibrotactile feedback), and aided with final assembly. Ethan created the research poster and video for expo. Further description of each member's contribution is detailed in Table A-10.

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Appendix A – Figures & Tables

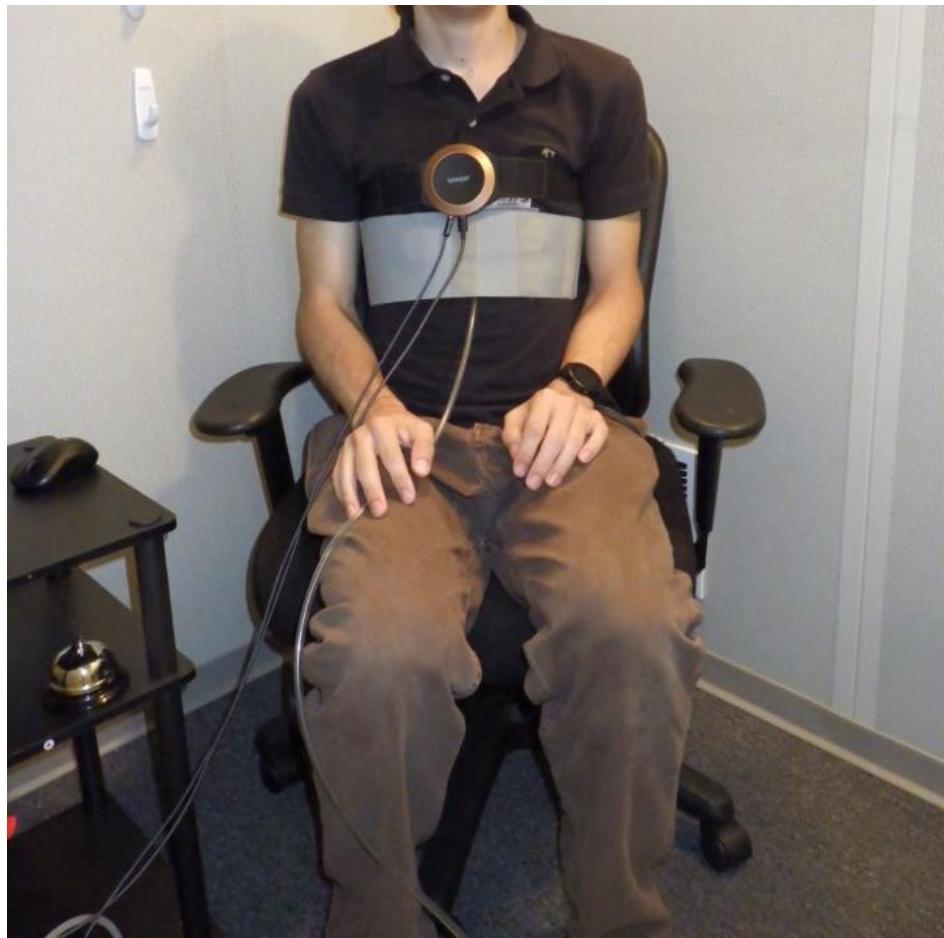


Figure A-1: Current Setup at FaniLabs

TABLE A-1: Gantt Chart

Items	G	SEP	OCT	NOV	DEC
<input checked="" type="checkbox"/> CF2-19 Follow-up with Allie with team contacts					
<input checked="" type="checkbox"/> CF2-20 Follow up with Allie and Dr.Fani					
<input checked="" type="checkbox"/> CF2-48 Ask Dr. Fani to collect some data to define s...					
<input checked="" type="checkbox"/> CF2-14 Respond do Dr. Smith					
<input checked="" type="checkbox"/> CF2-38 Function/Task Tree					
<input checked="" type="checkbox"/> CF2-40 Weekly Email					
<input checked="" type="checkbox"/> CF2-2 Set up planning doc					
<input checked="" type="checkbox"/> CF2-3 Distribute responsibilities					
<input checked="" type="checkbox"/> CF2-15 Project Objective and Criteria Table					
<input checked="" type="checkbox"/> CF2-34 Sensor Selection					
<input checked="" type="checkbox"/> CF2-35 Market Research Analysis					
<input checked="" type="checkbox"/> CF2-39 Components to purchase					
<input checked="" type="checkbox"/> CF2-21 Ideation Slides (No presentation)					
<input checked="" type="checkbox"/> CF2-46 Group Check in/Dr.Fani meeting					
<input checked="" type="checkbox"/> CF2-41 Purchasing Excel					
<input checked="" type="checkbox"/> CF2-22 Concept Selection - Presentation					
<input checked="" type="checkbox"/> CF2-6 Report #1 - Conceptual Design					
<input checked="" type="checkbox"/> CF2-43 Low level prototyping w/ Sensors					
<input checked="" type="checkbox"/> CF2-23 CAD/Analysis Update					
<input checked="" type="checkbox"/> CF2-24 60-sec video upload					
<input checked="" type="checkbox"/> CF2-25 CAD/Analysis Update 2					
<input checked="" type="checkbox"/> CF2-26 FMEA Worksheet					
<input checked="" type="checkbox"/> CF2-7 Report and Presentation #2					
<input checked="" type="checkbox"/> CF2-27 CAD/Analysis Update 3					
<input checked="" type="checkbox"/> CF2-28 Prototype Update Presentation					
<input checked="" type="checkbox"/> CF2-29 FAB PACKAGE (Presentation)					
<input checked="" type="checkbox"/> CF2-33 Expo					
<input checked="" type="checkbox"/> CF2-31 Final Presentation					
<input checked="" type="checkbox"/> CF2-30 Final Video Upload					
<input checked="" type="checkbox"/> CF2-32 Final Report					

