AI-Driven Wearable Stress Detection System

BME Senior Design Team 09

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NOTE: After communicating with Dr. Tritt, he has allowed us to submit multiple submissions. This submission is a preliminary submission. There will be a second submission that is our polished version. We request that the second submission is the graded submission. Dr. Tritt has agreed to allow this.

Secondly, we have decided to break down our approach into 2 components: software and hardware. The software handles data cleaning, feature engineering, and stress classification, while the hardware provides the sensors, microcontroller, and power system needed to collect and transmit physiological data.

1. Revision History

Revision History			
Document Revision	Date	Description	Author
0.1			

Please do not remove this section and use it to track document revisions and history.

2. Project Statement

Children with neurodevelopmental conditions such as autism, ADHD, and anxiety often experience emotional and behavioral dysregulation that can interfere with their learning. These children may struggle to recognize rising stress levels which can lead to restlessness, hyperactivity, and emotional outbursts that disrupt classroom activities and place additional demands on teachers. Existing interventions are typically reactive and rely on teacher observation or therapeutic support after dysregulation has already occurred which limits their effectiveness.

The goal of this project is to design a proactive support system that helps children detect and manage stress before it escalates. The proposed solution is a wearable device that continuously monitors physiological and movement-based signals to predict rising stress levels in real time. A machine-learning model analyzes these signals to detect deviations from the user's baseline that corresponds to stress. Then the device can deliver personalized coping strategies when stress is identified. By combining physiological sensing, intelligent classification, and tailored feedback, the system aims to assist children in self-regulation which will reduce classroom disruptions and support teachers in maintaining an effective learning environment.

3. Introduction

Many children with neurodevelopmental conditions struggle to manage stress in classroom settings. When stress levels rise, children may become restless, have difficulty focusing, or experience emotional outbursts that interrupt learning for themselves and others. Teachers often step in only after dysregulation is already visible, making it difficult to prevent escalation and maintain a productive classroom environment.

Because current approaches are largely reactive, there is a clear need for a proactive way to identify early signs of stress. Detecting these changes before they lead to disruptive behavior would provide critical support to both students and teachers and help create a more stable and inclusive learning environment.

4. History and Context

4.1 Market Research

Market Overview & Trends:

The market for pediatric heath monitoring is growing rapidly. This is fueled by increased awareness for mental health and demand for non-invasive interventions/monitoring solutions.

Child Health Wearables Market: Valued at $2.1 billion in 2023 and projected to reach $7.5 billion by 2032, growing at a CAGR (compound annual growth rate) of 15.2% [1].

Wearable Medical Devices Market: Valued at $42.74 billion in 2024 and projected to reach $168.29 billion by 2030, growing at a CAGR of 25.53% [2].

Stress Tracking Device Market: Valued at $3.2 billion in 2024 and projected to reach $8.7 billion by 2034, growing at a CAGR of 10.5% [3].

Pediatric Medical Devices Market: Valued at $34.9 billion in 2024 and projected to reach $70.3 billion by 2033, growing at a CAGR of 8.1% [4].

Target Market:

Total Addressable Market (TAM): Based on CDC prevalence data, the target demographic in the U.S. includes approximately 4–6 million adolescents:

- ADHD: ~9.8% of children (approx. 6.0 million total) [5].
- Anxiety: ~7.1% of children (approx. 4.4 million total) [6].
- Autism Spectrum Disorder (ASD): ~2.8% of children (1 in 36) [7].

Table 1: Stakeholder Analysis

User Group	*Needs & Value Proposition*
Primary Users (Teens 13-18)	Discretion & Self-Regulation. They require a device that is comfortable, simple, and avoids a stigmatizing "medical" aesthetic.
Parents & Caregivers	Insight & Objective Data. They seek tools to understand their child's emotional state to aid regulation outside of therapy.
Schools & Educators	Classroom Management. With ~130,000 K-12 schools in the U.S., educators seek tools to reduce challenges providing care to children with dysregulation issues.
Clinicians	Therapists value supplementary data on physiological states in "natural" environments to help refine treatment plans.

Primary Market Validation:

To validate the specific needs of the educational sector, our team conducted primary research within the Chicago metropolitan area.

