A Device for the Assisted Detection of Neonatal Asphyxia (ADONA)

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Abstract

Hypoxic-ischemic encephalopathy (HIE) is a condition that arises from inadequate oxygen delivery or blood flow to the brain around the time of birth, resulting in long-term neurological damage. HIE is responsible for up to 23% of neonatal deaths worldwide. While effective treatments exist, current diagnostic methods require specialized neurologists to analyze an infant's electroencephalography (EEG) signal, requiring significant time and labor. In areas where such resources and specialized training are even scarcer, the challenges are even more pronounced, leading to delayed or complete lack of treatment, and poorer patient outcomes.

The Assisted Detection of Neonatal Asphyxia (ADONA) device is a non-invasive screening tool that streamlines the detection of HIE. ADONA is an EEG helmet that collects, wirelessly transmits, and automatically classifies EEG data using a proprietary machine learning algorithm in under two minutes. Our device is low-cost, automated, user-friendly, and maintains the accuracy and reliability of a trained neurologist.

Our classification algorithm was trained using 1100 hours of annotated neonatal EEG data and achieved >85% specificity and >90% sensitivity on an independent 200 hour dataset. Our device is now entering final stages of development to reduce production costs, form factor, and ensure regulatory compliance. Our hope is that ADONA will turn the promise of a safer birth into a reality for families all across the world, ensuring instant peace of mind and equitable access to healthcare, for every child and their families.

Background

Inadequate oxygen delivery or blood flow to the brain around the time of birth can cause significant acute and long-term neurological damage, as well as widespread multisystem cardiovascular and respiratory failure.[1] Hypoxic-ischemic encephalopathy (HIE), secondary to perinatal asphyxia, is the leading cause of death and disability in full-term neonates, especially in low-to-middle income countries.[2] Therapeutic hypothermia has been shown to be an effective treatment for neonatal HIE and successfully reduce adverse neurological outcome in early infancy; however, the window for diagnosis and treatment is extremely short and sensitive.[3] The gold standard of diagnosis is electroencephalography (EEG), which has been shown to predict short-term outcomes of HIE and can help clinicians determine which infants may benefit from therapeutic hypothermia.[1,4] Abnormal patterns in the normal background pattern of EEG have been correlated with severity of neonatal HIE.[5]

However, review of the EEG demands specialist expertise, which is not consistently accessible in neonatal intensive care units (NICUs), and physician-led evaluations struggle to keep pace with the high volume of neonates requiring assessment within the critical time frame for diagnosis.[2] As such, there exists a need for a rapid, automated diagnostic tool capable of identifying patterns of perinatal HIE through ambulatory EEG (aEEG) and direct physicians to initiate treatment directly after birth. Our proposed solution is an adjustable, centralized helmet device that collects multi-electrode aEEG data for machine-based identification of HIE. Our device will be trained on open-access physician-graded EEG data sets collected from neonates with varying severity of HIE.[2] We anticipate that the automation of the diagnostic process and seamless integration of this device into existing OB/GYN practices will alleviate the existing burden on neonatal neurologists to diagnose HIE within a critical time frame, and allow

physicians to rapidly diagnose HIE and initiate treatment, ultimately improving long-term neurological outcomes.

Of the 1 in 500 neonates who suffer from HIE, 60% will sustain permanent neurological disability or die before the age of 2.[6] HIE is responsible for 23% of neonatal deaths worldwide, making it the 5th leading cause of death for children under the age of 5.[7,8] ADONA's capabilities, with >85% sensitivity and specificity across all four grades, offer a breakthrough in early diagnosis and intervention. By bridging the gap between medical expertise and technology, ADONA will not only save lives but reduce costs, environmental burdens, and the profound psychological toll on families dealing with the consequences of delayed diagnoses.

Table 1. Needs specification and requirements for the ADONA device.

Criterion	Target	Justification
Speed	<2 minutes	Maximum time from placing helmet on infant to collecting risk diagnosis to ensure rapid screening.
Sensitivity	>85%	Established clinical standard for pediatric neurological diagnostic devices.[9]
Specificity	>85%	
Repeatability	100%	Ensures consistent measurements across trials.
Number of Electrodes	9	Minimum number of channels required for accurate grading.[10]
Interface Circumference	5.02"	Fits various newborn head sizes with adjustable velcro straps and flexible material properties.[11]

To our knowledge, there are no existing devices capable of aiding in HIE diagnosis. Current methods include physical observation or standard EEG readouts through a specialist. Physical observation is fast but provides minimal sensitivity and specificity, whereas a standard EEG readout lacks portability and speed requirements (**Table 3**). ADONA matches current EEG readout accuracy while expanding to an automated, wireless mechanism.

Project Overview

## Objectives, Design Goals, and Mechanism
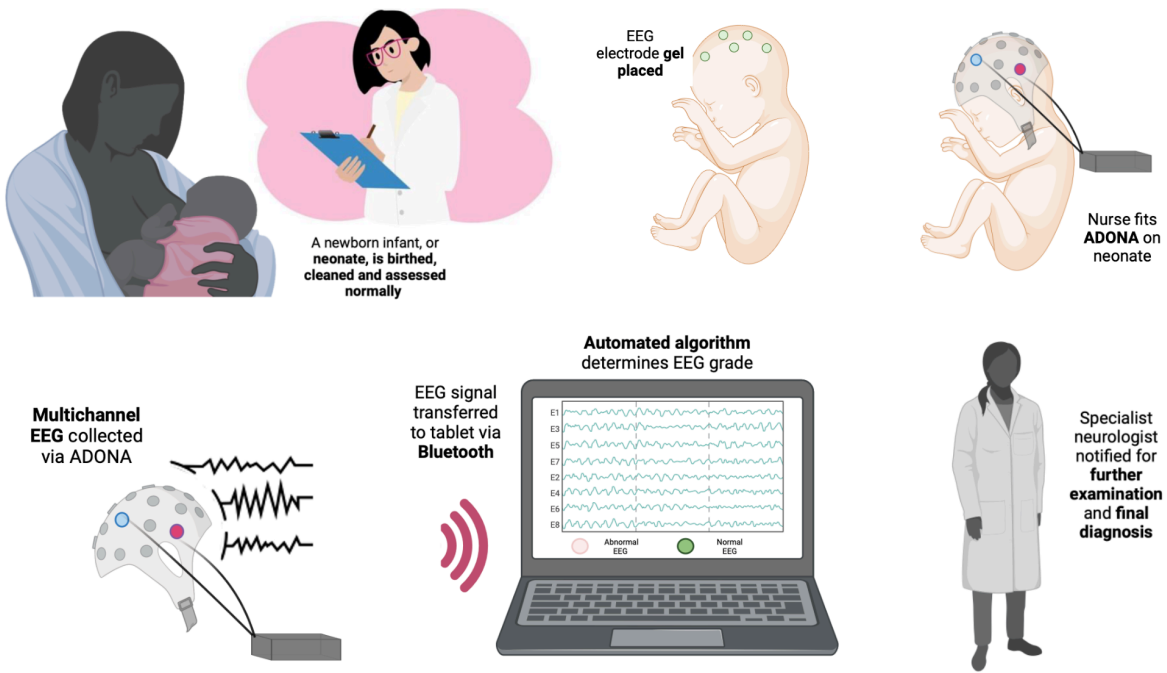
Figure 1. Intended integration of ADONA into existing clinical workflows. As part of a standardized postpartum clinical testing routine, a newborn infant will have multichannel EEG data collected by ADONA for one minute, prior to receiving a risk diagnosis and alerting a specialist neurologist (if necessary) for further examination and final diagnosis.

ADONA will improve the burden on nurses in the neonatal space, while also providing peace of mind to the mother. Moreover, it will directly help the newborn by ensuring that no case of HIE goes undetected. ADONA will integrate into existing clinical workflows; after the baby is birthed, cleaned, and assessed with traditional tests such as the APGAR score, a NICU nurse will fit ADONA onto the newborn (**Figure 1**).