TABLE A-2: Detailed Specification Sheet

Changes	Need/Want	Requirements	Source
Operation			
	Want	Can be used by one person w/out assistance	Dr. Fani
	Need	No training needed to operate	Dr. Fani
	Need	No external wired connection needed for response	Dr. Fani
	Need	Vibration delay < 250ms	Journal Research [17]
	Need	Sample rate target, 5ms	Prototype Testing
Forces			
4-Nov	Need	Weight target ~350-500g	Market Research
	Need	Vibration strength > 2 x 0.8Grms	Dr. Fani / Market Research
Energy			
4-Nov	Need	Minimum Battery Continuous Use Range > 180 mins	Market Research
	Want	Rechargeable, (USB-C)	Market Research
	Want	Charge time < 2hr	Market Research
4-Nov	Want	Battery size, 1200mAh	Engineering Analysis
	Want	Replaceable battery	Market Research
	Want	Serviceable Temperature > 60°C	Battery Temperature
Inputs/Outputs			
	Need	Receives Breath Signal	Dr. Fani
	Need	Delivers breath-synced vibrations	Dr. Fani
	Need	Control of vibration strength from 0 - 100% Grms	Dr. Fani
	Want	Control of vibration feel	Dr. Fani
	Need	Output breath amplitude waveform	Dr. Fani
	Need	Output vibration profile	Dr. Fani
	Want	Power on/off and monitoring	Dr. Fani
Ergonomics			
	Need	Force holding vibrator to sternum > 5 N	User Testing
	Need	Max separation between vibrator and chest, 0 mm	User Testing
	Need	Strap stretch for chest expansion > 9.5 cm	Journal Research [24]
	Want	No perceivable pinch points or rubbing	Market Research
	Need	Comfortable wearing duration > 30 mins	Dr. Fani
	Need	5th to 95th percentile anthropometrics	Dr. Fani
Quality Control			
	Need	Can be calibrated if necessary	Dr. Fani
	Need	>= 5 Year Lifespan in design conditions	Dr. Fani
Costs			
	Need	<\$150	Dr. Fani

BREATHING SENSOR MORPH CHART - DESIGN FOR CLINICAL RESEARCH

sensors	accelerometer	strain gauge	acoustic sensor	piezoresistive pressure sensor (normal force)	radio frequency
sensor form factor	strap adjustable strap sensor + vibration device	vest user's shirt sensing device	necklace pendant w/ sensor + vibration device	stone held at sternum by user stone w/ sensor and vibration device	at a distance / not on the body
packaging	1 self-enclosed design case w/ sensor, vibration device, motor, electronics		2 device design vibration device		
microcontroller	ESP	Raspberry Pi zero	Custom PCB		
power source	rechargeable battery		disposable battery		
power status	3 LEDs COLOR BAR GREEN YELLOW RED	WARNING LED GREEN for good RED for low	BATTERY TO DISPLAY 60 %		
sensor connectivity	ON LAPTOP - DISPLAY STATUS sensors connected	status on GUI for researchers to monitor	LED SHOWING CONNECTIVITY ON for connected OFF for disconnected		
vibration method	linear resonant actuators		Eccentric Rotating Mass Motor		

Figure A2: Clinical Research Breath Sensor for Mindfulness Practice - Morphological Chart

TABLE A-3: Initial Design Concepts

Initial Design Concept	Description
Accelerometer Integrated into Strap	Two accelerometers integrated into a strap worn by the user will be used to measure chest movement, a relative metric for respiration volume. The two-sensor system aims to minimize noise added to the signal due to change in body movement (i.e. tilting or slouching) that is not related to the breath.
Strain Gauge Embedded in Strap	The integrated strain gauge and strap device would work by measuring the change in chest expansion/contraction. As the user inhales, the chest expands and causes tensile deformation in the strain gauge strap. Similarly, as the user exhales, the chest contracts and the strain gauge undergoes compressive deformation. This mechanical deformation causes a change in resistance of the strain gauge, which can then be correlated to the respiratory volume.
Acoustic Sensor Pendant for a Necklace	The acoustic sensor will be worn as a necklace and rest at the user's sternum, the stethoscope-like device will allow for the inhale and exhale of the user to be measured, and a corresponding vibration will be delivered on the user's inhale.
Piezoresistive Pressure Sensor secured with Strap	The pressure sensor will be embedded into a strap worn around the user's chest and will measure the differences in pressure based on chest expansion which is a relative respiratory volume measurement. The sensing of the inspiration will then administer a vibrational output.
RF Illumination Sensor System	The two-device design includes the RF sensor on a table pointed towards the user to monitor frequency shifts related to the rise and fall of the chest during the breath cycle (a relative measure of respiratory volume) and the vibration device which will be held by the user against their sternum.

TABLE A-4: Breath Sensor for Mindfulness Practice – An Evaluation of Proposed Designs

Criteria associated with the sponsor's fundamental research needs were ranked with an importance level of 5, while sponsor wants were ranked 4, and customer-facing product criteria were ranked 3.