- **Methodology:** Survey distributed to teachers, therapists, social workers, and other professionals in school districts around the Chicagoland area. We received over 100 responses outlining critical issues faced in classroom settings.
- **Key Findings:**
    - **The Intervention Gap:** Only **33.9%** of professionals can intervene before a full outburst, validating the need for our device's early detection capabilities.
    - **Validated Strategies:** The device mimics preferred coping mechanisms (sensory tools and breaks) to manage high-frequency behaviors like excessive movement.
    - **Educator Relief:** By automating monitoring, the device reduces the burden on staff managing multiple students with complex needs.

4.2 Existing Technology and Competitive Products

While high-end consumer wearables and medical devices exist, a gap remains for a mid-range, pediatric-focused solution for stress regulation.

Table 2: Competitive Products

Competitor	Target Market	Key Technology	Price Point	Gap Analysis (Our Advantage)
Empatica EmbracePlus	Clinical Research	PPG, EDA, Accelerometer, Gyroscope	**$1,499+**	Empatica is the clinical gold standard but is cost-prohibitive for average families. Our device offers similar sensor utility at a consumer price.
Oura Ring	General Wellness	PPG, NTC, Accelerometer	**$299 - $549**	Excellent form factor, but focuses on sleep/recovery rather than real-time stress intervention or pediatric use.
WHOOP	Athletes/Fitness	PPG, Accelerometer	**Subscription ($239/yr)**	Optimized for physical strain and athletic recovery, not emotional regulation or mental health monitoring.
Apollo Neuro	Stress Management	Vibration (Tactile)	**$300 - $350**	Focuses on active intervention (haptics) rather than monitoring/detection. It is a biofeedback tool, not a detection tool.

4.3 Global, Social, Ethical, Environmental, and Economic Factors

4.3.1 Global Factors

Stress-related behavioral dysregulation affects adolescents worldwide and impacts learning environments, mental health, and caregiver burden across cultures. Because the final system is software-based, it can be deployed across a variety of wearable platforms without requiring specialized hardware. This improves global accessibility, allowing the software to scale in both resource-rich and resource-limited environments as long as a compatible wearable device exists. The software-centric design reduces barriers to adoption since institutions do not need to purchase proprietary hardware, only devices capable of providing the required physiological signals.

4.3.2 Social Factors

The software is designed to support adolescents experiencing stress or hyperarousal by providing early detection and subtle feedback mechanisms that promote self-regulation.

Social acceptance is improved because the system relies on common consumer wearables or open-source devices rather than medical-looking sensors. By keeping feedback discreet and non-disruptive, the system preserves student dignity and reduces stigma. Additionally, teachers and caregivers gain access to supportive, non-punitive behavioral insights that can improve classroom dynamics and reduce escalation events. Social benefit is derived not from the hardware form factor, but from the interpretability, reliability, and responsible use of the data the software analyzes.

4.3.3 Ethical Factors

Ethical emphasis is placed on proper handling of physiological data from minors. All data acquisition and storage must comply with HIPAA and FERPA when used in school settings. Encryption, access control, and minimal data retention are required to protect user privacy. Because machine-learning models may exhibit bias due to skin tone, motion patterns, and physiological variability, the system must be trained and validated using diverse datasets to ensure equitable performance. The software should provide supportive insights rather than deterministic or punitive classifications to avoid unintended psychological or disciplinary consequences.

The software must clearly communicate uncertainty and avoid overconfident predictions. Caregivers must understand that the system is a decision-support tool—not a diagnostic device—and should not replace clinical judgment. These ethical considerations are central to the development and deployment of behavioral-intervention software.

4.3.4 Environmental Factors

Environmental impacts of this project are significantly reduced due to its software-focused nature. No new hardware is manufactured as part of the final product; instead, the system is intended to operate on existing wearable devices. This minimizes material consumption, reduces electronic waste, and avoids the need for large-scale physical production. The only hardware used throughout development is an open-source prototyping device, which functions as a temporary test platform rather than a deployable component. As a result, environmental footprint is limited primarily to energy usage for computation and data processing.

