Medical Device Innovation and Realization

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Patient Monitoring Team 1

MindShield

EEG Monitoring for Military Personnel

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Executive Summary:

Traumatic brain injuries (TBI) are a common issue amongst US military members, with almost a quarter of soldiers during the Global War on Terror experiencing some form of a TBI [1]. Symptoms are variable but can lead to a wide range of consequences, such as lack of focus, spatial misperception, blurred vision, difficulty walking, or even changes in breathing. Such issues can have severe ramifications for soldiers on and off the field; therefore, we propose an EEG monitoring system integrated into the helmets of military personnel to output brain signal data to soldiers and military leaders for the purposes of monitoring general brain health, activity, and potential for TBI. Electrodes located throughout the helmet and connecting to a microprocessor at the back will be responsible for picking up EEG signals, which can then be processed and provided to military persons of interest.

While EEG devices and protective helmets are in development or on the market, a combination product that integrates monitoring capability along with protective capability does not currently exist. In addition, a military-specific design that has rugged reliability and the ability to be used in harsh conditions is not available or in development.

The Problem:

The main issue we are tackling is the prevalence of traumatic brain injuries and brain damage in general among US military members. The incidence of mild TBI among soldiers who participated in the Global War on Terror was estimated to be as high as 22.8%, with the most important cause of brain injury being long-term exposure to explosive weapons [1]. TBIs can have a severe impact on a patient's quality of life, with age-specific mortality rates increasing with TBI severity for post-9/11 military veterans [2]. Although the majority of these injuries are mild, even mild TBIs can lead to symptoms such as poor memory, sleep disturbance, and fatigue, with 53% of patients reporting such symptoms even a year following injury [3]. As such, the timely diagnosis of brain injuries and regular brain monitoring of soldiers is crucial for optimizing the health of our military while preventing the costs of lost duty time, early retirement, and retraining or replacing personnel.

The first step in diagnosing TBI is with a neurological exam evaluating thinking, motor function, sensory function, coordination, eye movement, and reflexes. Imaging tests like CTs or MRIs cannot necessarily detect all TBIs, but can help rule out more serious brain injuries or detect internal bleeding. TBIs are classified using the Glasgow Coma Scale (GCS) score, where mild is indicated by a score of 13-15, moderate by a score of 9-12, and severe by a score of 3-8. A clinician can measure a patient's functioning in terms of ability to speak, open eyes, and move. For example, a mild TBI may be associated with a lack of loss of consciousness or loss of consciousness for less than 30 minutes and a memory loss lasting less than 24 hours, while a severe TBI may be associated with a loss of consciousness for more than 24 hours and memory loss lasting more than 7 days [4]. Other tests that might be used could be speech and language tests, social communication skills tests, swallowing and breathing tests, cognition tests, or neuropsychological tests. TBIs can lead to three types of injuries: intracranial hematoma (ICH) which is a collection of blood within the skull, elevated intracranial pressure (ICP), or a midline shift (MLS) [5]. The long-term effects of TBI can be drastic, as TBI is highly associated with subsequent development of PTSD, depression, and anxiety, and a recent study has also observed that the rate of suicide among veterans with TBI is significantly higher than that among veterans without TBI by about 90 to 60 instances per 100,000 person-years respectively [6].

Considering the significance of TBI among the US military, our team has identified a need for minimally invasive EEG tracking with real-time signal processing. While there are numerous EEG headsets and explorations in research regarding combining EEG into helmets for various purposes, a gap exists for a consistent, military-specific design. This solution develops an easy and effective service for soldiers or military leaders to track EEG signals, TBIs, and overall health status. Doing so allows for proper intervention of brain injuries, as well as a deeper analysis on the levels of fatigue or concentration experienced by soldiers.

Problem Objective Statement:

Our design aims to solve the proposed problem by creating a comfortable, durable, and minimally invasive technology that can be integrated into the helmets of military personnel for the purposes of tracking EEG signals, identifying TBIs or other brain-related issues, and monitoring overall health status, thereby effectively reducing the severity of brain injuries. The device will incorporate silver chloride electrodes located in military-standard helmets that will record EEG signals from the soldier, process these signals, and output the resulting waves and any notable information or correlations associated with brain injuries or different types of brain activity. This solution ultimately allows for soldiers or military leaders to track neurological health with long-term data.

Design Documentation:

Product Requirements

The Advanced TBI Helmet System is designed to revolutionize the monitoring, detection, and management of Traumatic Brain Injuries (TBIs) within military environments by leveraging cutting-edge technology for real-time EEG signal processing, long-term brain health monitoring, immediate data transmission, and real-time TBI detection.

To address the challenges identified in current TBI detection and monitoring systems, our redesigned TBI helmet system must be user-friendly, adaptable to various military environments, and aesthetically designed to ensure user compliance while maintaining its safety, effectiveness, and operational integrity.