Criteria		Importance	Design 1: Accelerometer in Strap		Design 2: Strain Gauge Strap		Design 3: Pressure Sensor in Strap		Design 4: Acoustic Sensor Necklace		Design 5: RF Sensor with Stone		
			Rating	Weighted	Rating	Weighted	Rating	Weighted	Rating	Weighted	Rating	Weighted	
Form Factor	Delivers effective vibration response	5	4	20	4	20	4	20	4	20	4	20	
	Device rests at sternum	5	4	20	4	20	4	20	5	25	5	25	
	Reaches 5th to 95th anthropometrics of adult population	4	3	12	3	12	3	12	5	20	5	20	
	Comfortable to use when sitting, standing, or laying down	3	4	12	4	12	4	12	3	9	3	9	
	Small, compact size (able to hold in one hand)	3	3	9	3	9	3	9	4	12	1	3	
	Minimalistic/inconspicuous design	4	3	12	3	12	3	12	3	12	1	4	
	Capable of independent use	5	4	20	4	20	4	20	4	20	4	20	
Items	Operates without external connection	4	4	16	4	16	4	16	4	16	3	12	
	Limited set-up required	4	5	20	3	12	3	12	3	12	3	12	
	Accurately captures relative respiratory volume	5	4	20	4	20	3	15	2	10	5	25	
	High ease of use	4	4	16	4	16	4	16	3	12	2	8	
	Can be used with minimal noise	4	2	8	4	16	3	12	1	4	3	12	
	Provides breath waveform w/ minimal additional processing	5	3	15	3	15	4	20	3	15	3	15	
	Ease of maintenance	4	4	16	4	16	4	16	2	8	2	8	
Perfect score / Total			295		216		216		212		195		193
Relative Total					0.73220339		0.732203		0.718644		0.661017		0.6542373
Rank					1		1		3		4		5

TABLE A-5: FMEA of Electronics

Item / Function	Potential Failure Mode(s)	Potential Effect(s) of Failure	S e v	Potential Cause(s)/ Mechanism(s) of Failure	P r o b	Current Design Controls	D e t	R P N	Recommended Action(s)	Expected Action Results			
										New Sev	New Occ	New Det	New RPN
Vibration source	Vibration overload	Fatigue to system	7	Insufficient vibrational output control	2	Control power to the vibrational output and have tested what max output feels like	3	42	None	7	2	3	42
	Insufficient vibrational output	User unable to detect vibration, decreasing intended function	4	Limited resonant frequency from selected vibration source	2	User feedback	3	24	Amplify vibrational output by stacking two ERMs or by reducing the resistance prior to the input	4	1	1	4
			4	Resonant frequency muffled by packaging	5	User feedback	3	60	Amplify vibrational output by stacking two ERMs, reducing the resistance, decreasing housing thickness, or improving ERM mounting	4	2	3	24
Battery	Battery degradation	Slow system response	4	Poor life span	4	Use of industry standard Li-ion battery with sufficient battery life	2	32	Easy battery replacement or minimize power requirement	4	2	2	16
			3	Overheating	3		4	48	Heatsink and/or fan if needed	5	2	4	40
		No function of system	8	Poor life span	4		2	64	Easy battery replacement or minimize power requirement	8	2	2	32
			3	Overheating	3		4	96	Heatsink and/or fan if needed	8	2	4	64
	Broken charging port	Contaminants	2	None	2	Implementing charging extender to reduce stress to actual board. Designing so that port is at bottom of device, to minimize potential interference/stress	4	64	Additional secure containment of battery	8	2	3	48
			5	Fatigue / stress	5		5	200	Design for durability and test system when excessive stress is applied. Consider difficulty to replace	8	4	5	160
		Inaccurate readings of breath	6	Noise interference	6		3	126	Additional filtering can be added if needed	7	6	2	84
			4	Fatigue / temperature sensitivity	4		4	112	If needed, can add "dummy gauge" to account for temperature effects	7	4	3	84
Strain gauge	Inaccurate readings of breath	Ineffective function of system	6	False breath	6	Signal Processing	5	210	Additional filtering can be added if needed	7	5	4	140
			6	Insufficient deformation to strain gauge	6	None	3	126	Increase sensitivity of spec'd strain gauge	7	6	1	42

TABLE A-5: FMEA of Electronics continued

Item / Function	Potential Failure Mode(s)	Potential Effect(s) of Failure	S e v	Potential Cause(s)/ Mechanism(s) of Failure	P r o b	Current Design Controls	D e t	R P N	Recommended Action(s)	Expected Action Results			
										New Sev	New Occ	New Det	New RPN
Electronic system	Thermal overload	Damage to electronics * ineffective system	8	Poor thermal regulation/cooling	6	The minimal protection included in the selected off the shelf modules	6	288	Add heat sinks / ventilation	8	5	3	120
				Excessive voltage supply, current, etc.	4	Protection included in the selected off the shelf modules	5	160	Add circuit protection around vulnerable electronics	8	2	2	32
		Damage to housing unit	5	Poor thermal regulation/cooling	3	None	9	135	Add heat sinks / ventilation	5	4	3	60
		Potential cause of harm to user	10	Poor thermal regulation/cooling	3	None	9	270	Add heat sinks / ventilation	10	5	5	250
				Excessive voltage supply, current, etc.	4	Use of off the shelf power modules with built in protections	6	240	Resistor networks and circuit protections will minimize threat	10	1	6	60
Electronic system + Wiring	Loose wiring / stress to wiring	Damage to entire system and decrease in function / no function	8	User exerts unexpected tensile forces on wearable system	6	Design for durable system, ensure that wiring is only present in non-moving components and protected with a sleeve	5	240	Additional cable management and length added to prevent strain. Use of proper/robust connectors.	8	5	4	160