4.3.5 Economic Factors

The software-based approach offers substantial economic advantages. Because the system can operate on widely available wearables, there is no need for institutions to purchase specialized hardware. This lowers costs for schools, clinics, and families. The software provides a low-cost supplement to traditional behavioral interventions by offering early detection of stress escalation, potentially reducing the need for intensive staffing or crisis response procedures.

Development costs are reduced by leveraging open-source tools and existing physiological sensors. Long-term economic sustainability improves because updates, model improvements, and new features can be delivered through software updates rather than hardware replacement cycles. For users and educational organizations, this results in a cost-effective behavioral support tool with minimal ongoing expenses.

5. User Requirements

Table 3: User Requirements

UR	Description	Linked PDS
UR1	The device must provide immediate feedback to the user upon detection of target behaviors.	PDS1, PDS13
UR2	The device must monitor physiological signals (PPG, EDA, IMU) continuously in real time.	PDS2, PDS14
UR3	The device must be lightweight and biocompatible for continuous daily wear.	PDS3
UR4	The system must detect indicators of rising stress or hyperactivity prior to a full behavioral outburst.	PDS4, PDS12, PDS13
UR5	The feedback mechanism must be discreet (non-auditory) to avoid disrupting the classroom environment.	PDS5
UR6	The system must encrypt data during storage and transmission to ensure user privacy.	PDS6
UR7	The device must be water and sweat-resistant to withstand daily use by active adolescents.	PDS7
UR8	The hardware must be impact-resistant to withstand drops and physical handling typical of the school environment.	PDS8
UR9	The device battery life must exceed the duration of a standard school day (≥8 hours).	PDS9, PDS16
UR10	The user interface (dashboard/app) must be intuitive and allow for easy visualization of historical data.	PDS10, PDS15
UR11	The physical design must be subtle and resemble a standard consumer smartwatch to avoid stigmatization.	PDS11
UR12	The algorithm must be robust against motion artifacts to minimize false positives during normal activity.	PDS12, PDS14

6. Use Case Scenario

Picture a child with autism in a busy classroom, surrounded by loud noises and bright lights. Their heart rate increases, breathing becomes more rapid, and anxiety sets in. They are getting restless, fidgety, overwhelmed, and are on the verge of an outburst. Before the situation escalates, our device picks up these stress signals through machine learning algorithms.

Instead of disrupting the class or overwhelming the student with verbal instructions, the device discreetly activates a programmable LED display. The student recognizes this specific color-coded signal (e.g., a pulsing blue light, or stick figure walking) as their personalized cue to initiate a pre-planned coping strategy, such as stepping into the hallway for a walk.

7. Project Design Specifications

Table 4: Product Desgin Specifications

PDS	CTQ	Product Design Specification Description
PDS1	**Critical**	The device shall provide immediate and interpretable feedback (LED or optional caregiver notification) upon detection of stress or hyperactivity. (UR1)
PDS2	**Critical**	The device shall collect PPG (≥25 Hz), EDA (≥10 Hz), temperature, and IMU (≥25 Hz) data continuously to support real-time stress classification. (UR2)
PDS3	Moderate	Device mass shall be <50 g, thickness <12 mm, and all skin-contact materials shall comply with ISO 10993 biocompatibility standards. (UR3)
PDS4	**Critical**	The system must classify rising stress at least 30 seconds prior to a behavioral outburst using physiological signals and motion features. (UR4)
PDS5	**Critical**	The feedback system must use subtle LED patterns or haptic indicators that do not distract peers or interrupt instruction. (UR5)
PDS6	**Critical**	All data shall be encrypted during transmission and storage, and the system shall support at least 7 days of secure onboard data retention. (UR6)
PDS7	Moderate	The device must be sweat-resistant, water-resistant (IPX4+ preferred), and resistant to frequent handling. (UR7)
PDS8	**Critical**	Device shall survive a 1-meter drop test (IEC 60068-2-31) and tolerate daily wear impacts typical of adolescent users. (UR8)
PDS9	Moderate	Battery must support at least 8–10 hours of continuous monitoring, classification, and feedback. (UR9)
PDS10	Moderate	LED feedback and interface elements must be simple, non-distracting, and intuitive for ages 13–18. (UR10)
PDS11	Low	The enclosure design shall resemble a standard smartwatch and avoid medical or clinical aesthetic features. (UR11)
PDS12	**Critical**	The Machine Learning algorithm shall achieve a classification accuracy of ≥90% for binary stress detection on validation datasets. (UR4)
PDS13	**Critical**	The software pipeline must have a total system latency of <5 seconds from physiological event capture to feedback generation. (UR1, UR4)
PDS14	**Critical**	The preprocessing stage must include motion artifact removal filters (e.g., low-pass, moving average) to maintain Signal Quality Index (SQI) >0.8 during moderate movement. (UR2)
PDS15	**Moderate**	The companion dashboard shall visualize historical stress data and device usage logs with a refresh rate of at least 1 minute. (UR10)

