ADONA

Instant peace of mind

Team

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EXECUTIVE SUMMARY - <u>OR WATCH OUR PITCH HERE!</u>

PROBLEM

One in 500 babies will experience inadequate oxygen delivery or blood flow to the brain around the time of birth, resulting in long-term neurological damage. This birth complication, known as hypoxic-ischemic encephalopathy (HIE), is responsible for 23% of neonatal deaths worldwide. While established treatments exist, diagnosis currently requires a specialized neurologist to analyze an infant's electroencephalography (EEG) signal, requiring significant, usually unavailable, time and labor. Neonatal intensive care units (NICUs) and specialists struggle to keep pace with the high volume of neonates, leaving many undiagnosed and untreated for HIE. As such, there exists a need for a rapid, automated diagnostic tool capable of screening risk for perinatal HIE.

OUR SOLUTION - <u>DEMO HERE!</u>

A device for the Assisted Detection of Neonatal Asphyxia – ADONA – is a non-invasive diagnostic aid that streamlines the detection of HIE. ADONA is a software and hardware package product; a neonate-specific EEG helmet collects and wirelessly transmits EEG data, and a proprietary machine learning algorithm automatically diagnoses HIE in under one minute. After an infant is born, ADONA is strapped onto the neonate's head, collecting just 1 minute of data before analyzing and notifying the healthcare team of HIE risk. ADONA improves on existing hospital methods through its quick and automated capabilities, while maintaining the accuracy and reliability of a neurologist. ADONA was validated using 10,805 hours of clinical data recorded from 53 infants in hospitals around the world. The output results were compared to expert grading by two independent neurologists. Our device has demonstrated >90% specificity and >90% sensitivity, resulting in a 97% overall accuracy.

MARKET AND DISTRIBUTION OVERVIEW

The U.S market for HIE is valued at just over $1.04 billion and is projected to reach around two billion by 2030, boasting a compound annual growth rate of 7.9%. The market includes sub sectors such as administration methods, distribution channels, and end users. ADONA will be used as a non-invasive diagnostic aid, distributed through hospital networks and intended for use by neonatal intensive care units in healthcare facilities. During our pre-launch phase, we plan to offer ADONA through both relevant hospital networks and specialized clinics, later leveraging medical device distributors to reach a larger, global hospital network. We anticipate applying for distribution through group purchasing organizations to eventually sell to government-run neonatal and pediatric care services.

VALUE PROPOSITION

Our device is the first of its kind; no medical devices exist for the detection of HIE. ADONA costs $175 to manufacture and will be offered through a subscription-based leasing model in the future. As we scale, we will adopt a penetration pricing strategy and partner with medical device distributors. With our marketing and distribution strategies, we estimate a revenue of $3 million five years post-launch.

NEXT STEPS

ADONA revolutionizes the neonatal healthcare space as a quick, non-invasive diagnostic aid. A current minimally viable prototype (MVP) exists for the ADONA product. By April 2024, we will create a final working prototype with an improved form factor. Beginning in June 2024, ADONA will be clinically tested through joint trials and pilot studies at CHOP to validate the efficacy and safety of the device. At ADONA, we believe in celebrating the miracle of life. We're turning the promise of a safer birth into a reality, ensuring instant peace of mind, for every child and their families.
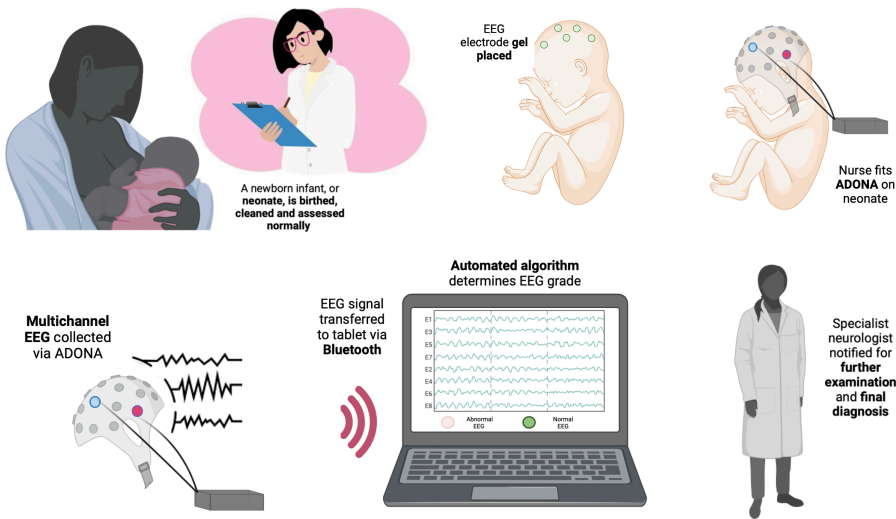
BACKGROUND