Our helmet is lightweight, and minimizes the required hardware of a standard EEG machine down to nine electrodes. It is also comfortable to wear for a variety of neonatal head circumferences and utilizes a spring-based adjustable electrode contact mechanism to ensure stable, yet gentle pressure on the infant's head during EEG collection (**Figure 2**). The collected data will then be wirelessly communicated to a nearby tablet via Bluetooth. After a minute of

data collection, the hat will be removed. The ADONA algorithm will then rapidly grade the collected EEG traces, alerting the nurse to notify a neurologist if a dangerous score is detected.
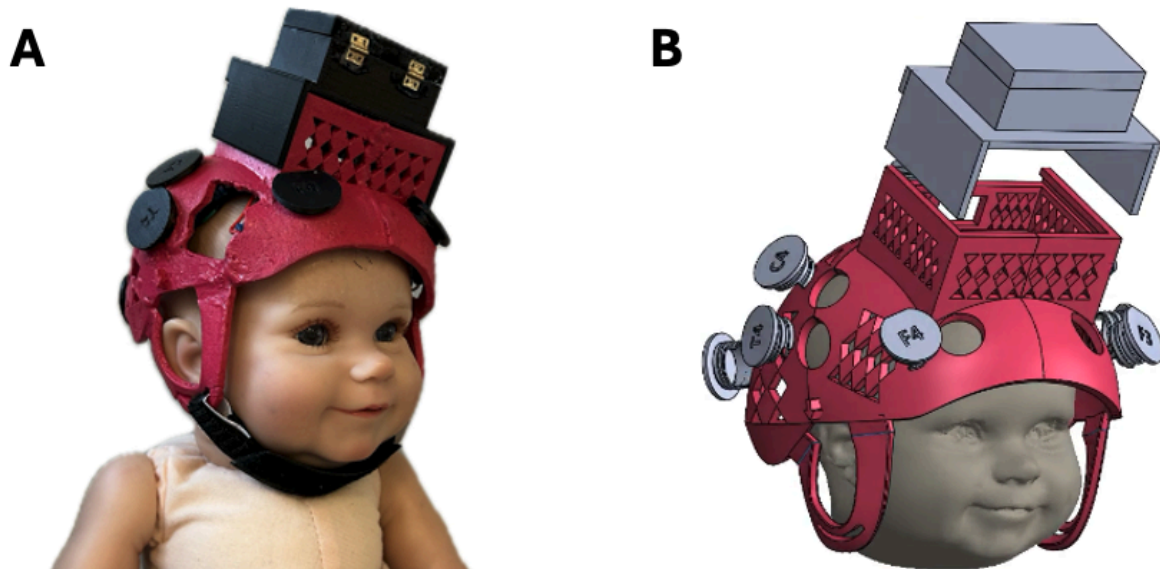
Figure 2. Final prototype of ADONA presented on A) baby model and B) in CAD form. Our lightweight and adjustable helmet design features a nine-electrode, spring-adjustable EEG electrode configuration, with a centralized electronics compartment that communicates wirelessly with external devices. The manufacturing material, Agilus 30, accommodates a range of neonatal head sizes.

Our final prototype is able to operate within this desired workflow, and fulfills all the aforementioned needs specifications (**Table 1**). As such, ADONA is a clear improvement on existing standards of care, which include physical observation by a physician and the use of standard EEG machines, at just a fraction of the cost (**Table 3**).

Table 2. Product specifications for final prototype of ADONA.

Product Feature	Specifications
Interface Circumference	5.02"
Material	Agilus 30
Electrodes	AgCl 15.5mm Diameter Flat Contact Electrodes
Software Platform	MATLAB (Mathworks, 2023)
Classification Model	Multiclass Support Vector Machine (SVM)
Classification Time	1 minute
Classification Accuracy	97% ($n=53$)
Classification Repeatability	100% ($n=53$)
Classification Sensitivity	>85% across all grades ($n=53$)
Classification Specificity	>85% across all grades ($n=53$)
Software Filters and Cutoffs	5th Order Chebyshev Type II (0.5-35 Hz) Anti-aliasing (64 Hz)
Sampling Rate	200 Hz (via Arduino MKR 1010)

Table 3. Differentiation of ADONA from existing processes.

Criterion	Physical Observation	Standard EEG	ADONA
Sensitivity	Low	High	High
Ease of Use	N/A	Difficult	Simple
Automated	No	No	Yes
Wireless	N/A	No	Yes
Cost	N/A	$10,000+	$1000

Impacts

We envision ADONA being used as a tool to significantly reduce the mortality and disability rate caused by undiagnosed cases of HIE worldwide. As a universal screening and diagnostic aid, our vision is that ADONA will be integrated into standard post-conception assessment protocols, ensuring that infants are not silently suffering after birth. ADONA reduces the burden on specialized neurologists, as well as alleviating the economic burden on hospitals to have neurologists manually screen infants. Consequently, this allows the product to reach hospitals globally, as the device can be applied in low and moderate income countries, where expensive EEG machines or specialized neurology training may not necessarily be available. While ADONA may not have a significant impact environmentally, the security that it provides to a mother after birth will have significant social impacts.

Limitations

In order to centralize and reduce the necessary hardware for EEG collection, our design utilizes less filtering apparatus and less electrode inputs, thus reducing the resolution and stability of the collected EEG signal. However, collecting raw, unfiltered signals also presents an opportunity to extract more features for classification, but the balance between sufficient data resolution and unique feature extraction is extremely delicate. Another limitation of our design is the potential for misalignment of the cap on the infant head and improper electrode localization. However, our design includes physical markings on the cap to guide proper placement, and our material selection, in addition to the spring-adjustable electrode contacts, should provide sufficient margins of error. Moreover, one functionality of our device that we have not yet explored is the potential to store and preserve collected data for post-hoc reference, which could be critical in future clinician decision-making.

Standards & Regulations

ADONA is classified as a Class II Medical Device according to the FDA under Code of Federal Regulations (CFR) Title 21 882.1400 (OMA).[12] This classification applies to devices that "measure and record electrical activity by acquisition of amplitude-integrated EEG". Class II devices must be accompanied by a 510(k) premarket notification, but not premarket approval, due to the established nature of EEG technology.[12] For FDA 510(k) clearance, ADONA must undergo clinical and electrical safety testing, software validation, biological risk assessment, and biocompatibility testing.[13] Our device also requires consideration of usability and human factors, as neonate size, weight, and physiological differences can greatly impact interface design, ergonomics, and ease of use. A similar Class II FDA-cleared device is the Arc EEG software by *Cadwell Industries, Inc,* which interfaces EEG test results with a platform for epilepsy monitoring.[14] In addition, our device is overseen by the Association for the Advancement of Medical Instrumentation (AAMI); standard EC53:2001 regulates the safety and requirements of the electrodes that are utilized in ADONA.[15] Internationally, ADONA falls under the purview of the International Electrochemical Commission (IEC) and the World Health Organization (WHO). The IEC controls global standards for electrical and electronic devices, while WHO provides worldwide guidance on medical devices.[16, 17]

Testing & Evaluation

The goal of our validation studies was to confirm that our device meets three key testable needs specifications; namely, the speed, accuracy, and repeatability of our algorithm (**Table 1**). Allotting 30±10 seconds for device operation and location, and 60 seconds to collect data, our device should take at most 30±10 seconds for signal analysis and grading. Our specificity/sensitivity and repeatability criteria of 85% and 100%, respectively, were based on FDA standards for similar neurological screening tools. A secondary goal was to validate design choices relating to our machine learning algorithm.

Our algorithm was trained on 1100 hours of open-source neonatal EEG data collated from the Hospital for Sick Children, Toronto, Canada and Helsinki University Hospital, Helsinki, Finland.[10,18] Recordings were collected up to the first five postnatal days from a previously published clinical cohort of 58 neonates with clinical signs of neonatal hypoxic-ischemic encephalopathy. Each recording was scored and annotated by two independent clinicians. An important consideration in training was to ensure that our algorithm was robust to various recording systems, sampling frequencies, and electrode positions. Our training dataset included data recorded using Xltek Brain Monitor ICU systems (Natus Neurology, Ontario, Canada) or NicoletOne ICU Monitor (Natus, Wisconsin, United States) at 200, 250, or 256 Hz, with 4-20 electrodes positioned according to the international 10-20 placements. We ensured an appropriate spread of annotated grades in our training data, with slight bias towards recordings labeled as healthy ("1") and high risk ("4") to ensure a high sensitivity and specificity for these grades. A five-fold cross validation scheme was implemented to minimize training bias, and the final training accuracy that we reported was 97.9±0.4%.