8. System Level Design and Block Diagram

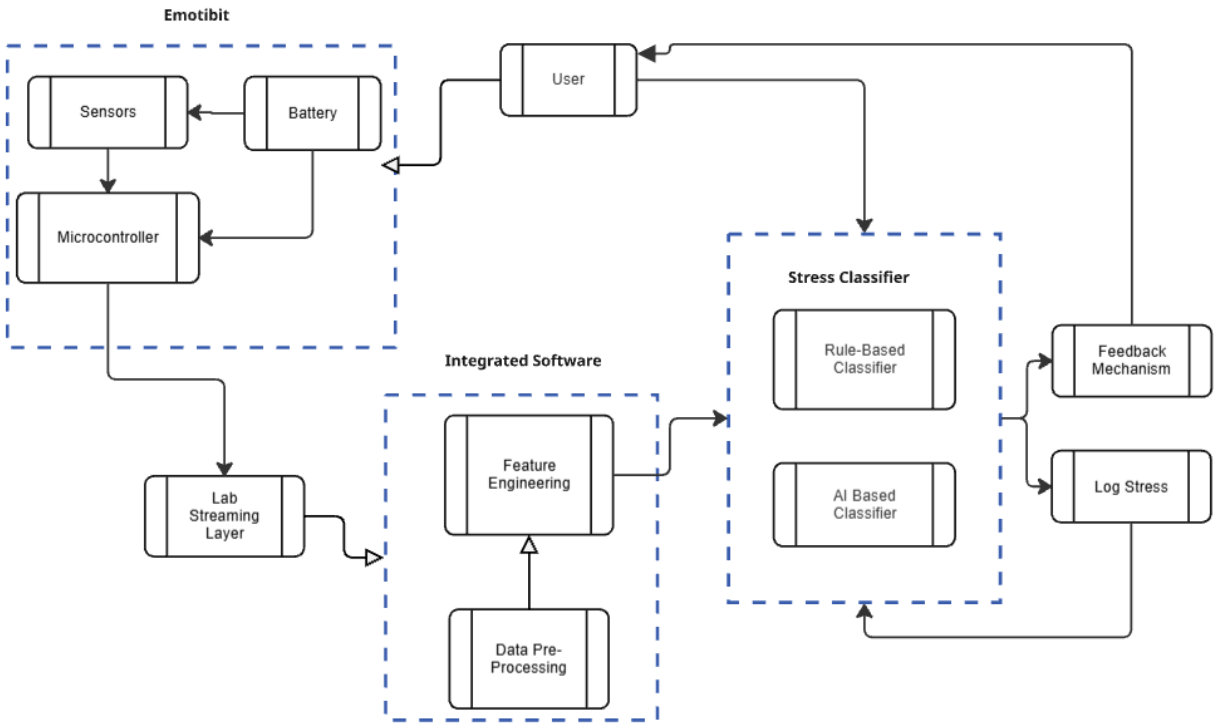

Figure 1: Block Diagram

The overall system architecture is shown at a high level in the block diagram in Figure 1. The workflow begins with the user wearing an EmotiBit device that integrates multiple sensors, a microcontroller, and a battery. The microcontroller then samples the physiological signals and streams them to a host device through the BrainFlow API. The API defines the first interface as time-stamped, multi-channel data frames. Within the integrated development software, the data-preprocessing pipeline filters, cleans, and windows the incoming signals before passing them to the feature-engineering module. The feature-engineering module converts raw sensor data into meaningful metrics by capturing deviations from each user's baseline and applying normalization. These features form the input to the stress classifier where we compare the outputted stress label and confidence score of a rule-based classifier and an AI-based classifier. These outputs are passed to a feedback mechanism that provides real-time feedback to the user and to a logging module that records time-stamped stress events for later review and personalization.