1. Real-Time EEG Signal Processing- Incorporates advanced algorithms for the immediate analysis of EEG data to identify signs of abnormal brain activity indicative of injuries or stress. Utilizes onboard processing units capable of executing complex algorithms to analyze EEG signals in real-time, ensuring minimal latency between data collection and interpretation. Enables the detection of acute changes in brain activity, potentially indicative of concussive events or other neural disturbances, allowing for swift action to mitigate long-term impacts.
2. Long-term EEG Monitoring - Offers continuous EEG data collection, providing a comprehensive overview of an individual's brain health over time. Equipped with EEG electrodes and microcontroller for storage solutions to facilitate ongoing signal processing without impacting helmet usability or requiring frequent maintenance. Supports the tracking of recovery processes post-injury and enables the assessment of general brain health, aiding in the early identification of patterns that may indicate developing health issues especially in a military environment.
3. Real-Time Data Transmission - Features integrated Bluetooth/WiFi connectivity for the instantaneous sharing of collected EEG data with medical teams, even in remote locations. Leverages secure and robust wireless communication protocols to ensure reliable and secure data transmission from the helmet to medical personnel. Facilitates immediate access to critical health data by medical teams, enabling quick decision-making and timely medical intervention, essential for optimal recovery and health management.
4. Real-Time TBI Detection - Capable of analyzing EEG signals on-the-fly to detect the presence of TBIs, leveraging predefined neural markers associated with brain injuries. Implements models trained on vast datasets of EEG readings to accurately identify TBI signatures in real-time EEG data. Provides a crucial capability for immediate TBI detection, significantly enhancing the response time for medical treatment and increasing the chances of successful recovery by addressing TBIs as they occur.
5. Accuracy and Sensitivity- Utilizes EEG signal analysis algorithms to ensure high accuracy in detecting TBIs, a significant leap against current devices that separate protective and monitoring functions. This diagnostic precision is vital for swift identification of TBIs, enabling prompt medical intervention which is critical in saving lives and reducing long-term disability.
6. Portability and Comfort- A lightweight, ergonomic design ensures the helmet can be worn comfortably for extended periods, addressing the lack of comfort and wearability in existing EEG or protective gear. Promotes continuous, non-intrusive monitoring, crucial for adherence and effectiveness, especially in prolonged military engagements.
7. Battery Life - Offers 12+ hours of continuous operation with quick recharge options, addressing the need for durable power solutions in field operations. Supports sustained missions, providing reliable monitoring without the constant need for recharging, a crucial advantage in remote or extended deployments.

8. Integration with Existing Military Gear - Provides seamless compatibility designed to work alongside standard military equipment without interference. Ensures the TBI helmet enhances rather than hinders soldier capability, integrating vital TBI monitoring into their existing gear without compromise.

Applicable Standards

1. **IEC 60601-1 -** Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance

This establishes the fundamental safety and performance requirements for medical electrical equipment. It covers risks associated with electrical shocks, mechanical hazards, radiation, and thermal effects.For the TBI Helmet System, this standard ensures that the device is safe to use in close proximity to the human body and in varying environmental conditions, mitigating risks related to electrical and mechanical components.

2. **IEC 60601-1-2** - Electromagnetic Disturbances - Requirements and Tests

This focuses on the equipment's ability to operate within its intended environments without causing or being affected by electromagnetic interference (EMI). It includes testing for electromagnetic compatibility (EMC). Given the helmet's electronic nature and its usage in diverse military settings possibly laden with electromagnetic disturbances, this standard guarantees the device's functional integrity against EMI, ensuring reliable operation.

3. **IEC 62304** - Medical Device Software - Software Life Cycle Processes

This provides a framework for the life cycle management of medical device software, emphasizing software development, maintenance, and risk management processes. As the helmet incorporates sophisticated software for EEG data analysis and communication, this standard ensures the software component is developed and maintained following rigorous safety and reliability guidelines.

4. **ASTM F2503-13** - Safety in the Magnetic Resonance Environment

This establishes guidelines for marking medical devices and other items to indicate their safety in the magnetic resonance (MR) environment. It helps in identifying devices that are MR Safe, MR Conditional, or MR Unsafe. Compliance ensures the TBI helmet can be safely used around MRI facilities, important for soldiers who may require MRI scans, by minimizing risks associated with the device's interaction with strong magnetic fields.

5. **ISO 10993-1** - Biological Evaluation of Medical Devices

This guides the assessment and testing of device materials for their biological compatibility, focusing on cytotoxicity, sensitization, irritation, and other potential biological hazards. This standard is crucial for ensuring that all materials used in the helmet, especially those in direct contact with the skin, are non-toxic, hypoallergenic, and safe for long-term wear.

6. **ISO 13485** - Quality Management Systems for Medical Devices

This specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Adherence to ISO 13485 assures that the helmet is manufactured under controlled conditions, ensuring consistent quality and compliance with regulatory standards.

7. **IEC 62061 / ISO 12100** - Safety of Machinery

This provides guidelines for the design, risk assessment, and risk reduction of machinery, focusing on ensuring safety throughout the machinery's lifecycle. For the TBI helmet, this standard ensures that mechanical components, such as adjustable fittings and modular parts, are designed to minimize risks of injury or malfunction, enhancing overall device safety.

8. **ISO/IEC 27001** - Information Security Management

This offers requirements for establishing, implementing, maintaining, and continually improving an information security management system (ISMS). This standard is critical for protecting the confidentiality, integrity, and availability of data collected and transmitted by the helmet, ensuring adherence to data protection laws and maintaining user trust.

The Prototype

Our product requirements for the EEG helmet prototype are to design a reliable device capable of capturing accurate brainwave signals using an array of eight electrodes. The prototype must be housed securely within a helmet and incorporate a form factor that supports consistent electrode contact with the scalp. Standards applicable to this device include those pertaining to the biocompatibility of materials used, such as the SLA print for electrode holders, and electronic safety and data protection standards for devices interfacing with Arduino and Bluetooth components (Figure 1).

The prototype construction involved several critical stages. Initially, a CAD model was developed to create a resin form factor that integrates into the helmet, positioning the electrodes optimally for signal acquisition. Elastic bands were employed to ensure electrodes maintain adequate pressure for consistent skin contact. The electronic circuitry includes an Arduino Uno, an accelerometer, an Adafruit Bluetooth module, and an ADS 1299 denoising chip to capture and process the EEG signals. A custom SLA mount for the Arduino was also designed and fitted onto the back of the helmet.