Validation Procedure

A unique challenge to validating neonatal EEG devices is that there are no established validation models. Our team developed our own custom low-cost validation model (**Figure 3**). Over 200 hours of neonatal EEG data sourced from the Cork University Maternity Hospital, Ireland and Barnes-Jewish Hospital, Missouri, United States was downloaded onto our validation system.[2,19] This data was collected using the NicoletOne ICU Monitor and Neurofax EEG-1200 (Nihon Kohden, Tokyo, Japan) at either 200 or 256 Hz from 53 infants. Our algorithm was completely blinded to this testing dataset during training to minimize training bias.
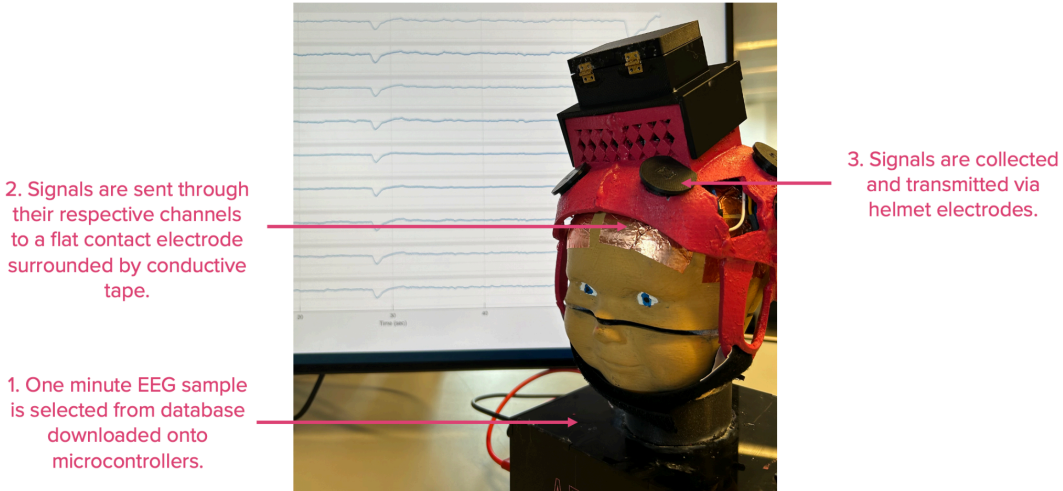
Figure 3. The ADONA validation system. Over 200 hours of neonatal EEG traces were downloaded onto five microcontrollers, which can select 1-minute samples to send to flat contact electrodes and conductive tape to their appropriate anatomical locations on a custom-printed neonate head. These signals were collected and transmitted by the ADONA helmet for grading.

For validation, we transmitted and collected a total of 10,715 one-minute epochs with three technical replicates for each epoch to provide adequate data for repeatability assessment. ADONA is a novel device; as such, there are no existing devices currently available in the clinic to use as a meaningful comparison. We compared our output grading to the annotations provided by two independent clinicians. To summarize our model's performance across multiple grades, we chose to report our results using a confusion matrix, with sensitivity and specificity

calculations for each grade. Statistics will be performed to evaluate the standard error of the mean (SEM) in each grade to understand the precision of the validation mean in estimating the long-term performance of the device.

Validation Results
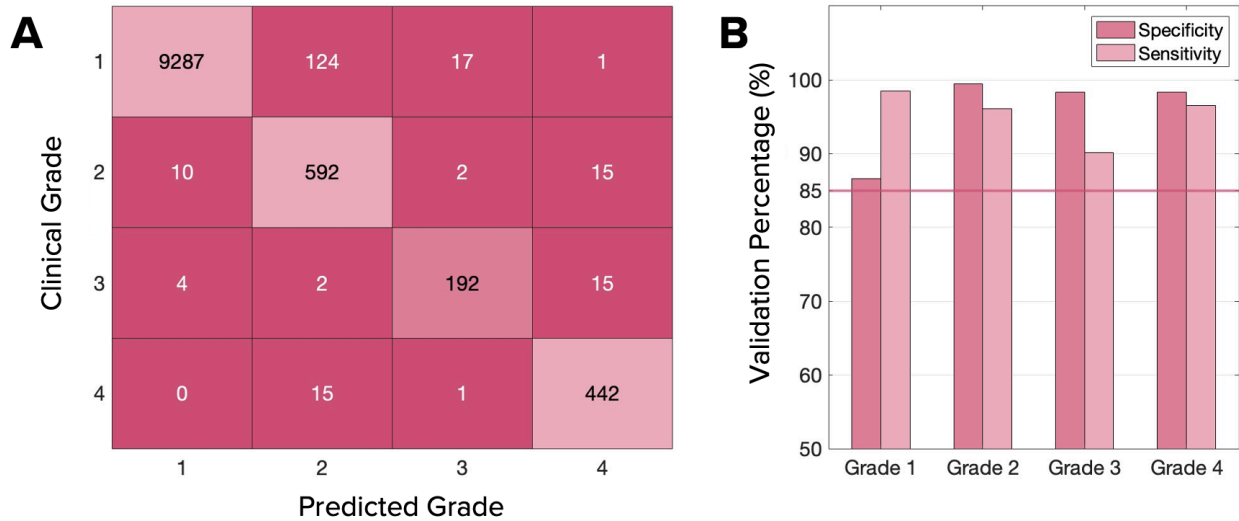
Figure 4. Summarized results from validation studies. (A) Confusion matrix of the algorithm's output and annotated grade by expert clinicians. High agreeableness is found across all four grades using open-source EEG recordings (*n*=53) with a total 97% classification accuracy. (B) Sensitivity and specificity across all four grades exceeded the target specification of 85%.

ADONA reported results within 5.2±1.4 seconds, with a diagnostic accuracy of 97.3±0.8% and 100.0±0.0% repeatability (reported as mean ± SEM). Our testing accuracy was not statistically different to our training accuracy (*t-test, p>0.05*), suggesting that our algorithm was not overfit to our training dataset. Validation results are summarized using a confusion matrix (**Figure 4**). Our findings demonstrate that automated classification of neonatal EEG is possible with high accuracy. As illustrated in **Figure 4**, misclassification is usually only 1 grade away, with limited exceptions. Given the intended context of our device as a high-throughput screening tool, our key goals were to maintain a high specificity for low risk, and high sensitivity for high risk, which our device ultimately fulfilled.
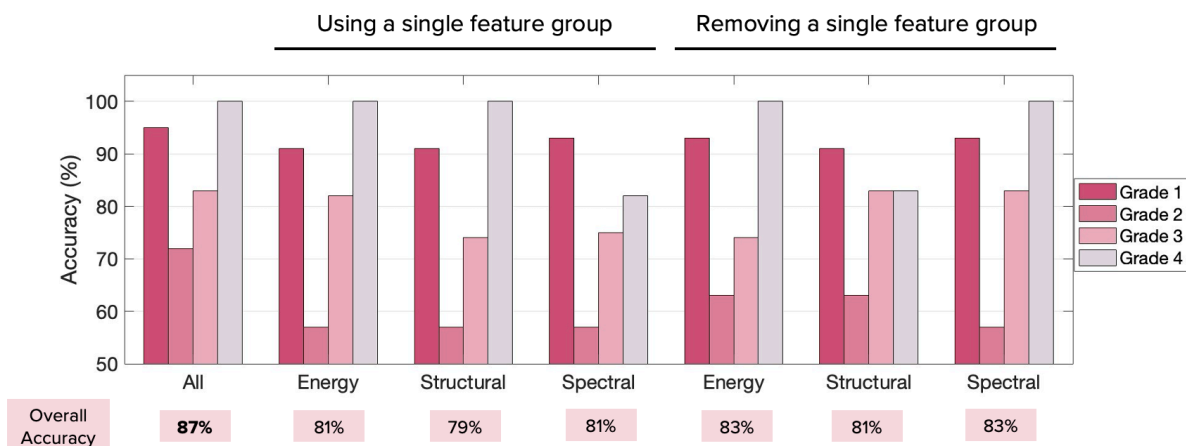
Figure 5. Contribution of each feature group to the overall and individual grade accuracy. Highest overall accuracy is achieved when all feature groups are included, and system accuracy degrades the most when structural features are removed from the original feature set.

A secondary goal of our validation studies was to validate and justify particular algorithm design choices by comparing model performance using smaller subsets of our training data (50% of original) and testing data (50% of original) with two technical replicates. Firstly, we examined the contribution of the individual feature groups as described in **Figure 5**. System accuracy was maximized when all features were evaluated, and degraded significantly when structural features were removed from the original feature set.
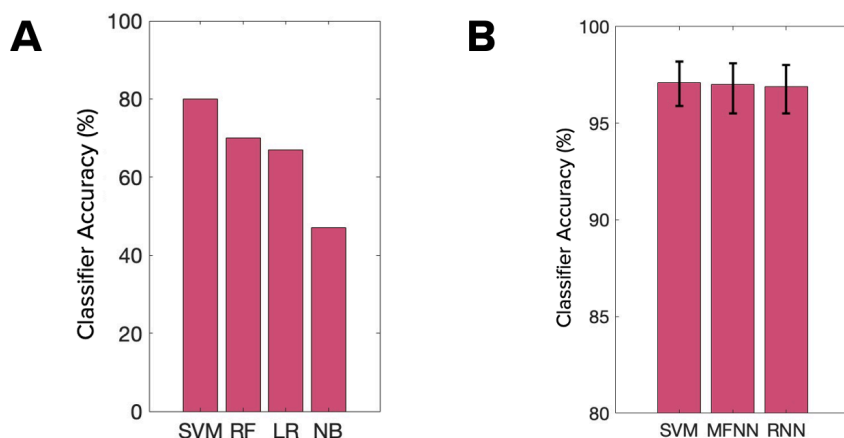
Figure 6. Comparison of support vector machine (SVM) performance in comparison to other feature-based and neural network models. (A) SVM outperforms random forest (RF), logistic regression (LR), and naive bayes (NB) and shows (B) no significant difference compared to more computationally-intensive neural network models, including multilayer feed-forward neural network (MFNN) and recurrent neural network (RNN).