9. Subsystem Design Descriptions

9.1 Sub-System Design Requirements Table

9.1.1 Software Design Requirements Table

Table 5: Software Sub-System Design Requirements

Requirement Category	Specification	Target Value	Validation Method
Performance - Accuracy	Binary stress classification accuracy on held-out subjects	≥ 85%	Leave-One-Subject-Out cross-validation
Performance - Sensitivity	True positive rate for stress detection	≥ 85%	Per-class metrics on test set
Performance - Specificity	True negative rate for non-stress states	≥ 80%	Per-class metrics on test set
Performance - F1-Score	Balanced precision-recall metric	≥ 0.83	Harmonic mean of precision/recall
Latency - Inference Time	Time from feature extraction to prediction	< 100 ms	Benchmarked on target hardware
Latency - Update Frequency	Time between consecutive predictions	30 seconds	Sliding window step size
Model Size	Compressed model file size for edge deployment	< 5 MB	Serialized model inspection
Robustness - Missing Data	Graceful handling of sensor dropouts	Maintain functionality with 1-2 missing modalities	Ablation testing
Robustness - Noise Tolerance	Performance with realistic signal artifacts	< 5% accuracy degradation	Synthetic noise injection testing
Personalization - Calibration Period	Time to establish user baseline	1 day typical use	Field testing evaluation
Training Data - Class Balance	Ratio of stress to non-stress samples	0.35 - 0.50	Dataset composition validation

These requirements ensure the model meets both technical performance standards and practical deployment constraints for real-world classroom use.

9.1.2 Hardware Design Requirements Table

Table 6: Hardware Sub-System Design Requirements

Requirement Category	Specification	Target Value	Validation Method
PPG Signal Quality	Must allow accurate HR and HRV extraction	SNR ≥ 10 dB	Signal-to-noise analysis, waveform inspection
EDA Signal Quality	Must allow tonic + phasic decomposition	Usable signal bandwidth 0-7.5 Hz	FFT analysis, test under rest + movement

Real-Time Data Latency	Time from sensing to classification output	< 5 seconds	Timestamped latency measurement
LED Feedback Latency	Time from classification to LED update	< 200 ms	Measure frame-to-frame display update time
Battery Life	Continuous operation for full school day	≥ 8–10 hours	Continuous runtime test
Charging Time	Recharge duration	≤ 2 hours	Charge/discharge cycle testing
Durability (Drop Resistance)	Must withstand typical classroom handling	Survive 1-meter drop	Drop testing (multiple surfaces)
Durability (Wear & Tear)	Daily adolescent use	No functional damage after simulated daily handling	Repeated stress testing
Water/Sweat Resistance	Must tolerate sweat and incidental moisture	Equivalent to IPX4 splash resistance	Spray test, sweat simulation
Comfort & Wearability	Safe, comfortable for 13–18-year-olds	Weight < X g, thickness < X mm	Wear testing, ergonomic evaluation
I^2C Communication Reliability	LED matrix control must remain stable	≤1% transmission error rate	I^2C error logging
Electrical Safety	Safe for skin contact; low-voltage operation	Operating voltage ≤ 3.3 V	Hardware inspection, standard compliance check
Material Safety	No skin irritation from enclosure	ISO 10993-compliant materials	Material spec review, manufacturer documentation

9.2 Design Approach

9.2.1 Hardware integration and feedback system:

The hardware subsystem design approach is centered around the integration of the EmotiBit watch, which contains the EmotiBit sensor module and the Adafruit Feather ESP32 microcontroller, and the Adafruit Charlieplex LED matrix. This entire system will then be

enclosed in a 3D printer case. The EmotiBit watch was selected due to its high-quality sensing capabilities for emotional, physiological, and movement data. The Feather ESP32 allows for wireless data streaming using LSL to a desktop for further data processing, feature extraction, and stress classification. This data is then relayed to an HTML file which will handle the user interface. The LED matrix serves as the primary feedback mechanism to the user and/or caregiver. The display of the LED matrix will be driven by the continuous stress-confidence score output by our ML model. The displays will correlate to the stress score and aim to aid the user without overstimulating them.