The military helmet is designed to safeguard soldiers by monitoring for traumatic brain injuries in real time. At its core, the helmet features strategically placed EEG sensors within its lining, interfaced with an Arduino Uno microcontroller for robust data acquisition and processing. This setup ensures minimal interference with the helmet's structural integrity while providing crucial health data. With its dual focus on safety and usability, our prototype maintains the traditional look and feel of military gear, allowing for seamless integration into soldiers' equipment. Its design reflects a commitment to operational excellence, comfort, and the well-being of military personnel in the field.

Verification and Validation

To create a functional design, we would like to integrate an EEG headset into a helmet that has the capabilities of analyzing the user's EEG signals wirelessly. We would like to develop software that can monitor a subject's health status and provide notification if a subject appears to have suffered brain damage, is lacking brain activity, is mentally fatigued or highly concentrated, or is suffering from post concussion syndrome or even PTSD symptoms. We would also ultimately like for the design to be integrable with a field cap as well to ensure its usage across a variety of military settings. While these are all viable areas to focus on with EEG signals, by the end of the semester, we would like to limit our scope to just monitoring and processing EEG signals, especially those that might be associated with a TBI, for a hard helmet worn by active military personnel.

For the purposes of presenting a functional prototype by the end of the semester, we will mechanically integrate a dry EEG headset with a minimum of 8 electrodes into a combat helmet. We will test comfort levels by having a minimum of 10 participants rank the helmet's comfortability with and without the EEG headset and attempt to minimize discomfort as best we can. A minimum of half of our wear trial subjects will be military trainees or personnel, to get more accurate and applicable results. An additional factor we will have to consider is the exposure to moisture on the scalp which cannot be disregarded during combat scenarios. We will have to evaluate system resilience, implement protective measures like waterproofing, or use moisture resistant materials to mitigate the risk of signal impedance or failure.

We will also develop a model using pre-existing software and adhering to validated methods that can record and conduct signal processing of EEG data and output these signals in a clear and understandable format for users. We will ensure that our software is properly processing EEG signals by validating by using data from a similar study which used EEG monitoring data to classify TBI incidents (Tewarie PKB et. al, 2023).We plan validating our software's processing capabilities to a ground truth of annotated EEG data to evaluate our model's accuracy and compare its performance with other models found in literature (Tewarie PKB et. al, 2023). If our software is capable of processing our own EEG signals in a normal brain state and results are comparable to EEG signals found in literature in a normal brain state and not significantly different, we can test that our software is properly functioning. We are also working on obtaining a dataset of EEG signals of TBI diagnosed patients and plan on evaluating our software's processing capabilities for injured brain states using this data.

Once this helmet and headset combination is achieved, we would like for it to recognize when brain damage has occurred; however, this may be beyond the scope of what we can achieve in the time we have and we believe that developing software capable of, in almost real time, processing EEG signals, is only a matter of time for clinical research and further software development. Therefore, the two major problems we will be focusing on initially will be the mechanical combination of helmet and EEG headset while maximizing comfortability and durability in addition to the software capable of processing EEG signals and outputting results in a user-friendly GUI format.

Prototype Design:

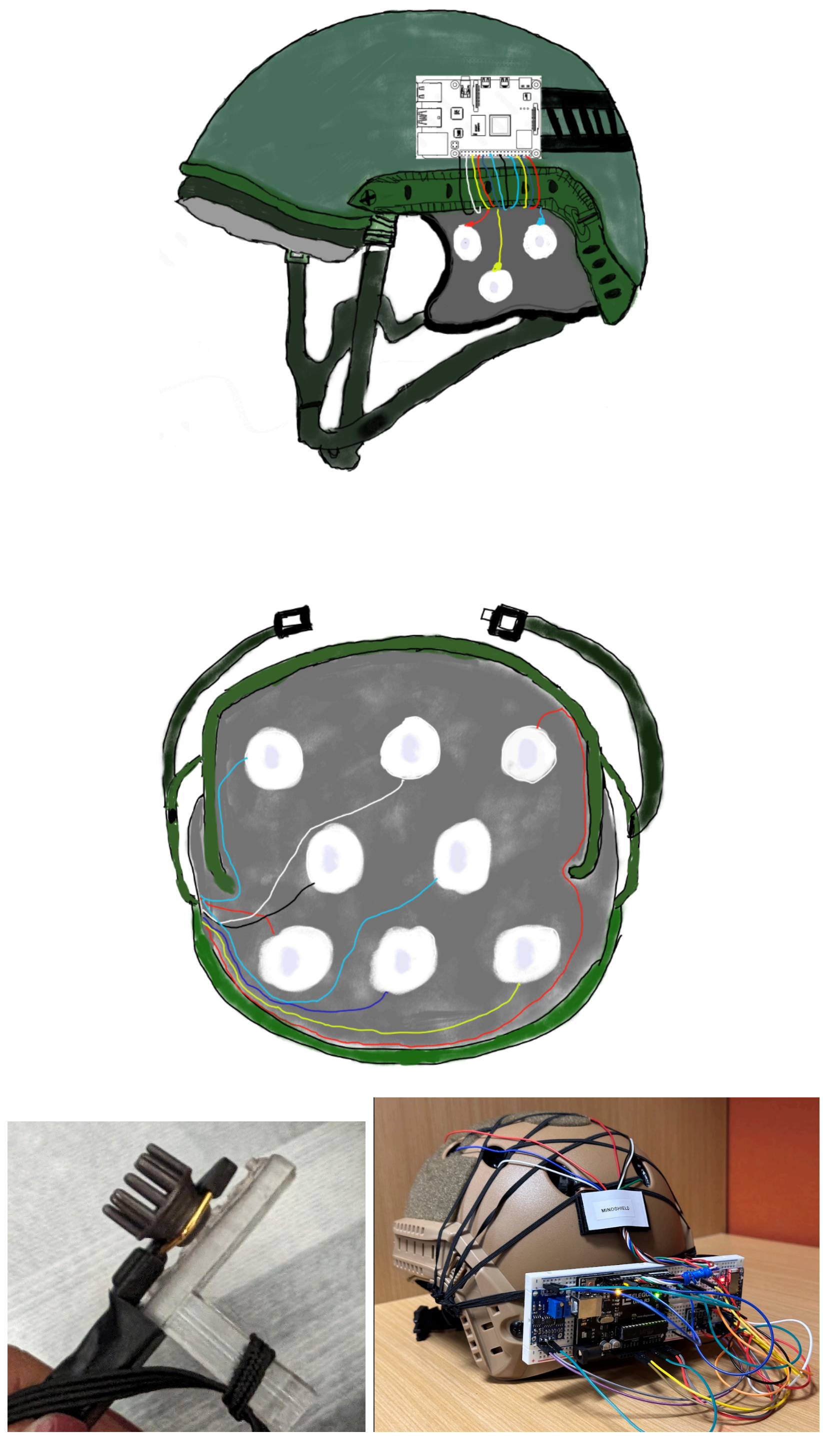


Figure 1. - Prototype Sketch and Prototype 1 : Military helmet with embedded electrodes and a microcontroller

Prototype Testing

The verification and validation process for the EEG helmet was thorough and multi-faceted to ensure the prototype met both functional and performance criteria. Initially, we conducted baseline recording sessions where the EEG signals were captured from eight strategically placed electrodes across various brain regions (Fig 1a). These recordings were subjected to band-pass filtering to isolate specific brainwave frequencies—namely Delta, Theta, Low Alpha, High Alpha, Low Beta, High Beta, Low Gamma, and High Gamma (Figure 1b). The accuracy of these signals was rigorously analyzed against an established EEG dataset from healthy controls, using the same electrode placement. Our prototype showed remarkable accuracy, with less than 5% variance in eight out of ten metrics compared to the control data. Further validation involved the use of a custom-developed BrainGrapher script using Processing software version 3.0.2 (Figure 1c). This script enabled the dynamic visualization of EEG signals across the ten defined metrics, providing a real-time graphical representation of brain activity. The visualization was instrumental in identifying any discrepancies or anomalies in real-time, thereby validating the efficacy of the signal processing algorithms used.
Practical tests were designed to simulate typical usage scenarios. These included:

1. Attention Measurement: A test where a participant focused on a white screen displaying a central "+" symbol for ten seconds followed by a second second rest screen. This test aimed to measure the brain's response to visual fixation and was repeated three times to ensure consistency in the data.
2. Mediation and Relaxation: Participants were asked to meditate with their eyes closed, allowing us to measure brainwave patterns associated with relaxed cognitive states.
3. Motor Function Testing: Participants performed a task of picking up an object and placing it back on a desk in a set 15-second interval with a 5-second rest in between, testing the helmet's ability to record brain activity during physical movement.

Lastly, to explore the prototype's potential in clinical settings, particularly for traumatic brain injury (TBI) diagnosis, we applied a classification model using a classifier on an existing dataset (Tewarie PKB et. al, 2023). This model was trained and validated using a separate TBI EEG dataset to classify the occurrence of TBI (TBI Present or Not Present), focusing on eight of the ten metrics(Delta, Theta, Low Alpha, High Alpha, Low Beta, High Beta, Low Gamma, and High Gamma). The classifier's performance (90%) added a critical layer of validation, demonstrating the prototype's applicability in diagnosing and assessing the severity of neurological conditions based on EEG data.

The combination of these rigorous testing protocols, from basic signal verification to practical application tests and advanced clinical modeling, provided strong proof of the prototype's functionality and its potential to solve complex neuro-monitoring problems. This extensive validation ensures that the EEG helmet is not only a functional tool for recording brain activity but also a promising device for broader applications in medical diagnostics and cognitive research.

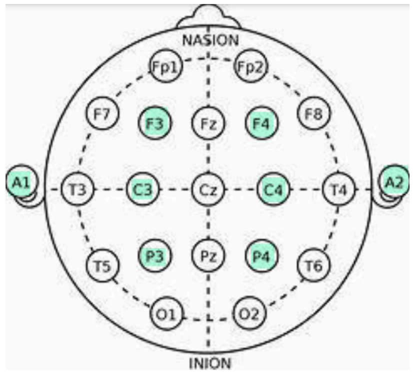


Figure 1a. Prototype electrode placements using a 10-20 EEG system (F3, F4, C3, C4, P3, P4, A1, and A2)

Brain Wave (Hz)	**What is Approximately Measured?**
Delta (1-4) Hz	Deep Sleep
Theta (4-7) Hz	First Stages of Sleep
Alpha (7-12) Hz	Relaxation and Mediation
Beta (12-40) Hz	Attention, Alertness, Conscious Reasoning
Gamma (40-70) Hz	Conscious Awareness, Happiness, Multisensory