In addition, our selected classification model, the support vector machine, significantly outperformed every other feature-based approach (*t-test, p<0.05*), and was statistically comparable to more computationally complex and intensive deep learning models (*t-test, p>0.05*), validating our design choice (**Figure 6**).

There are inherent limitations in our validation studies that should be acknowledged, which may necessitate further testing to further refine and validate ADONA's capabilities. The most prominent bottleneck to further classifier development is the lack of readily accessible, annotated neonatal EEG data. The device's performance was evaluated against a relatively small clinical cohort, which, although diverse, may not capture the full spectrum of HIE variations or co-occurring neonatal conditions that could affect EEG patterns. Future testing might benefit from developing broader industry standards for neonatal EEG device validation, which could include larger, more diverse datasets and standardized testing protocols to ensure reproducibility and comparability of results across different studies and devices. With regulatory approval, future testing would involve assessing ADONA's performance with live, clinical EEG recordings from neonates, as opposed to retrospective analysis of recorded data. Such testing would provide valuable insights into the practical usability and effectiveness of ADONA in neonatal care.

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Appendix

A. Bill of Materials

Category	Item	Quantity	Manufacturer	Cost (USD)
Mechanical	3D Printed Helmet (Agilus 30)	1	Children's Hospital of Pennsylvania CHAMP Lab	$300.00*
	3D Printed Electrode Housing (ABS)	9	University of Pennsylvania Venture Lab	$0.96*
	Assorted Stainless Steel Compression Springs *(B0C6KRQMSV)*	9	YUUGU	$0.24
	½ Inch Velcro Strip *(CT-50)*	1	NBTORCH	$0.26
	Hinges *(B07QJB55XQ)*	1	Hicarer	$0.17
	Small Magnet *(B0BWD7H7Z9)*	4	VSKIZ	$0.08
Electrical	Printed Circuit Board	1	OSH Park	$29.90
	Arduino MKR Wifi 1010 *(ABX00023)*	1	Arduino	$38.60
	Multiplexer *(CD74HC4051E)*	1	Texas Instruments	$0.22
	0.1 µF Ceramic Capacitor *(CL05A104KA5NNNC)*	1	Samsung Electro-Mechanics	$0.10
	1 µF Ceramic Capacitor *(GRM155R61H105ME05D)*	9	Samsung Electro-Mechanics	$0.90
	Diodes *(BAS16J,135)*	18	Nexperia USA Inc.	$3.78
	3.3 kΩ Resistors *(CR0402-FX-3301GLF)*	9	Bourns Inc	$0.90
	2.54mm Male Pin Header Connector *(RS-70)*	10	Risingsaplings	$6.49

	Item	Quantity	Manufacturer	Price
	2.54mm Female Pin Header Connector (*P-037*)	28	Ruibapa	$9.99
	5V Linear Voltage Regulator (*LM7805*)	1	STMicroelectronics	$1.05
	9 Volt Alkaline Batteries (*B00MH4QM1S*)	1	Amazon Basics	$1.50
	9 Volt Battery Connector (*B08SL9X2YC*)	1	VWEICYY	$0.49
	EEG Flat Snap Electrodes	9	OpenBCI	$45.00
	EMG/ECG Snap Electrode Cables	9	OpenBCI	$48.00
	Rocker Switch (*RA1113112R*)	1	E-Switch	$0.67
Software	Arduino IDE	1	Arduino	$0.00
	MATLAB Compiler	1	MathWorks	$99.00*

***** *Estimate of cost, as materials were procured free of charge via student licenses and/or partnerships through the University of Pennsylvania.*

B. Build Procedure

Part 1 - PCB Assembly
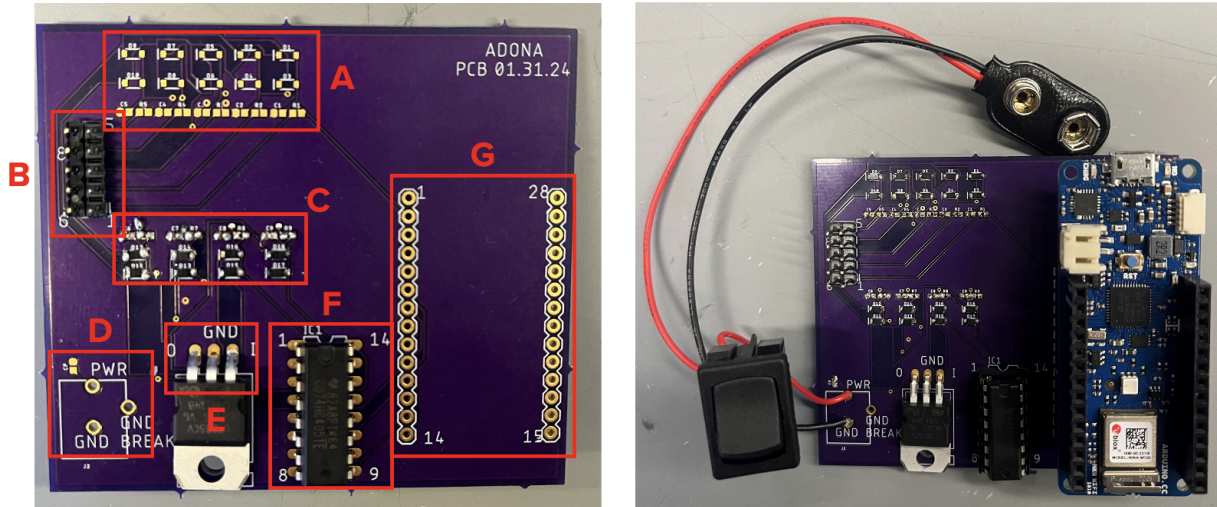
Supplemental Figure B1. *Labeled diagram and fully assembled picture of physical Printed Circuit Board (PCB).*

a. Solder all components in **section A**. Solder diodes into positions marked D1-D10, 1μF capacitors into positions marked C1-C5, and 3.3k resistors into positions marked R1-R5. All components should be soldered with the text in the same orientation as the *'ADONA'* marking on the top right of the PCB.

b. Solder male pin header connectors into **section B**.

c. Solder all components in **section C**. Solder diodes into positions marked D11-D18, 1μF capacitors into positions marked C6-C9, and 3.3k resistors into positions marked R6-R9.

d. Solder all components in **section D**. Solder a 0.1μF capacitor into the position marked CP. Then, solder the power and ground connections of the battery connector to their appropriately marked pins. Ensure that the battery is soldered to or operable using a rocker switch.

e. Solder the 5V regulator into **section E**.

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f. Solder the multiplexer into **section F**.

g. Solder female pin header connectors into **section G**. Once the headers have been soldered into the board, insert the Arduino MKR 1010 with the correct orientation. Once completed, the PCB should be fully assembled (refer to **Supp. Figure B1**).

Part 2 - Helmet Assembly

a. Insert each electrode housing part into its appropriate location on the helmet.

b. Attach an electrode cable to each housing part. Use a small dot of superglue (or equivalent) to firstly attach the spring in the center of each housing. Glue the other end of the spring to the cable as shown below.

c. Attach a flat snap electrode attachment to each cable.
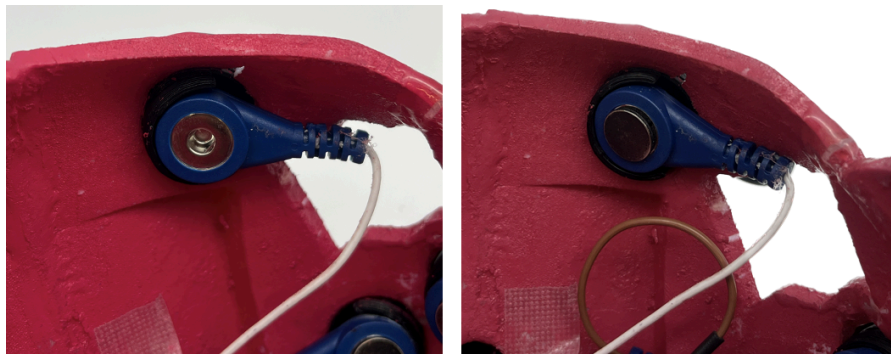
d. Cut two complimentary (hook and loop) ~20 cm lengths of velcro tape.

e. Wrap each length of velcro tape around the chin strap holder as shown below.

f. Insert the assembled PCB into the electronics compartment at the top of the helmet.

g. Wire each individual cable through the slit at the crown of the helmet and wire them to the eight male pin header connectors on the PCB. Each cable should be attached according to their position of the helmet. Refer to the appropriate markings on the PCB.