1. Sensing Layer: EmotiBit collects physiological (PPG, EDA, temperature) and motion (accelerometer and gyroscope) data from the user.

2. Processing Layer: The ESP32 transmits data to a desktop which will handle the core computations for feature extraction and signal processing (HR, HRV, EDA components).

3. Feedback Layer: The LED matrix renders visual cues according to the model stress-classification score. The microcontroller runs animations while continuously monitoring the physiological changes.

The 3D printed case and strap will aim to prioritize comfort and durability while also being discrete. The housing must withstand daily wear for approximately 8 hours, exposure to sweat and moisture, and routine physical impacts. The enclosure design should closely resemble a consumer smartwatch to maintain discretion and ensure the device does not draw unwanted attention in the classroom.

9.2.2 Machine Learning Model Design Approach:

The design approach taken for the machine learning model was to use transfer learning strategy to bridge the gap between the adult WESAD dataset and the target adolescent classroom population. Transfer learning allows general stress-related physiological patterns to be learned from the adult WESAD dataset and then be adapted to an adolescent classroom population from our custom data. This is necessary since collecting large amounts of labeled stress data from children is difficult and existing public datasets primarily contain adult subjects. The first stage of transfer learning is to train a baseline machine learning model on the adult WESAD physiological data to learn generalizable stress response patterns based on the physiological patterns. Rather than using raw absolute physiological values, the model learns stress signatures defined by deviations from personal baselines which are created through feature engineering. This is crucial since each subject is different and our device needs to support cross-age generalization. The second phase focuses on adaptation to our specific use case. The idea is that each new user undergoes a calibration period where their personal baseline statistics are established from true resting-state measurements. This follows the same experimental design for the training of our machine learning model to ensure that the model trained on the WESAD dataset is transferable to our specific real-world use case. Then all subsequent features are normalized using these individualized baselines. This transforms raw absolute physiological measurements into person-invariant normalized measurements for the machine learning model to use.

The design approach for the overall pipeline follows a six-stage architecture: data ingestion, preprocessing, windowing, feature extraction, normalization and feature selection, and final classification. First, data ingestion collects synchronized signals from the wearable device as streams of data. Second, preprocessing applies signal-specific filtering and data cleaning to ensure signal quality. Third, we break the signals into 60-second windows with a 30-second step size. Since each sensor records at a different sampling rate, windowing allows us to match them on the same time segment and generate predictions regularly. Fourth, each window is transformed into a set of features that capture heart rate variability, electrodermal activity, movement characteristics, and temperature trends. Fifth, we normalize these features using the user's baseline so the model focuses on changes rather than absolute values. Then we examine each individual features importance and only keep the most useful features for efficiency to avoid overfitting the model. Finally, a Random Forest model outputs a stress probability from our features. This setup is designed for real-time edge deployment while still giving reliable stress estimates.

9.3 Test Plans and Results

9.3.1 Signal Quality and Real-Time Streaming Test Plans and Results

Testing for this subsystem will focus on ensuring that the physiological signals are captured accurately and are streamed reliably for real-time detection. These tests will verify compliance with our product design specifications 2 and 4. We plan to conduct a variety of tests to help validate our device and model. These test include, a Signal Preprocessing Verification Test where synthetic and prerecorded sensor signals will be passed through our filtering pipeline and compared against MATLAB-generated reference signals. This will confirm that noise removal, motion-artifact reduction, and baseline stabilization function correctly. A Windowing and Overlap Test will verify that the system correctly implements 60-second sliding windows with proper indexing and no data leakage between windows. This ensures a consistent window segmentation which is critical for timely and accurate stress classification. We also plan to validate real-time performance by conducting a Streaming Stability Tests, which examines packet continuity, sampling-rate consistency, and latency under extended use. These tests will help verify that the system maintains reliable data flow during typical classroom conditions throughout the school day.