TABLE A-6: FMEA of Form Factor

Item / Function	Potential Failure Mode(s)	Potential Effect(s) of Failure	S e v	Potential Cause(s)/ Mechanism(s) of Failure	P r o b	Current Design Controls	D e t	R P N	Recommended Action(s)	Expected Action Results			
										New Sev	New Occ	New Det	New RPN
Wearable device material	Wear of material	Loose fit to user * decrease of function in intended use	5	Material degradation due to normal or unintended use (ex: user clips on keys)	4	Use of industry standard wearable elastic/materials (i.e., sports performance)	3	60	Continue exploration of alternative materials (nylon, elastic, polyester)	5	3	2	30
		Complete failure * user unable to wear	7	Material degradation due to normal or unintended use (ex: user clips on keys)	3	Use of industry standard wearable elastic/materials (i.e., sports performance)	3	63		7	3	2	42
Attachment mechanism of electronics housing unit and wearable system	Wear of attachment mechanism from housing unit to strap	Loose fit to user * decrease of function in intended use	5	Material degradation due to use	3	Use of high heat PLA or SAN for prototyping. Testing durability with general wear.	5	75	Test various materials with pull force and compression to determine limitations of materials at worst case.	5	2	2	20
		Complete failure * user unable to wear	7	Material degradation due to use	2	Use of high heat PLA or SAN for prototyping. Testing durability with general wear.	6	84		7	2	2	28
Attachment mechanism of wearable device (don/doff mechanism)	Attachment mechanism failure	User unable to wear and utilize device	7	Material failure due to use	3	Use of industry standard buckles/clips/hooks.	2	42	Test various attachment mechanisms to determine one most optimal for desired function (durability, ease of use, etc.)	7	2	2	28
Electronics housing unit	Broken housing for electronics	Minor break - decrease in function	7	Material failure + excessive vibration	3	Use of high heat PLA or SAN for prototyping. Testing durability with general use.	4	84	Test various materials with pull force and compression to determine limitations of materials at worst case.	7	2	3	42
		Major break - internal system exposed	8	Material failure	3	Use of high heat PLA or SAN for prototyping. Testing durability with general use.	4	96		8	2	3	48

TABLE A-6: FMEA of Form Factor continued

Item / Function	Potential Failure Mode(s)	Potential Effect(s) of Failure	S e v	Potential Cause(s)/ Mechanism(s) of Failure	P r o b	Current Design Controls	D e t	R P N	Recommended Action(s)	Expected Action Results			
										New Sev	New Occ	New Det	New RPN
All wearable form factors (running vest, backpack, racerback)	User overheating	Decreased user comfort	4	Poor thermal regulation in material selection	3	Use of industry standard wearable materials (i.e., sports performance).	4	48	Conduct user testing with just vest and fully integrated system including electronics to determine comfortability	4	3	4	48
	User comfortability related to weight/bulk of device	Decreased user comfort and appeal of design	4	Added weight / position of electronics in front may weigh down front of vest	2	Design is intended to disperse weight of components throughout wearable device	2	16		4	2	2	16
	Strap discomfort	Localized pressure points, decreasing comfort	4	Too small of strap width or strap material	3	Prototype uses 1-2 inch wide straps	2	24	Test various strap widths amongst various users to determine comfortability	4	2	2	16
		Skin abrasion	4	Material irritation to skin if worn under clothes	4	Use of industry standard clothing materials	7	112	Test wear and comfortability of various materials across different users	4	3	3	36
	Strap tension and increased pressure on user shoulders	Pressure points and decreased comfort	4	Too tight of straps / tension held	3	Use of industry standard elastic material and incorporating ability to adjust	2	24	Review further material options for increased durability and lifetime	4	2	2	16
		Increased tension leads to wear of straps and loosens over time	4	Too tight of straps / tension held	3		2	24		4	2	2	16
	Hard to access detachment mechanism, could lead to user discomfort in unclasp behind the back by awkward arm rotation	Could lead to user discomfort in unclasping behind the back by awkward arm rotation	2	Design for wide user range, means the adjustment mechanism, can move a lot depending on the user	10	Placement on shoulder area, should overcome this.	1	20	Conduct fitment tests with 5th-F and 95th-M users for feedback	2	6	1	12
	Wearable device gets caught on an object	Potential risk of injury to neck, shoulder, or torso area	10	Especifically if worn over clothes, the fabric could get caught in a protruding object, like a doorhandle	1	Make adjustments so that there are no loose straps which may get caught. Components are meant to fit tightly.	1	10	Review as-built prototype for potential risk areas	10	1	1	10
	Twisting and misalignment of wearable device donning/doffing	Discomfort or possible choking	10	User incorrectly dons/doffs device	1	Intuitive design for easy don/doff	4	40	Test ease of use (don/doff) with range of users	10	1	2	20

TABLE A-7: FMEA Severity Ratings

Effect	SEVERITY of Effect	Ranking
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe system operation without warning	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe system operation with warning	9
Very High	System inoperable with destructive failure without compromising safety	8
High	System inoperable with equipment damage	7
Moderate	System inoperable with minor damage	6
Low	System inoperable without damage	5
Very Low	System operable with significant degradation of performance	4
Minor	System operable with some degradation of performance	3
Very Minor	System operable with minimal interference	2
None	No effect	1

TABLE A-8: FMEA Occurrence Ratings

PROBABILITY of Failure	Failure Prob	Ranking
Very High: Failure is almost inevitable	>1 in 2	10
	1 in 3	9
High: Repeated failures	1 in 8	8
	1 in 20	7
Moderate: Occasional failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively few failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure is unlikely	<1 in 1,500,000	1