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. 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.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. The gold standard of diagnosis is amplitude-integrated electroencephalography (aEEG), which has been shown to predict short-term outcomes of HIE and can help clinicians determine which infants may benefit from therapeutic hypothermia. Abnormal patterns in the normal background pattern of EEG have been correlated with severity of neonatal HIE.

However, review of the aEEG 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. As such, there exists a need for a rapid, automated diagnostic tool capable of identifying patterns of perinatal HIE through aEEG and direct physicians to initiate treatment directly after birth.

Of the 1 in 500 neonates who suffer from HIE, 60% will sustain permanent neurological disability or die before the age of 2. HIE is responsible for 23% of neonatal deaths worldwide, making it the 5th leading cause of death for children under the age of 5. ADONA's capabilities, with >90% sensitivity and >80% 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.

PRODUCT OVERVIEW - <u>DEMO HERE!</u>

A newborn infant, or neonate, is birthed, cleaned and assessed normally

EEG electrode **gel** **placed**

Nurse fits **ADONA** on neonate

Multichannel **EEG** collected via ADONA

EEG signal transferred to tablet via **Bluetooth**

Automated algorithm determines EEG grade

Abnormal EEG / Normal EEG

Specialist neurologist notified 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, the ADONA hat will be fitted onto the newborn. This will be achieved through the manufacturing of a hat that meets the needs of being adjustable, having 9 electrodes, and being the correct circumference for a neonate. During this time, the data will be wirelessly communicated to a nearby tablet via bluetooth. One minute later, the hat will be removed. Simultaneously, the ADONA machine learning algorithm will grade the neonatal EEG in under a minute, alerting the nurse to notify a neurologist if a dangerous score is detected.

This will be achieved through a classifier that meets the needs of requiring under one minute, having a specificity >90% and a sensitivity >80%, and having a repeatability of 100%.

We envision ADONA 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.

VALUE PROPOSITION
Ultimately, ADONA provides unparalleled ease of use, automated wireless data collection, and superior reliability, empowering clinicians to make rapid, informed decisions for early HIE intervention.

Taking a closer look at our minimal competitive landscape, current methods include physical observation or the use of the standard EEG readouts through a specialist, highlighting a significant gap in the market. Our device has clear advantages; we are able to replicate the reliability and precision of standard EEG measurements, with simpler, automated implementation. While ADONA's competitive advantages are clear, we are cognisant of the fact that end implementation will require training for clinical staff and our device may have size limitations during early years, but we plan to mitigate this with a strategic marketing plan and investment in R&D for universal usage. We will also address regulatory concerns and have already begun working with pediatric neurologists to ensure ADONA's suitability for clinical use.

STAKEHOLDERS
Direct stakeholders include: Neonatal Intensive Care Units (NICUs), neonatal and pediatric neurologists, and nurses & care providers. NICUs are the primary direct users of ADONA, as they deal with neonates requiring urgent care, including those at risk of HIE. NICUs would benefit from the quick, non-invasive diagnostic capabilities of ADONA, enabling faster intervention. Specialists who diagnose and treat neonates with conditions like HIE will also be involved in conception, marketing, and usage – ADONA could serve as a crucial tool in their diagnostic process, reducing the need for immediate specialist intervention and allowing for broader, more efficient screening by frontline healthcare workers in NICUs and other neonatal care settings.