PCB VIEW   BOTTOM VIEW
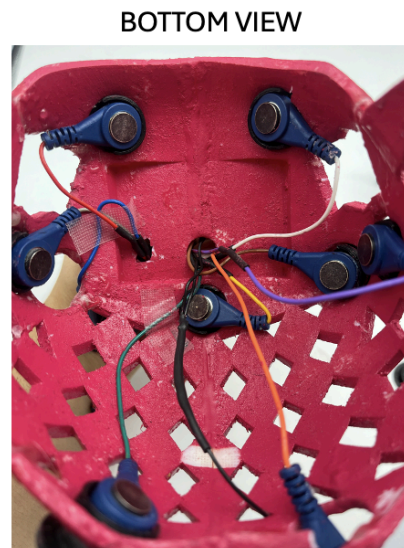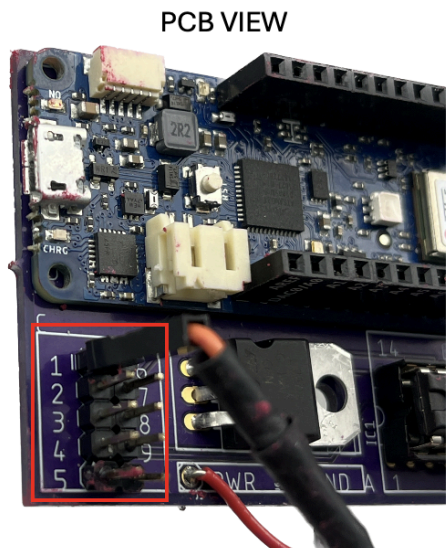
h. Place the lid of the electronics compartment on the helmet, using small magnets to secure the lid in place.

INSIDE ADONA VIEW   CASING VIEW
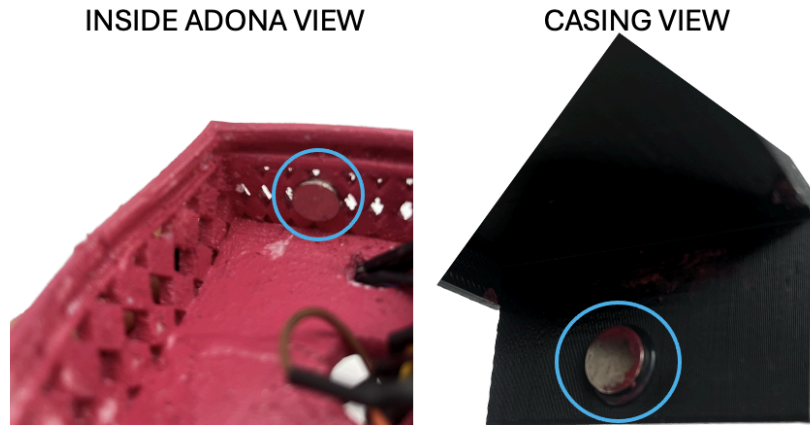
i. Use a small amount of glue to fix the rocker switch into its appropriate cut-out in the compartment.

j. Attach a battery to the PCB using the soldered battery connector. Turn the switch to the 'on' position. A light should appear on the Arduino MKR1010 chip. Once verified, return the switch to the 'off' position.

k. Use two small hinges to secure the lid of the battery compartment in place.

l. Enclose the electronics compartment. The helmet is now fully assembled and ready for use (refer to **Supp. Figure B2**).

Supplemental Figure B2. *Fully assembled helmet shown on baby model.*

Part 3 - Software Set-Up

a. Download and launch the executable ADONA file on an external device.

b. Refer to the instructions on the User Manual (**Appendix Part C**) to pair the ADONA device to your external device. Note that no calibration or additional set-up is required for the device to operate.

C. User Manual

Device Description & Intended Use

The Assisted Detection of Neonatal Asphyxia (ADONA) device is a streamlined diagnostic aid tool that allows for automated clinical screening of hypoxic-ischemic encephalopathy (HIE) in neonatal infants. The device is composed of an adjustable, nine-electrode electroencephalogram (EEG) cap, and an accompanying graphical user interface (GUI) software with a proprietary HIE detection algorithm.

ADONA is intended for use in clinical and hospital settings, including labor, delivery, and recovery rooms (LDRs) and neonatal intensive care units (NICUs). Safe and appropriate device usage requires no specialized training. The successful application of our device can be completed in under two minutes and is designed such that it integrates seamlessly with existing clinical workflows. Once a neonate is born and assessed (typically by an allied healthcare provider), the ADONA device is fitted on, and the software can be launched to collect and transmit up to a minute of live EEG data. Once collection is complete, the algorithm will output a HIE risk score on a scale from 1 (low) to 4 (severe).

Cautionary Statements & Safety Considerations

Use as directed. The ADONA device is intended for use by qualified healthcare professionals only. It should not be used for purposes other than clinical screening of hypoxic-ischemic encephalopathy (HIE) in neonatal infants.

Handle with care. Dropping or mishandling the EEG cap may result in damage or inaccurate readings.

Electrode positioning. Ensure that the electrodes are correctly positioned on the infant's head according to this manual. Incorrect placement may lead to inaccurate HIE risk assessments. Do not apply electrodes to damaged or sensitive skin.

Electrical safety. ADONA includes electrical components. This device should be used in accordance with appropriate electrical safety standards. Ensure all components are free from damage before use. If a malfunction occurs, immediately remove the electrode cap from the patient and turn off the device.

Compatibility. Do not use the ADONA device in conjunction with other electrical medical devices without confirming compatibility, as this may result in interference or inaccurate results.

Device Sanitization. Follow the recommended guidelines for cleaning and disinfecting the device between uses to prevent cross-contamination between patients.

Device Limitations. Understand the limitations of the ADONA device. It is designed to aid in the detection of HIE risk but does not replace comprehensive clinical evaluation and diagnosis by a qualified healthcare professional.

Signal Interference. Be aware of potential electromagnetic interference in the clinical setting, and ensure that the device is being used in an appropriate environment.

Device Users. ADONA is not intended for use on adults or children above the age of 1 week.

Directions for Use

1) **Install the ADONA software package** on a computer or laptop device.

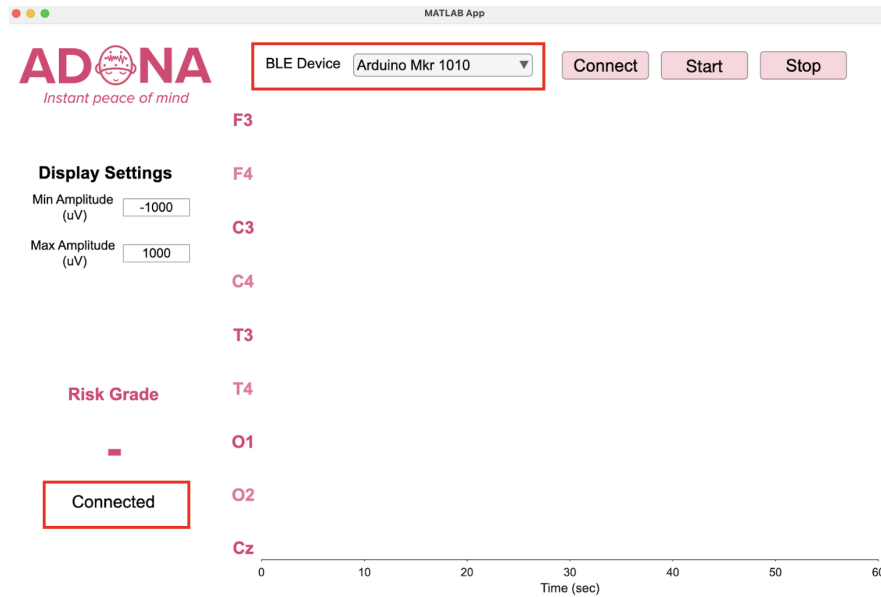2) **Open the ADONA software package.** The graphical user interface (GUI) will appear after a brief moment.
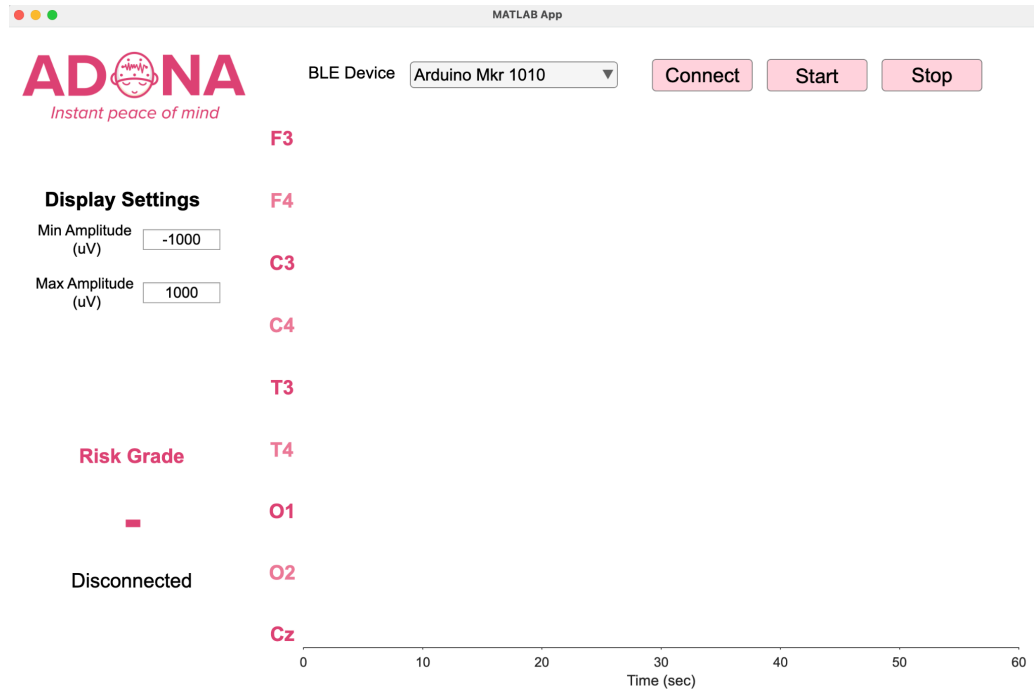
3) **Turn the device on** using the switch at the back of the helmet.