9.3.2 Machine Learning Model Test Plans and Results

Model evaluation and testing is critical to ensure that the model makes accurate and trustworthy stress predictions before it can be used with students. Our machine learning model is evaluated using a Leave-One-Subject-Out (LOSO) cross-validation framework to measure generalization to new users. This method trains on all but one subject and tests on the held-out subject then rotates until each subject has served as the test set. This is the standard for validation on smaller datasets. This approach matches our deployment scenario, where the system must perform well on individuals whose physiology was not seen during training. The evaluation metrics that have chosen to consider during model evaluation are accuracy, precision, recall, F1-score, ROC-AUC, and confusion matrices to identify whether errors are caused by missed stress events or false stress alarms. In addition to these metrics, we will also measure inference time and power usage on the device to make sure the system can run smoothly in real time.

Early results are encouraging with Random Forest and XGBoost consistently achieving LOSO accuracies between 93% and 96% with the best model reaching 96.4% accuracy, 88.8% recall, and 91.1% F1-score. Even simpler models such as Logistic Regression and SVM show strong performance, with accuracies around 92–93% and recall values above 86%. These findings show that the model is learning meaningful physiological stress patterns and performs well even under the strict LOSO protocol.

Moving forward, we will collect our own data using the wearable device. Team members will wear the device during naturally stressful events such as class presentations and exams. We will also run the Cold Pressor Test which is a standard method for safely inducing stress. This will help us capture clear stress responses under controlled conditions. We will label these sessions using timestamps and self-reported stress levels. This custom dataset will be evaluated using the same metrics applied to WESAD. This will allow us to compare model performance across datasets and verify that it generalizes well to real-world stress in a younger age group.

10. Regulatory and Standards Considerations

Since this project involves a physiological-monitoring wearable intended for use in schools, regulatory classification depends heavily on the device's intended use statement. Even though our system measures physiological signals commonly used in medical devices (PPG, EDA, accelerometer), the team does not claim to diagnose or treat a medical condition. Instead, the device is positioned as a behavioral self-regulation aid that identifies rising stress to support coping strategies in educational environments. This intended use significantly influences FDA classification and determines which regulatory pathways and standards are applicable.

10.1 FDA Class, Intended Use, and Indications for Use

Under FDA policy, a wearable device that collects physiological data for general wellness, behavioral support, or stress self-management, and does not claim to diagnose anxiety disorders, monitor vitals for safety, or guide clinical intervention will fall under the FDA General Wellness Discretion category rather than medical device regulation.

Our intended use for this device is a wearable device that monitors physiological and motion signals to help students and supervisors recognize rising stress and practice self-regulation strategies in a school environment.

Since our intended use relates to behavioral well-being and not medical diagnosis or intervention, the system would be a non-medical device from a regulatory standpoint. The FDA typically does not enforce premarket review for a device of this nature as it is treated as a consumer wellness device. If we wished to claim our device as a medical device, it would most likely become a Class II medial device, requiring additional controls and approval.

10.2 Premarket Pathway

Since we intentionally scoped our device as non-medical, the expected FDA pathway in no premarket submission. This is because the device falls under the General Wellness Enforcement Discretion Framework..

If in the future we shift our product towards a clinical use, the FDA pathway would change as well. Since the device would be a Class II medical device, 510k premarket approval would be required.

10.3 Standards Considerations

Below are the list of standards that we have taken into consideration as of now and have helped us shape the tests that we hope to run in the future.

Table 7: Relevant Collateral Standards (IEC 60601-1-x Series)

Standard	Title	Why Relevant
60601-1	General Safety and Performance	Applies to all electrical medical devices
60601-1-2	Electromagnetic Compatibility	Ensures EMC safety in classrooms/homes
60601-1-6 / 62366-1	Usability	For adolescent-friendly, safe interaction
60601-1-8	Alarm Systems	Governs vibration/audio/visual stress alerts
60601-1-10	Physiologic Closed-Loop Control	If automated feedback is implemented
60601-1-11	Home Healthcare Environment	Applies to wearable, non-clinical use

Table 8: Relevant Particular Standards (IEC 60101-2-xx Series)

Standard	Title	Why Relevant
IEC 60601-2-47	Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	Most analogous to your wearable watch. Provides guidance for continuous physiological monitoring in mobile conditions — relevant for verifying PPG-based heart rate and HRV accuracy during movement.
IEC 60601-2-27	Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	Useful for benchmarking signal accuracy, reliability, and performance verification of heart-related features derived from PPG. Helps define essential performance metrics for stress detection based on cardiovascular data.
IEC 60601-2-49	Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	Applies conceptually since the device measures multiple physiological signals (PPG, EDA, accelerometer). Provides design insight for integrated multi-signal monitoring, data display, and coordinated alert systems.