TABLE A-9: FMEA Detection Ratings

Detection	Likelihood of DETECTION by Design Control	Ranking
Absolute Uncertainty	Design control cannot detect potential cause/mechanism and subsequent failure mode	10
Very Remote	Very remote chance the design control will detect potential cause/mechanism and subsequent failure mode	9
Remote	Remote chance the design control will detect potential cause/mechanism and subsequent failure mode	8
Very Low	Very low chance the design control will detect potential cause/mechanism and subsequent failure mode	7
Low	Low chance the design control will detect potential cause/mechanism and subsequent failure mode	6
Moderate	Moderate chance the design control will detect potential cause/mechanism and subsequent failure mode	5
Moderately High	Moderately High chance the design control will detect potential cause/mechanism and subsequent failure mode	4
High	High chance the design control will detect potential cause/mechanism and subsequent failure mode	3
Very High	Very high chance the design control will detect potential cause/mechanism and subsequent failure mode	2
Almost Certain	Design control will detect potential cause/mechanism and subsequent failure mode	1

TABLE A-10: Team Member Contributions

Team Member	Contributions
Audrey Ball	Report: Rewrote complete report (all previous sections) to update to final report, wrote new sections including Design Iteration, Feasibility Assessment, Final Solution, and Next Steps & Conclusions. Other: Supported test plan development (of thermals and user testing) and conducted user testing and lab compatibility. Contributed to user testing content of Expo Poster, outlined and contributed new slides (testing, next steps) to presentation. Managed team deliverables for class, expo, and sponsor contact. Created patenting materials for Emory.
Pedro Luiz Balabuch Dal Bo	Designed electronics housing, conducted all destructive testing and structural FEA analysis, conducted material selection study, manufactured all 3D printed components and final prototype assembly. Also wrote FEA analysis of Feasibility Assessment section and contributed to report, presentation, poster, and expo video content.
Hanna Khor	Worked on soldering and purchasing for fabrication of 2 additional units. Completed theoretical battery analysis and supported BOM finalization/thermal analysis power consumption. Summarized team's progress in weekly emails, edited report and product diagrams, pulled together electronics and final solution content for final presentation, expo poster, and product poster.
Jose Rodriguez	Outlined user testing plan and new testing methods to determine delay and eliminate confounding variables. Performed 9/10 30min user tests and lab setting testing at Emory. Updated LRA housing design to improve tolerancing and allow for internal dampening in order to smooth out feel. Updated report sections. Completed BOM for 500-unit scale.
Ethan Stone	Designed form factor straps and adjustment range, and manufactured racerback form factor for prototypes. Aided in assembly of electronics package. Wrote code for device operation including signal processing and haptic feedback. Created final poster from content made by the group and created expo video. Created final prototype photography and visuals. Contributed content to report and presentation.
Shreya Terala	Set up thermal testing plan and ran associated thermal simulations. Continued working on lab software development to ensure real-time monitoring and storing of data collected during trials. Helped with updating previous report sections and contributed to presentation.

Appendix B – Preliminary Surveys

B.1 FaniLab User Feedback

1. Gender?
 - a. Male
 - b. Female
 - c. Prefer not to say
2. What issues, if any, do you have with the current placement of the vibration device (woojer)?
 - a. Does not rest at sternum
 - b. Not flush with chest
 - c. Uncomfortable
 - d. No issues
3. Are you comfortable with the level of vibration felt?
 - a. Yes
 - b. No, I would like it increased
 - c. No I would like it decreased
4. On a scale of 1 to 5, how comfortable is the pressure sensor strap (the wide band worn around the torso)?
 - a. 1 – extremely uncomfortable
 - b. 5 – extremely comfortable (i.e., could sleep with this on)
5. If you could use a more refined version of the existing device in the home, how many times a day would you use it?
 - a. 0
 - b. 1-2
 - c. 3+
6. If you could use a more refined version of the existing device in the home, how many days a week would you use it?
 - a. 0
 - b. 1-2
 - c. 3-4
 - d. 5-7
7. In what situations would you see yourself using the device most often in?
 - a. For general meditation (daily use, sleep, etc.)
 - b. To reconnect to the present
 - c. To reduce anxiety/stress
 - d. Other (write in)
8. Any other comments you would like to share about the current device setup or what you would like to see in a future design iteration.
 - a. Free response

Appendix C – Design of Experiments

C.1 Material Selection Analysis

An investigation into material selection was conducted, setting up a trade-off (Eq. 1) between mass (Eq. 2) and thickness (Eq. 3). A cost function was developed, with reference to the most widely available material and manufacturing method available to the team: Low Modulus PLA. Zone I in Figure 7 is where we want to select, where the material would be lighter and thinner per volume than the PLA.

$$Z = \frac{m}{m_0} + \alpha \cdot \frac{t}{t_0} \quad Eq. 1$$

Where:

$$\frac{m}{m_0} = \left(\frac{\rho}{E^3} \right) \cdot \left(\frac{E_0^3}{\rho_0} \right) \quad Eq. 2$$

$$\frac{t}{t_0} = \frac{E_0}{E} \quad Eq. 3$$

4

m = mass, m_0 = PLA mass, t = thickness, t_0 = PLA thickness, ρ = density,

ρ_0 = PLA density, E = Modulus of Elasticity, E_0 = PLA Modulus of Elasticity

The Greek symbol α in Eq. 1 indicates the penalty variable, represented by the black line in the image. Where a higher value of α means thickness matters more, and a value below 1 indicates that mass matters more; for this instance, $\alpha = 1$. The values highlighted in blue indicate the materials which passed the criteria of minimum service temperature $> 60^\circ\text{C}$ and excellent properties for polymer extrusion manufacturing (3D printing).