4) After approximately 10 seconds, **select the correct Bluetooth device** from the drop-down menu on the GUI. The GUI will confirm that the device has successfully connected at the bottom left of the screen.


5) **Spread a thin layer of electrode gel** over the infant's head. Apply as evenly as possible.

5) **Place the cap on the infant's head.** Ensure that the electrodes are positioned correctly. Align the upper helix of the infant's ears with the indicators imprinted on the side of the helmet. Ensure a stable fit on the infant's head using the chin strap.

6) **Select the 'Start' button from the GUI window to begin collecting EEG data.** Traces from the nine electrodes should appear on your screen. Adjust the viewing parameters on the left side of the screen to view the entirety of the trace. Minimize infant head movement as much as possible during signal acquisition.
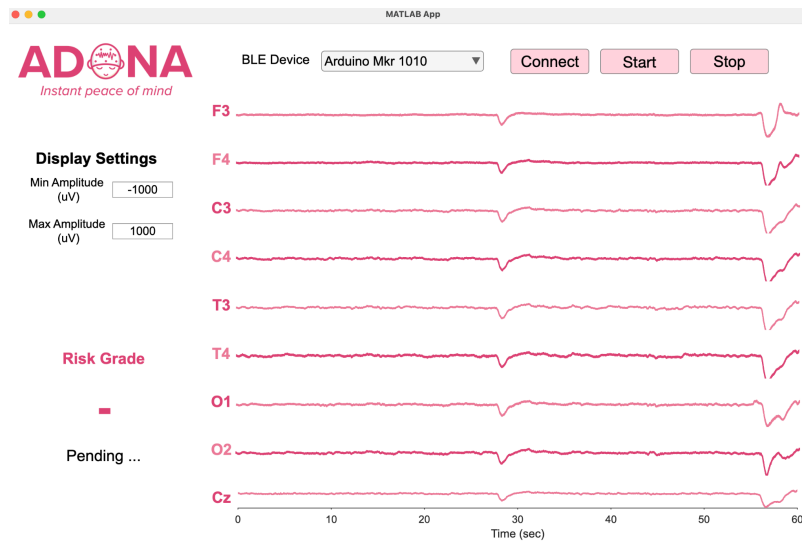
To stop acquisition at any point, select the 'Stop' button from the GUI window to clear existing data and restart acquisition.

7) Once a minute of data has been acquired, the software will begin analyzing the results. After a brief period of time, the **risk grade will appear** on the left side of the screen. Based on this risk score, an appropriate healthcare professional should be contacted for further diagnosis.
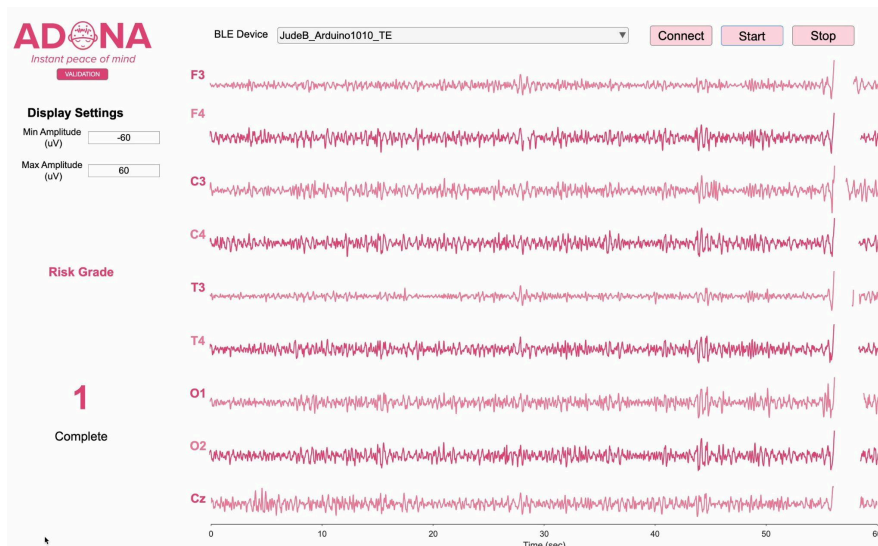
8) To **turn off the device**, close the software, and toggle the switch on the back of the helmet to the 'off' position. Remove any visible contamination or electrode gel from the electrodes using a soft, disposable cloth or pad. Use a hospital-grade disinfectant to gently clean the electrodes, and wipe dry before re-use.

Troubleshooting Tips

Helmet Operation:

- **If the device does not power on**, check for damaged or loose wiring in the main compartment of the helmet. If all connections are stable, try replacing the 9V battery, which is housed in the main compartment.

- **If the helmet becomes loose during signal acquisition**, press the 'Stop' button on the software, adjust the helmet positioning, and press 'Start' to restart acquisition.

- **If one or more channels are not recording**, remove the appropriate electrode housing from the helmet, disconnect the electrode and cable, and wipe any debris or contaminants off the electrode, before returning it to the original position. If the problem persists, replace the electrode and/or housing entirely.

- **If the signal quality is poor**, ensure that the EEG cap is fitted snugly on the neonate's head without being too tight. Follow the appropriate placement guidelines. Ensure the skin under each electrode is unobstructed and appropriately gelled before placement. Any other oils, moisture, or debris can affect signal quality.

Software Operation:

- **If the entire signal is not visible on-screen**, use the window on the left-hand side of the screen to adjust the 'Min' and 'Max' amplitude values for a more appropriate viewing window.

- **If the device fails to connect**, switch the device off and ensure that an adequate period of time passes before searching for the device on the drop-down menu. If the problem persists, open the main compartment. You should see lights blinking on the Bluetooth chip when the switch is turned on. If no lights are present, the Bluetooth chip will need to be replaced.

- **If the output grade is not present or N/A**, ensure proper electrode contact and signal tracing from each channel during signal acquisition. Contact a healthcare professional if the result is ambiguous.