Figure 1b. The Brainwaves recorded during Prototype Testing

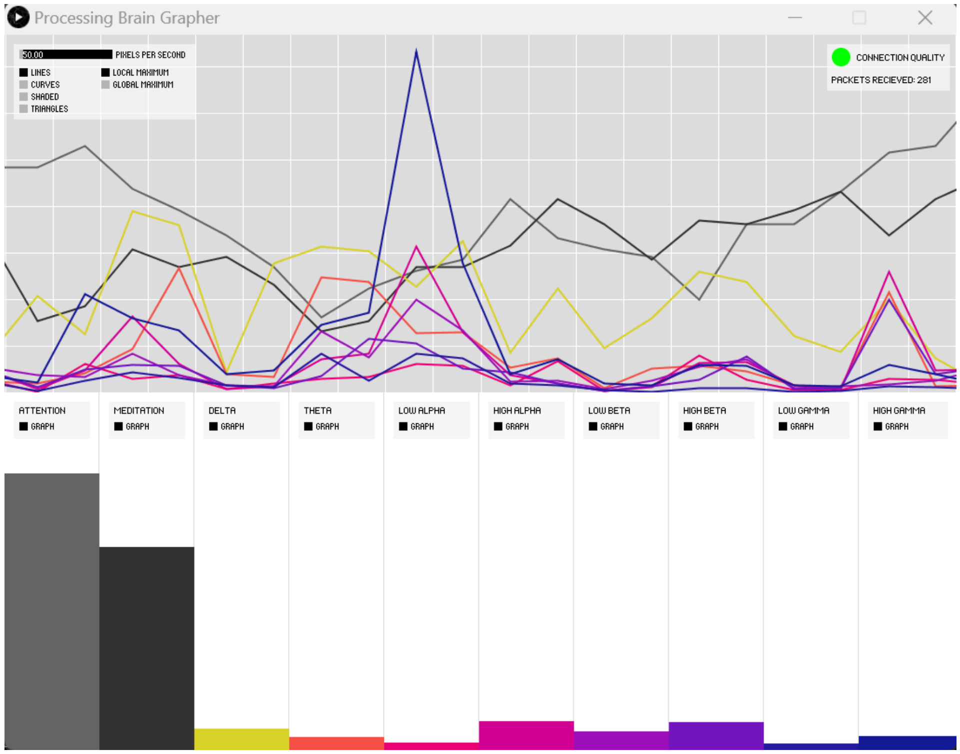


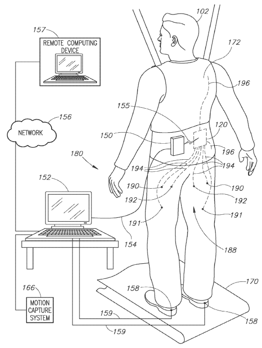
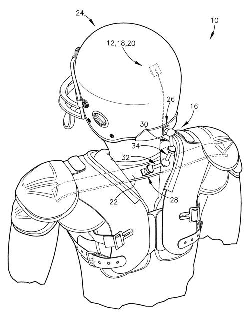
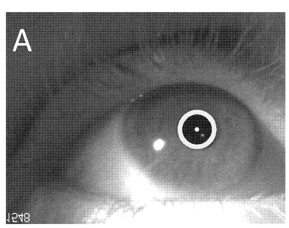
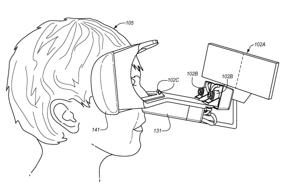
Figure 1c. Time Frame capture of BrainGrapher Visualization to show real-time data acquisition

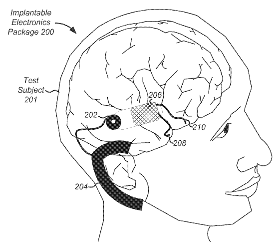
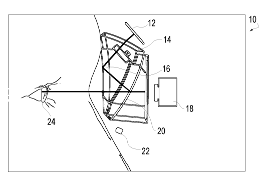
<u>Patent Analysis:</u>

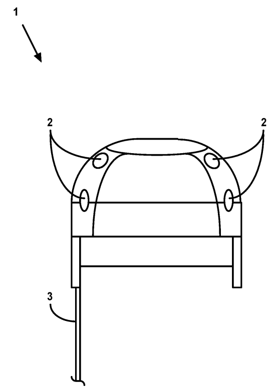
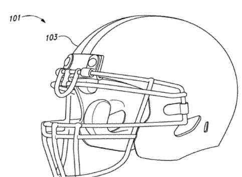
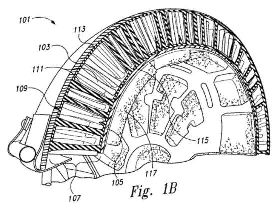
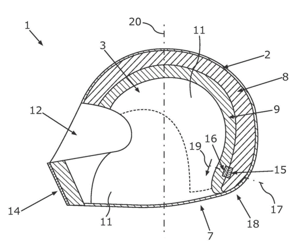
The chart below summarizes the current patent landscape that relates to the design in question.

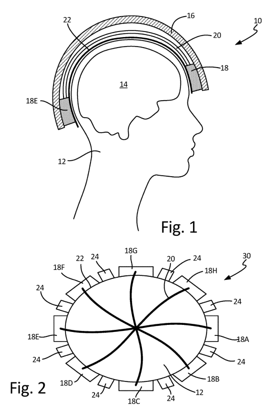
Existing Patents & Prior Art

Name	**Subject**	**Type of Prior Art**	**Important Content**
[Field deployable concussion assessment device USRE46189E1]		Patent	This patent was awarded in 2015 And is extended till 2031. The device is configured to acquire brain electrical signals from a patient's forehead using one or more neurological electrodes.