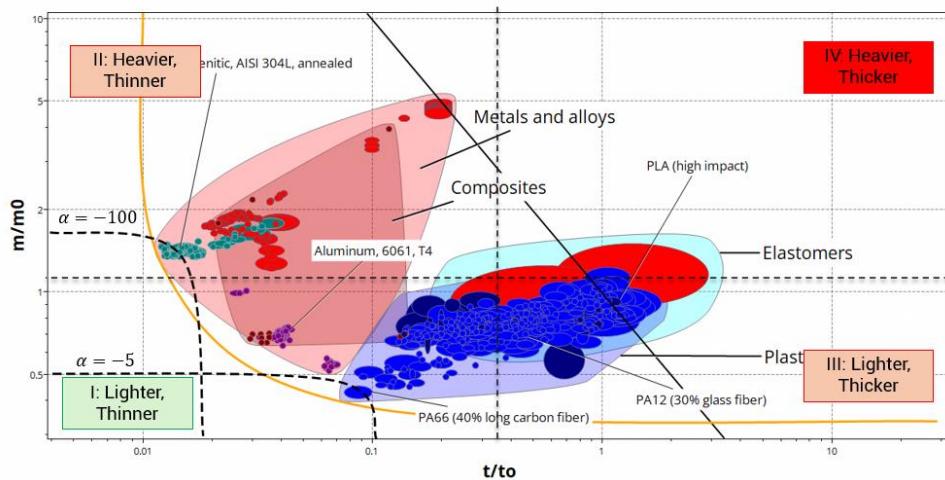


Figure C-1: Material Selection

Note that some of the materials closest to the trade-off curve are PA66 with $\alpha = -5.41$, and 304L Stainless Steel at $\alpha = -100$. For this trade-off curve a large magnitude alpha means we care more about making it thin at the cost of weight, and a small one means we care more about making it light at the cost of thickness.

Of these, the ones easiest to scale with the design to a high-volume manufacturing would likely be the plastics (due to injection molding compatibility). For a part with general small details designed for 3D printing at its initial phases, the most compatible process to scale would be injection molding. Thus, we can further explore the plastics, of which PA66 is a common injection molding material which shows excellent promise.

C.2 Destructive Testing

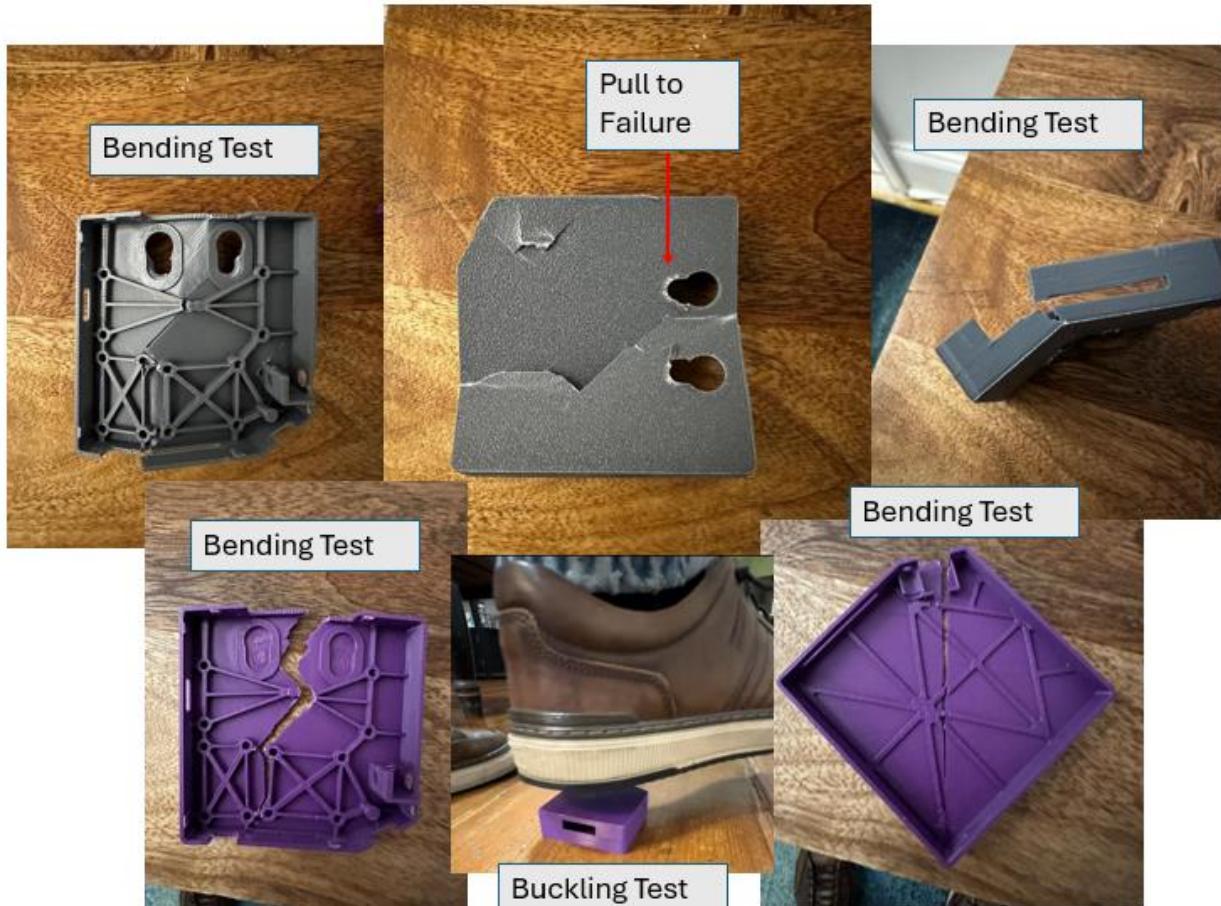


Figure C-2: Results of destructive testing

Table C-1: Results of destructive testing

Test	Max Load Applied	Failure Mode
Bending Test	50lbf	Fracture
Pull To Failure	32lbf	Local Yielding
Buckling Test	180lbf	None

All failed regions shown in Figure C-2 were reinforced or re-designed to eliminate the failure mode. Further testing must be done to update the max load rating as reported in Table C-1. However, it is of note that the pre-reinforced load rating was already exceeding specifications.