- **If the software does not launch or crashes**, ensure the software is updated to the latest version. Outdated software can lead to compatibility issues or crashes.
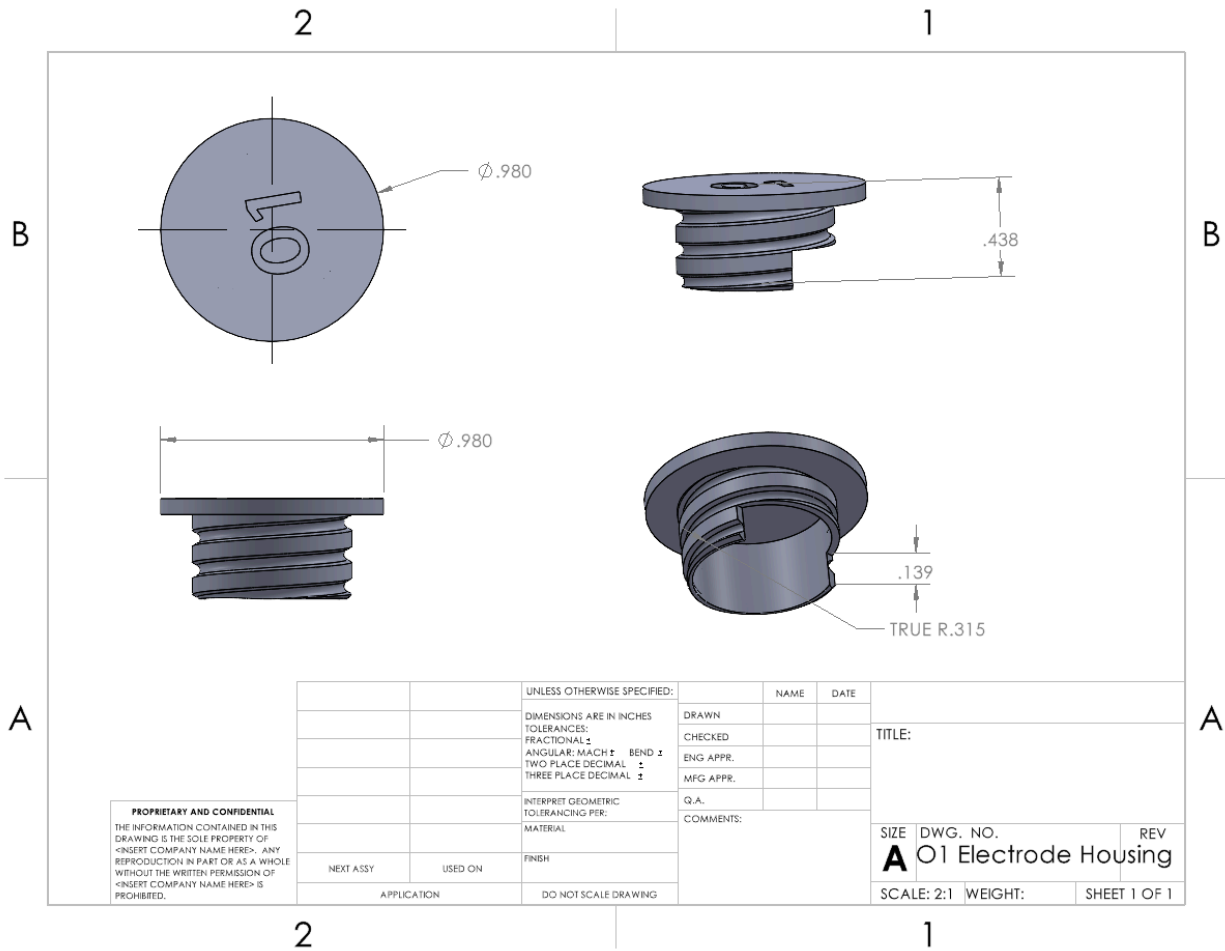
Additional Tips:

- **Document error messages** as they appear, as these can provide valuable clues to the technical support team.

- **Safety first**. Prioritize safety and do not attempt repairs or adjustments that require professional service.

D. Engineering drawings
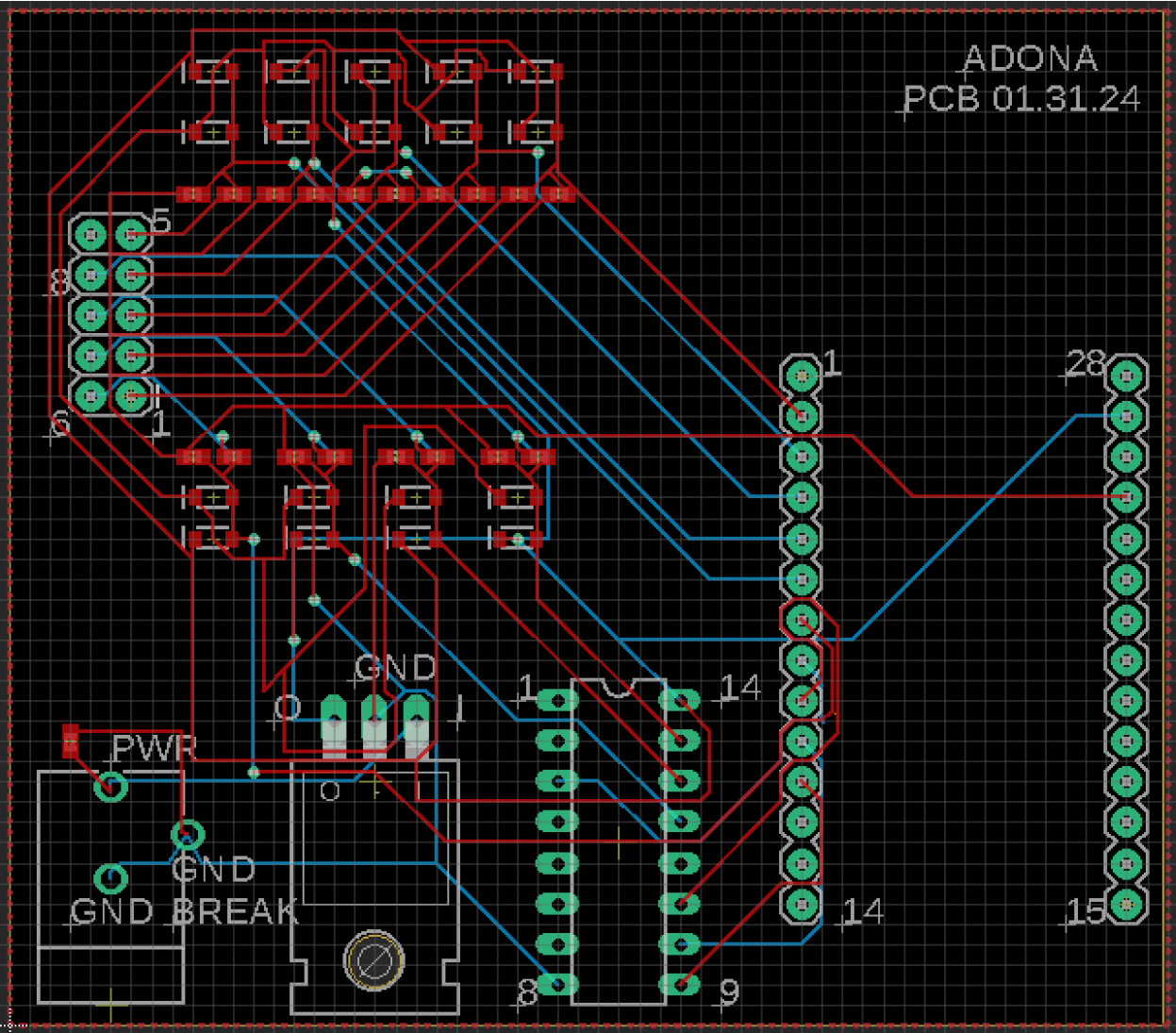
Mechanical Drawings
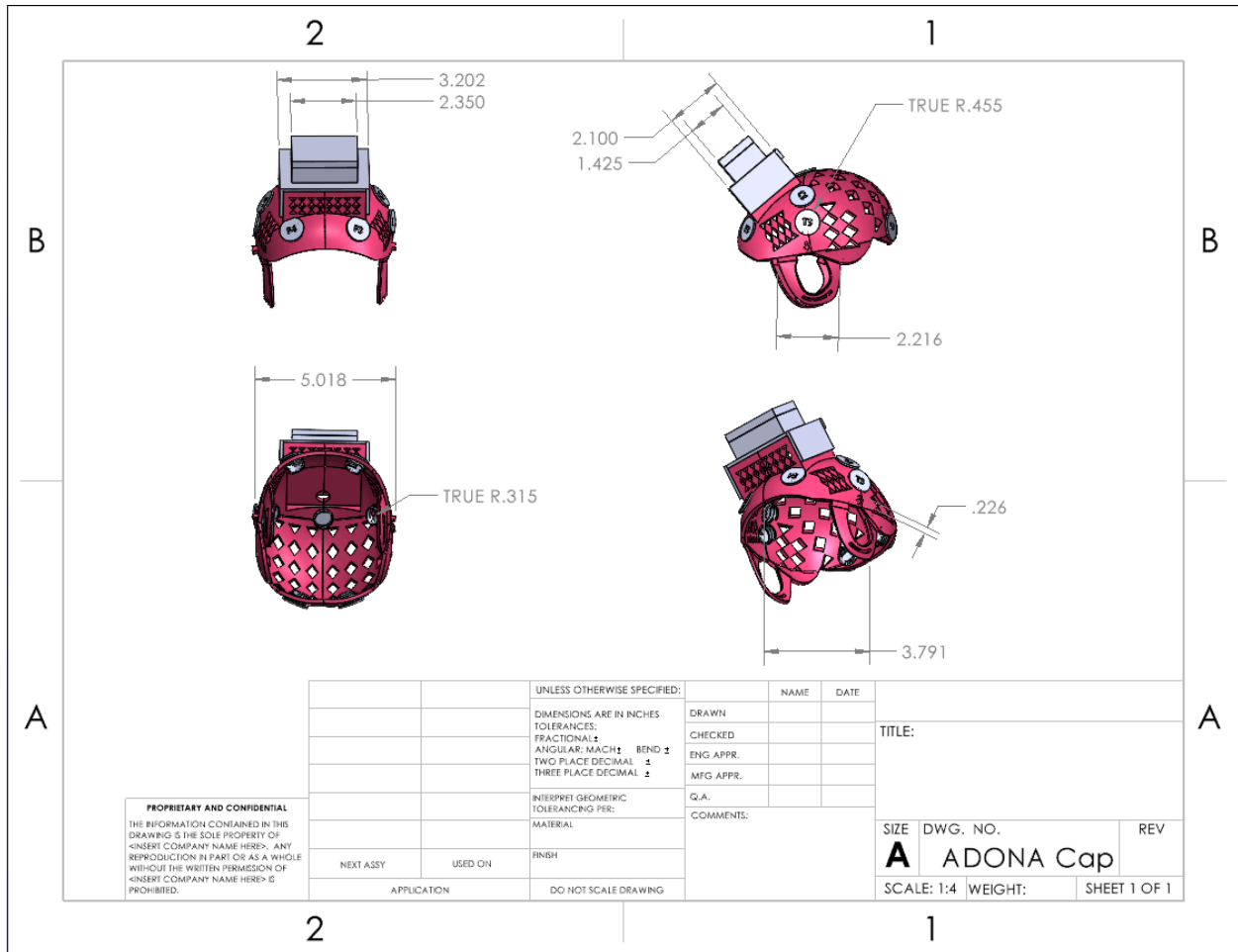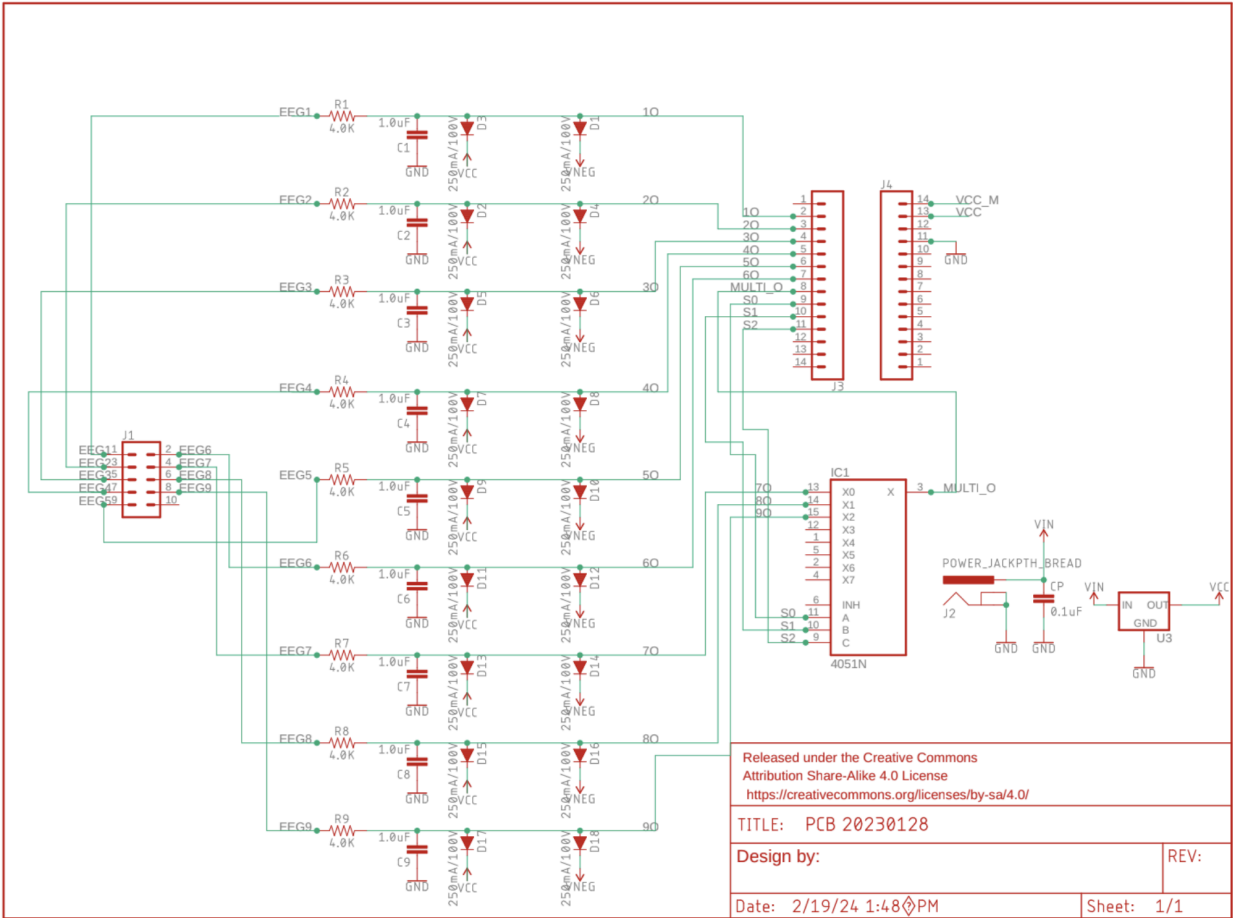