Neurostimulator devices using a machine learning method implementing a gaussian process optimization US9931508B2		Patent	Patent is active and was awarded in 2018. Devices include a stimulation assembly connected to multiple electrodes that stimulate the spinal cord. They also have sensors and a processor. The processor adjusts the electrode stimulation pattern using data from the sensors, using machine learning with Gaussian Process Optimization.
Device and system to reduce traumatic brain injury US9226707B2	 Fig. 1	Patent	This patent was awarded in 2014 and expired in 2016. A device for reducing traumatic brain injury includes a sensor measuring head acceleration, a flexible/rigid linkage between head and body components switched by a locking signal, and a processor generating the locking signal when head acceleration surpasses an injury threshold.
System for traumatic brain injury detection using oculomotor tests EP3110308B1	 FIG. 1A	European Patent Office	This patent was awarded in 2023 And this patent is active Neurological impairment device: portable, microcontroller, light display; measures user's tracking time after random light reversal.
System for the physiological evaluation of brain function US8668337B2		Patent	This patent was awarded in 2014 and the patent is active The OculoKinetic Device assesses brain functions and detects traumatic brain injuries through high-speed eye

			tracking. It integrates stimuli with cognitive and balance assessments.
[Systems and methods for restoring cognitive function](#) [US10363420B2](#)		Patent	This patent was awarded in 2019 and the patent is active This approach involves precise stimulation of brain structures, refining models based on recorded responses to restore object-specific and location-specific memories in animals.
[Devices and systems to mitigate head injuries and other injuries caused by concussion or blast forces](#) [ES2851676T3](#)	**N/A**	European Patent Office (Spain)	This patent was awarded in 2021 and the patent is active The system includes a collar or partially circumferential collar and a shirt/sweater with a matching opening, applying pressure to neck veins to restrict blood flow. The design allows the flap to conceal the collar when folded over it.
[Quantitative, non-invasive, clinical diagnosis of traumatic brain injury using VOG device for neurologic testing](#) [US9039631B2](#)		Patent	This patent was awarded in 2015 and the patent is active Portable VOG device for efficient TBI screening in remote military settings. It establishes baseline brain function, enabling follow-up assessments and advanced applications for diagnosis and rehabilitation.
[Biomarkers of Traumatic Brain Injury](#) [KR102618993B1](#)	**N/A**	Patent (South Korea)	This patent was awarded in 2023 Diagnose and monitor mild traumatic brain injury by measuring miRNA levels in

			saliva samples. Provided are sensor elements, detection systems, and treatment methods for subjects with suspected mTBI.
[Thermal Safety Helmet For Treating And Prevention Of Head Injuries](US20140101830A1) US20140101830A1		Patent abandoned	Patent was granted in 2014 and then was abandoned. A conforming thermal safety helmet has pockets for removable thermal packs, offering hot or cold treatment for injuries or infections at specific head locations. Optionally, the thermal packs can be non-removable and integral to the helmet.
Protective helmets including non-linearly deforming elements US20210037906A1	 Fig. 1A  Fig. 1B	Patent	Patent was granted in 2021 and then was abandoned. A protective helmet has an inner and outer layer with an interface layer containing impact-absorbing material. The material, such as filaments, non-linearly deforms in response to an incident force on the helmet.
Protective helmet and method of use CN111417326B		Patent (China)	This patent was awarded in 2022 and the patent is active A helmet designed to mitigate mild traumatic brain injury incorporates fluid-filled flexible chambers, distributed around the helmet, compressing upon impact to cushion and shield the head. It includes impact-resistant pads and a snug-fitting flexible inner shell for enhanced protection.

[Protective headwear to reduce risk of injury US20170280814A1](#)		Patent	Patent was granted in 2017 and then was abandoned. A helmet designed for mild traumatic brain injury protection features fluid-filled flexible chambers, spaced around the helmet, compressing upon impact to cushion and protect the head. Impact-resistant pads and a flexible inner shell enhance the protective design.

Although EEG-based TBI and health monitoring devices do currently exist, a device that combines rugged protective capabilities in combination with monitoring is not currently available. Existing brain monitors are typically stand-alone devices and to date, have not yet been effectively integrated into a protective device, namely a helmet. In addition, most devices on the market or in the development pipeline are not designed for military applications, which presents its own unique set of requirements when compared to sports-centric or other civilian devices.

As such, the combination of a protective shell with an electrode-based monitoring system is a unique application of existing technologies, avoiding any problems of infringing on patent rights. Current solutions on the market only account for one of the two aspects of brain health monitoring. In addition, the needs of the device to survive potentially extended combat operations requires the electronics suite to become ruggedized, and in combination with wireless transmission of health information in near real-time, presents a unique solution to a specific problem that has yet to be addressed.

Competitive Analysis:

The competition in the marketplace for protective headgear and brain injury prevention technologies is multifaceted, reflecting the diverse approaches companies and researchers are taking to mitigate the risks associated with head injuries. While the current solutions are unique, our proposed device presents a novel integration of protective gear with advanced monitoring technology, aiming to fill a critical gap in the current landscape of head injury prevention and management.

Current Solutions

1.) Advanced Combat Helmet (ACH): This solution emphasizes the balance between protection and practicality. The ACH (Figure 2.), with its level 3A ballistic rating, offers substantial defense against handgun rounds and shrapnel, catering to military and law enforcement needs. Its suspension system plays a critical role in absorbing and dispersing the energy from blunt-force impacts, thereby protecting the wearer's brain. The ACH's current status as a standard-issue helmet in many military forces worldwide is testament to its effectiveness and reliability.

2.) Nonlinear Deforming Helmet (Figure 3.): This innovative design introduces a sophisticated approach to impact absorption. By integrating a deformable layer between two rigid ones, the helmet dynamically adjusts to absorb and dissipate shock more efficiently than traditional models. This technology's potential lies in its ability to reduce the force transmitted to the skull and brain, promising enhanced protection against a broader range of impact scenarios. Its performance in real-world applications, especially in sports and motorcycle helmets, could position it as a significant competitor in the protective gear market.
3.) Field Deployable Device (Figure 4.): Focusing on diagnosis rather than prevention, this device represents a shift towards managing the aftermath of head injuries. By enabling in-field concussion diagnosis through EEG electrodes, it offers a practical solution for military, sports, and emergency medical services. The patent protection until 2031 secures its unique position in the market, though its success will depend on its accuracy, ease of use, and integration with treatment protocols.
4.) Wearable Sensing Device (Figure 5.) : Though not a protective device, this technology complements the aforementioned solutions by offering advanced monitoring capabilities. Its high electrode density and wireless data transmission make it ideal for research and potentially for real-time monitoring of athletes or soldiers to detect early signs of concussions or other neurological disturbances. While it currently does not diagnose diseases, future advancements could broaden its application scope.