C.3 Thermal Analysis

(1) Operating Thermal & Safety Analysis – Evaluate how the heat is distributed and transferred throughout the electronic housing unit when the system operates under normal and worst-case conditions. Additionally, test device's capabilities of effective thermal management to ensure the device does not exceed safe temperature limits.

- Dependent variables: Internal temperature distribution, surface temperature
- Independent variables: Housing unit material (thermal conductivity), housing unit geometry and (layout and any present heat sinks)
- Control variables: Ambient temperature, constant watt loss of electronics, operating time
- Confounding variables: Modeling assumptions (may not capture complete real-world discrepancies), transient effects, modeled vs real-world material properties and manufacturing variabilities, inaccurate heat generation rates (constant generation vs fluctuation), simulation resolution
- Method: Utilize ANSYS or SolidWorks thermal analysis to model temperature effects of existing designs of electronics and effects onto housing unit. Thermal simulation (ANSYS) will be utilized to understand whether additional thermal management is required for the electronics. Testing will be conducted in worst-case operating conditions to check the safety of the design in these conditions.
 - Part 1 - Utilize ANSYS or SolidWorks thermal analysis to model thermal behavior of design and optimize thermal management through implementation of heat sinks / ventilation if necessary.
 - Part 2 - Test device to ensure temperatures do not exceed the safe temperature threshold of 43C [21].

C.4 User Testing

Experiment 1 – Quantify don time to understand intuitiveness and ease of use of design

- Dependent variable: Don time of device.
- Independent variables: User demographic.
- Confounding: External environment, user clothing.
- Control: Same testing environment (in home/lab), device form-factor, and packaging.
- **Method:** Time user how long it takes for them to don the device on and adjust sufficiently.
- **Results:** On average, it took users to don the device for the first time approximately 1 minute.

Experiment 2 – Quantify device detection of exhale and delay of vibration response to user’s actual exhalation.

- Dependent variable: Delay between exhalation start/end detection and vibration response start/end.
- Independent variables: User demographic and breath pattern.
- Confounding: External environment (external unknown airflow source), user clothing.
- Control: Assist users in donning and adjusting device to proper fit as in clinical setting, same vibration order for all users, same testing environment (in home/lab), device form-factor and packaging.
- **Method:** Compare start and end of user’s exhale to device’s recognition and response indicated via LED. The user’s exhale is captured through an airflow reference, specifically a flame is held near the user’s nose such that the change in the flame is captured during inhalation and exhalation. The flame and device LED must be captured in the same frame of a slow-motion camera. Using this, the delay between the two can be determined using the time scale on the video. Additional user interview questions concerning synchronization were asked (as presented in “User Interview”).

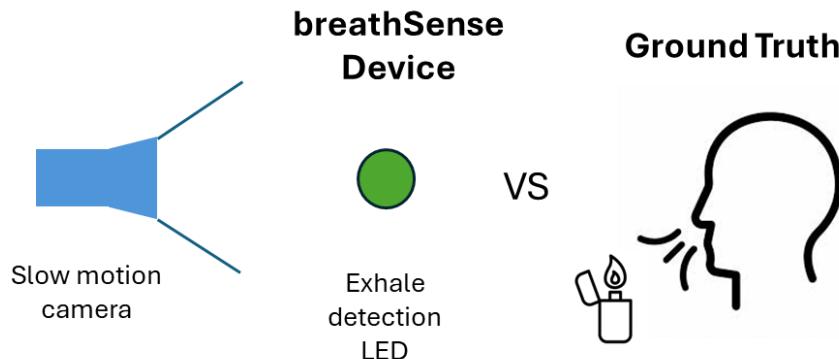


Figure C-3: Test Setup for Detection vs Delay Testing

- **Results:** The average delay between the users’ true breath phase change and the response of the device ranged from 150-350ms, approximately reaching the target delay of 250ms which corresponds to the average human reaction time. Additionally, the users rated the device’s synchronization performance on average as 7.3/10 (10 being completely in sync). This value is rated lower due to 2 outliers present in female population; these outliers are hypothesized to be due to poor device fitting / oversized clothing.