Supplemental Figure D1. *ADONA Helmet*

Supplemental Figure D2. *Electrode Housing*
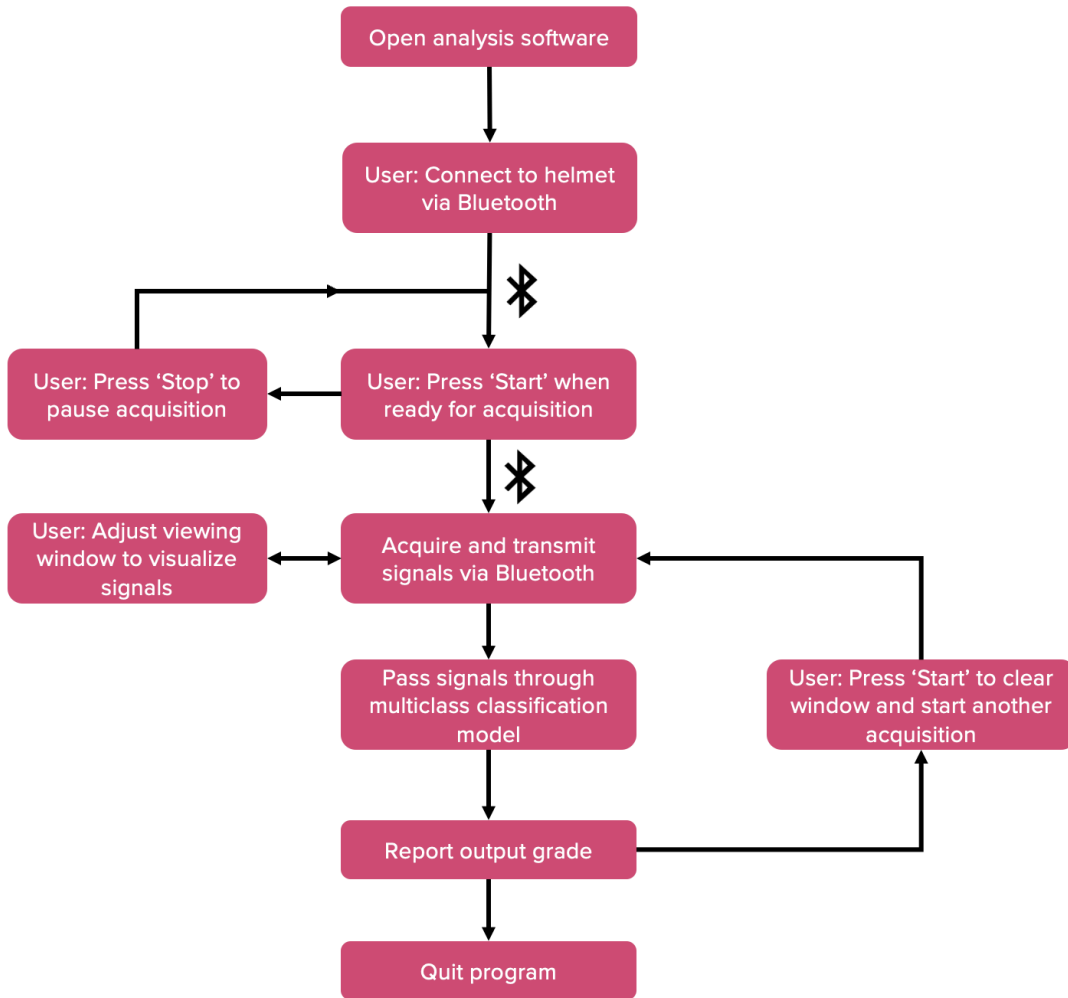
Circuit Diagrams

Supplemental Figure D3. *PCB design with track paths (top view)*

Supplemental Figure D4*. Circuit schematic*

Software Diagrams

Supplemental Figure D5. *EEG Acquisition & Analysis Software Flow Chart*