Figure 2. ACH Ballistic Helmet

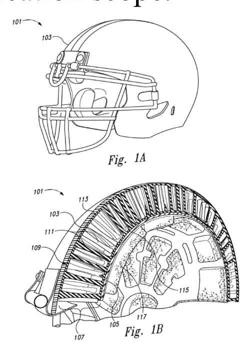


Figure 3. Nonlinear Deforming Elements Helmet

Figure 4. Field Deployment Concussion Device

Figure 5. Wearable Sensing DSI-24

Regulatory:

The device design in question will take existing electroencephalography (EEG) technology and integrate it into a military designed headgear system to create a neural monitoring apparatus that could also be potentially utilized to detect traumatic brain injury. The headset would be implemented into current-issue military helmets and would have the capability to stream in real-time the EEG data recorded from the soldier. Currently, there are devices that are of similar design to the one proposed here, however, these devices are marketed only for research or in-patient use, and are not designed for the rigors and environmental challenges of the battlefield.

As per current FDA regulations, all EEG devices are given a Class 2 designation. As with our device, this headset is capable of wireless transmission of data via Bluetooth technology, although the range is limited to the power of the transmitter. In order to avoid the regulatory concerns associated with claiming this device as an acute life-saving instrument, no real-time analysis and response resulting from the streamed data will be claimed. Our proposed device would be evaluated by the Office of Device Evaluation: Division of Neurological and Physical Medicine Devices. The anticipated regulatory pathway includes seeking a traditional 510(k) based on a predicate device. The predicate device in this instance is one that was cleared by a 510(k)- the Wearable Sensing DSI-24, a dry EEG headset containing 24 electrodes primarily used in research and clinical applications.

As per the EU regulations, our proposed device would fall under the Class I designation. According to (Figure 6), EU Class I medical devices either do not touch the patient or contact only intact skin. The latter holds true for our proposed device.

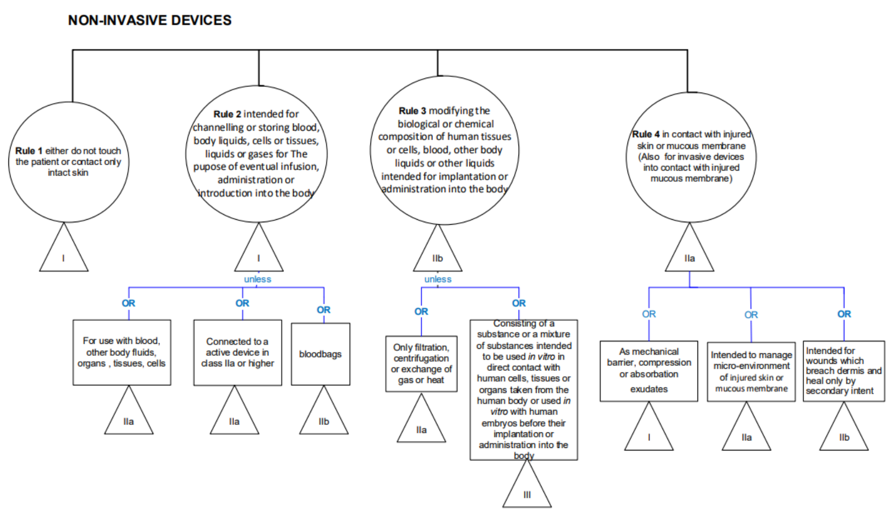


Figure 6. EU medical device non-invasive classification

The device design in question will take existing electroencephalography (EEG) technology and integrate it into a military designed headgear system to create a neural monitoring apparatus that could also be potentially utilized to detect traumatic brain injury. The headset would be implemented into current-issue military helmets and would have the capability to stream in real-time the EEG data recorded from the soldier. Currently, there are devices that are of similar design to the one proposed here, however, these devices are marketed only for research or in-patient use, and are not designed for the rigors and environmental challenges of the battlefield.

As per current FDA regulations, all EEG devices are given a Class 2 designation. As with our device, this headset is capable of wireless transmission of data via Bluetooth technology, although the range is limited to the power of the transmitter. In order to avoid the regulatory concerns associated with claiming this device as an acute life-saving instrument, no real-time analysis and response resulting from the streamed data will be claimed. Our proposed device would be evaluated by the Office of Device Evaluation: Division of Neurological and Physical Medicine Devices. The anticipated regulatory pathway includes seeking a traditional 510(k) based on a predicate device. The predicate device in this instance is one that was cleared by a 510(k)- the Wearable Sensing DSI-24, a dry EEG headset containing 24 electrodes primarily used in research and clinical applications. As per the EU regulations, our proposed device would fall under the Class I designation.

Reimbursement:

Our proposed medical device exhibits a promising potential for Medicare/Medicaid reimbursement, provided it fulfills several critical benchmarks. First, its capacity to significantly enhance patient outcomes, particularly in processing EEG signals and integrating the helmet and EEG headset while maximizing comfortability and durability, is essential. This must be backed by substantial clinical evidence, demonstrating its efficacy and safety. Achieving FDA clearance or approval is crucial , serving the device's reliability and meeting a key prerequisite for reimbursement consideration.