Indirect stakeholders include parents and families, healthcare facilities/hospitals, medical device distributors, and insurance companies. Parents are indirect beneficiaries who stand to gain peace of mind and potentially better outcomes for their newborns through the early detection and treatment of HIE. Institutions that could see improved patient outcomes, enhanced reputation, and potentially lower costs from reduced long-term care needs through the use of ADONA. Distributors would handle the manufacturing and selling of ADONA to healthcare facilities, playing a key role in the product's market penetration and availability. Insurance companies most likely will have an interest in supporting or providing coverage for ADONA's use, given its potential to prevent long-term neurological damage and reduce associated healthcare costs.

MARKET OVERVIEW
The U.S market for HIE is valued at just over one billion dollars and is projected to reach around two billion by 2030, boasting a compound annual growth rate of 7.9% The key drivers of this growth include increasing rates of neonatal respiratory problems, a growing demand for treatments in this space, and a growing global market with significant contributions from the U.S. The market includes sub sectors such as administration methods, distribution channels,

and end users. ADONA will be used as a non-invasive diagnostic aid, distributed through hospital networks and intended for use by neonatal intensive care units in healthcare facilities

CUSTOMER SEGMENTS

Key segments include: hospitals with NICUs, specialized clinics, government-run neonatal and pediatric care services, and research instituions with academic hospitals. Hospitals with NICUs are the primary customer segment, given their direct need for and benefit from ADONA's capabilities. Specialized clinics, while not at the scale of hospitals, could also serve neonates at risk of HIE and would benefit from ADONA. Public healthcare services could implement ADONA in their facilities, potentially through purchases facilitated by group purchasing organizations. Lastly, entities that could be interested in the data and research opportunities such as research hospitals may be interested in purchasing ADONA to analyze improvements by ADONA's technology and its impacts on neonatal care.
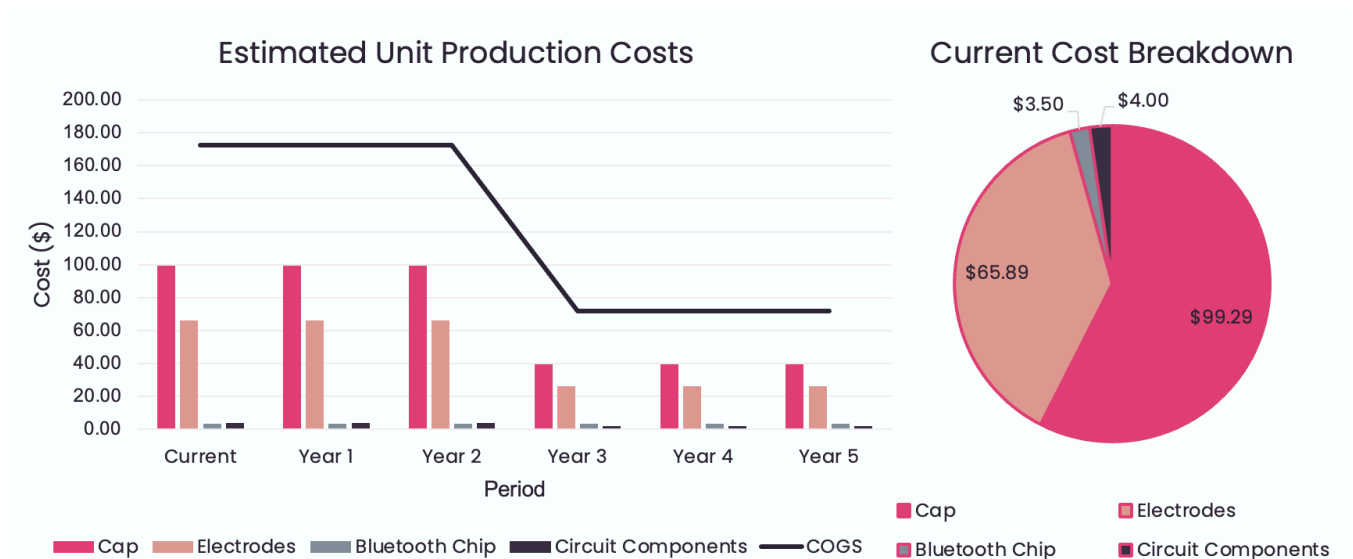
COMPETITION