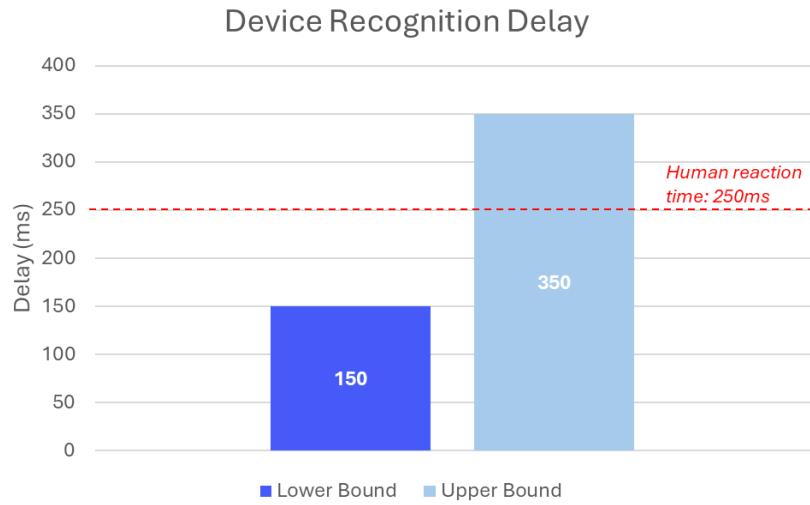


Figure C-4: Detection & Delay vs Avg. Human Reaction Time

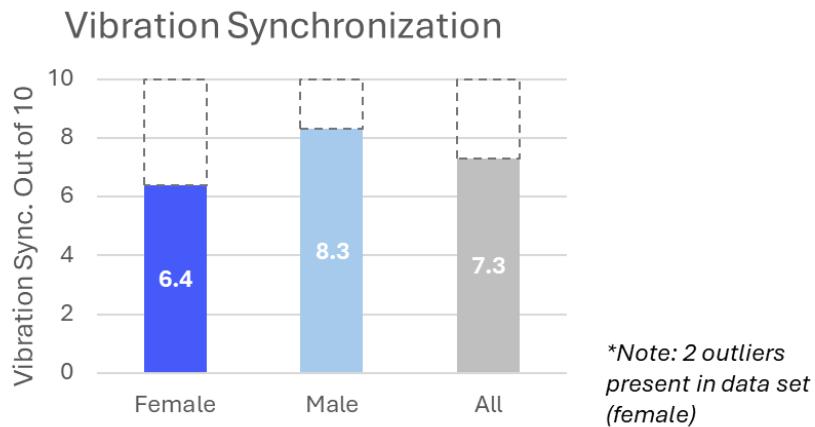


Figure C-5: User Synchronization

Experiment 3 – Test the comfort and usability of the device

- Dependent variable: User's level of comfort, synchronization, and overall experience / performance of device.
- Independent variable: User demographic and breath pattern.
- Confounding variables: External environment, user clothing.
- **Method:** Asked users a series of questions, presented in “User Interview” throughout study.

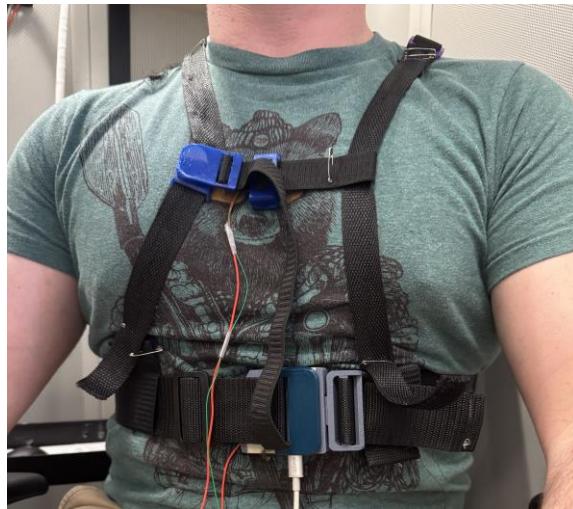


Figure C-6: Test Setup for Comfort & Usability Testing

- **Results:** Users rated the device's comfort 8.4/10 (10 being able to sleep with the device on) at initially donning and after 30 minutes of use. User testing revealed ways in which the device could be improved including a smoother, lighter, and quieter vibration and wire/strap management.

Experiment 4 – Test compatibility of device in FaniLab set up

- Dependent variable: Device performance.
- Independent variable: User demographic and breath pattern.
- Confounding variables: User clothing.
- **Method:** Have FaniLab participants don/doff and use the device in the lab setting. Demonstrate setup required to utilize the device within the lab setting (breath waveform output display and controls).
- **Results:** No expected issues occurred. Recommendations from FaniLab members included expanding the mid-section size range to better accommodate the FaniLab's subject population, increasing the vibration puck size to achieve more dispersed haptic feedback, and integrating a data collection warning into the lab interface. Additionally, these tests highlighted the need to explore special cases of chest versus belly breathing for improved adaptability. While panic breathing was noted during testing, it was deemed outside the project scope as the device is not intended for applications related to panic breathing.

User Interview – A series of questions are asked with each experiment to gain user feedback during/after the quantitative tests:

- At initial donning, how comfortable is the device? (Scale 1 to 10)
 - 1 – Extremely uncomfortable
 - 10 – Extremely comfortable (i.e., could sleep with this on)

- After 30 minutes of use, how comfortable is the device? (Scale 1 to 10)
 - 1 – Extremely uncomfortable
 - 10 – Extremely comfortable (i.e., could sleep with this on)
- Are you comfortable with the level of vibration felt?
 - Yes
 - No, I would like it increased
 - No, I would like it decreased
- How in sync is the vibration? (Scale 1 to 10)
 - 1 – Completely out of sync
 - 10 – Completely in sync (no difference felt)
- Additional comments on the vibration
- If you could use a more refined version of the existing device in the home, how many times a day would you use it?
- If you could use a more refined version of the existing device in the home, how many days a week would you use it?
- In what situations would you see yourself using the device most often in?
- If you could use a more refined version of the existing device in the home, how many times a day would you use it?
 - 0
 - 1-2
 - 3+
- If you could use a more refined version of the existing device in the home, how many days a week would you use it?
 - 0
 - 1-2
 - 3-4
 - 5-7
- In what situations would you see yourself using the device most often in?
 - For general meditation (daily use, sleep, etc.)
 - To reconnect to the present
 - To reduce anxiety/stress
 - Other (write in)
- Any other comments you would like to share about the current device setup or what you would like to see in a future design iteration.