Table 9: Relevant Standards for Software Development

Standard	Title
IEC 62304:2006/Amd 1:2015	Medical device software — Software life cycle processes
ISO 14971:2019	Medical devices — Application of risk management to medical devices
IEC/TR 80002-1:2009	Provides guidance for the application of the requirements contained in ISO 14971:2019. Works as a Bridge between ISO 14971 and IEC 62304 specifically for software

Table 10: Standards for Both Hardware & Software

Standard	Title
HIPAA	Health Insurance Portability and Accountability Act
FERPA	Family Educational Rights Privacy Act
IEEE 829	Software and System Test Documentation

11. Development Plan and Budget

Progress to Date (Fall Semester 2025) The team has completed the research, design, and initial prototyping phases. Key highlights include:

- **Machine Learning:** Selected WESAD dataset and built a 52-feature extraction pipeline, achieving **95.6%** on the binary stress classification model.
- **Hardware Integration:** Established real-time streaming between the EmotiBit sensor and an HTML visualization dashboard; initiated LED matrix integration for user feedback.
- **Market Analysis:** Validated the critical user requirement for discrete, visual-based intervention methods over auditory cues.

11.1 Plan and Timeline

Table 11: Semester 2 Development Timeline

Phase & Timeline	Key Objectives & Tasks
Phase 1: Verification & Setup	**Objective:** Verify EmotiBit signal quality against WESAD standards.

(Weeks 1–4)	▪ Conduct hardware testing (signal quality, sampling rates, noise characterization). ▪ Perform statistical comparison of EmotiBit vs. WESAD signal characteristics. ▪ Build Python verification pipeline for automated quality metrics.
Phase 2: Data Acquisition (Weeks 5–8)	**Objective:** Create a "gold standard" validation dataset using team members. ▪ Design stress induction protocols (cognitive tasks, timed challenges, relaxation). ▪ Conduct data collection sessions with all team members as subjects. ▪ Build real-time recording and labeling pipeline.
Phase 3: Model Tuning (Weeks 9–12)	**Objective:** Achieve >90% accuracy on real-time hardware. ▪ Implement transfer learning (freeze base layers, fine-tune on EmotiBit data). ▪ Perform hyperparameter optimization and cross-validation. ▪ Optimize model for real-time inference (reduce latency and memory footprint).
Phase 4: Integration & Delivery (Weeks 13–16)	**Objective:** Deliver a polished, integrated system demo. ▪ Develop UI/Dashboard for real-time stress visualization and history. ▪ Integrate inference pipeline with LED matrix feedback. ▪ Fabricate 3D printed enclosure for wearable components. ▪ Final system testing and documentation.

11.2 Development Budget

The project is supported by two primary funding sources provided by the Milwaukee School of Engineering (MSOE), totaling **$1,500.00**.

Table 12: Development Budget

Funding Source	Amount	Description
MSOE Senior Design Fund	$1,000.00	Standard department allocation for senior design prototyping.
Innovent Center Seed Grant	$500.00	Competitive grant awarded by the Rader School of Business for innovation.
Total Available Funding	$1,500.00	

Bill of Materials (BOM) & Expenditures

The following table details the hardware components purchased to date. The EmotiBit bundle was selected as the primary development platform to accelerate sensor validation, while the Adafruit LED matrix serves as the visual feedback mechanism.

Table 13: List of Purchases

Item	Qty	Unit Price	Total Cost	Notes
All-in-One EmotiBit Bundle	1	$482.98	$482.98	Includes EmotiBit MD board (medical-grade thermopile), Adafruit Feather Huzzah32, battery, straps, and electrode kit.
Adafruit 15x7 CharliePlex LED Matrix	1	$10.59	$10.59	Low-power visual feedback display (FeatherWing form factor) compatible with the main MCU.
Current Total Expenditures			$493.57	

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