The device's cost-effectiveness is another vital factor. If it presents a more economical or efficient solution compared to current practices, highlighting potential healthcare savings or better patient outcomes, it strengthens our case for reimbursement. Its relevance to significant healthcare challenges, such as TBI — underscored by compliance with recognized engineering standards like ISO 13485:2003 — suggests it addresses a critical need within the healthcare system.

However, achieving reimbursement will also depend on overcoming potential hurdles, such as conclusively demonstrating the device's advantages over existing technologies and ensuring strict compliance with all regulatory, coding, and billing requirements.

To be reimbursable:

Clinical Utility: If the device demonstrates clear clinical utility and contributes to improved patient outcomes, it may be considered for reimbursement. This involves having robust clinical evidence supporting the device's effectiveness in diagnosing or monitoring health conditions.
FDA Clearance or Approval: If our device has received clearance or approval from regulatory bodies such as the FDA, it may enhance its credibility and eligibility for reimbursement.
Cost-Effectiveness: Demonstrating that device provides a cost-effective solution compared to existing methods or technologies can positively impact reimbursement decisions.
Alignment with Healthcare Priorities: If the device addresses critical healthcare needs and aligns with national healthcare priorities, it may be more likely to receive reimbursement support.
Meeting Reimbursement Criteria: Understanding and meeting the specific reimbursement criteria set by Medicare/Medicaid is crucial. This may involve compliance with specific coding and billing requirements.

Challenges to Reimbursement:
Lack of Clinical Evidence: If there is insufficient clinical evidence supporting the efficacy and safety of the device, it may be challenging to secure reimbursement.
Unclear Clinical Benefit: If the clinical benefits of your device are unclear or if existing alternatives are deemed sufficient, reimbursement may be more difficult to achieve.
Regulatory Compliance Issues: Failure to comply with regulatory requirements or obtaining necessary clearances can be a barrier to reimbursement.
Economic Considerations: If the cost of our device is perceived as high without clear evidence of cost-effectiveness, reimbursement may face resistance.
Competing Technologies: If there are established and widely accepted technologies that provide similar benefits, convincing payers of the added value of the device may be challenging.
Coding and Billing Challenges: If a device does not align with existing reimbursement codes or presents challenges in billing and coding, it may face obstacles in the reimbursement process.

Codes:
Diffuse Traumatic Brain Injury (S06.2)
S06.2X1: Loss of consciousness of 30 minutes or less.
S06.2X2: Loss of consciousness of 31 minutes to 59 minutes.
S06.2X4: Loss of consciousness of 6 hours to 24 hours.
S06.2X5: Loss of consciousness greater than 24 hours with return to pre-existing conscious levels.
S06.2X6: Loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving.
S06.2X7: Loss of consciousness of any duration with death due to brain injury prior to regaining consciousness.
S06.2X8: Loss of consciousness of any duration with death due to other causes prior to regaining consciousness.

S06.2X9: Loss of consciousness of unspecified duration.
S06.2XA: Loss of consciousness status unknown.

Focal Traumatic Brain Injury (S06.3)
S06.301: Loss of consciousness of 30 minutes or less.
S06.302: Loss of consciousness of 31 minutes to 59 minutes.
S06.304: Loss of consciousness of 6 hours to 24 hours.
S06.305: Loss of consciousness greater than 24 hours with return to pre-existing conscious level
S06.306: Loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving.
S06.307: Loss of consciousness of any duration with death due to brain injury prior to regaining consciousness.
S06.308: Loss of consciousness of any duration with death due to other causes prior to regaining consciousness.
S06.309: Loss of consciousness of unspecified duration.

Potential Market:

The target demographic for our product primarily consists of individuals within the military profession who have endured traumatic brain injuries as a result of their service. These customers are seeking effective solutions to manage and alleviate the challenges associated with such injuries.

The Traumatic Brain Injury (TBI) assessment market size, valued at approximately $3.3 billion in 2022, is forecasted to surpass $7.2 billion by 2032. This growth trajectory is attributed to the escalating prevalence of traumatic brain injuries and the mounting demand for non-invasive assessment devices. The market expansion is further propelled by the necessity for comprehensive evaluations, precise diagnoses, ongoing monitoring, and treatment planning. For example, statistics from a 2021 publication indicate that about 2.5 million individuals in Europe are estimated to suffer from TBIs, with this figure expected to rise in the forthcoming years.

The global TBI assessment devices market, valued at $2.8 billion in 2021, is projected to grow at a Compound Annual Growth Rate (CAGR) of 8.57% from 2023 to 2028, reaching $4.57 billion by 2028. This growth is driven by several factors including the increasing incidence of road traffic accidents, rising prevalence of TBI cases, a growing senior citizen population aged over 65, and the uptick in regulatory approvals and launches of TBI assessment devices. In summary, the market for TBI assessment devices is expected to experience substantial growth during the forecast period from 2023 to 2028.

As for potential users, considering the prevalence of traumatic brain injuries and the increasing demand for effective assessment tools, there is a significant number of military professionals who could benefit from the use of such products. Given the global nature of the market, diverse distribution channels such as medical supply companies, online platforms, specialized healthcare providers, and government procurement contracts could be utilized to reach the target audience. Pricing strategies would likely vary depending on factors such as product features, competitive landscape, and target market segment, but could generally range from mid to high-tier pricing to reflect the value proposition of the devices.

Funding Strategy:

The primary seed funding strategy of this device is government contracts through DARPA which are awarded based on the innovation of the project itself. In addition, venture capital funds can be utilized provided the device piques the interest of military-centric venture capitalists. Finally, additional funding can be obtained from accelerator and incubator programs.

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