To our knowledge, there are no existing devices capable of aiding 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. ADONA matches current EEG readout accuracy while expanding to an automated, wireless mechanism.

|	Physical Observation	Standard EEG	ADONA
Reliability & Precision	Low	High	High
Ease of Implementation	N/A	Difficult	Simple
Automated	No	No	Yes
Wireless	N/A	No	Yes

COST OF PRODUCTION

Our $200 price is based on our current COGS at around $180 per unit, for which the breakdown is shown. We hope to decrease this cost over time with distributor partnerships. We also anticipate several additional costs related to marketing, manufacturing, and operations leading up to ADONA's launch, which are outlined in the appendix.

Estimated Unit Production Costs

Current Cost Breakdown

Current Cost Breakdown pie chart values: $3.50, $4.00, $65.89, $99.29 (Cap, Electrodes, Bluetooth Chip, Circuit Components)

REVENUE MODEL

Our gross profit is outlined and expected to grow over 5 years. We anticipate growth due to both price increases in line with our penetration pricing strategy and cost reductions from supplier and distributor partnerships. Starting at year three, we anticipate an increase in sales in our existing hospital networks and a shift in our distribution channel mix to include partnerships.
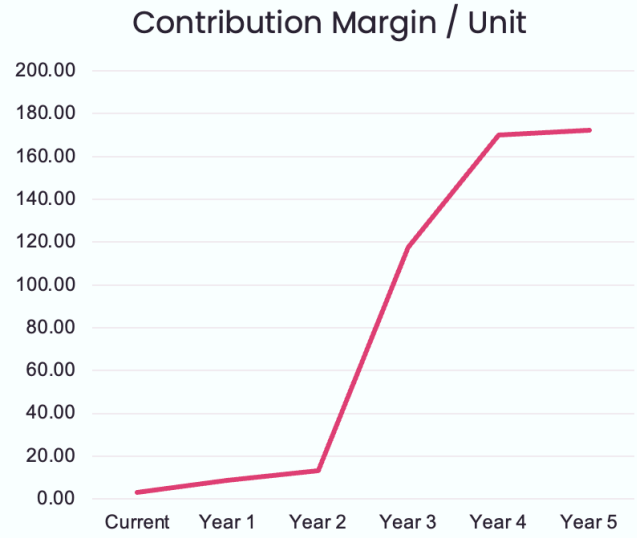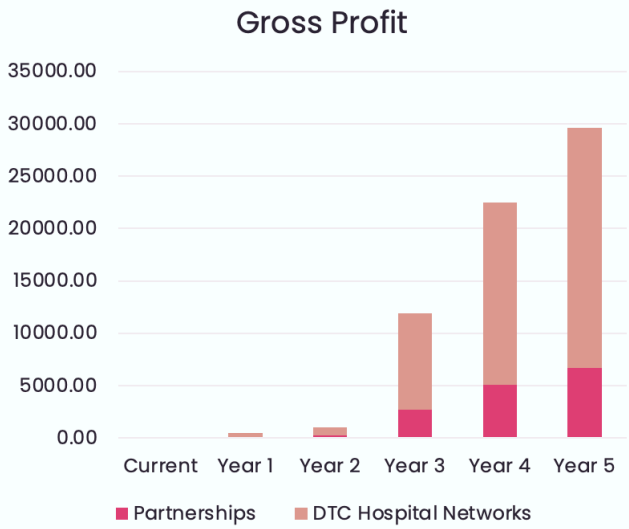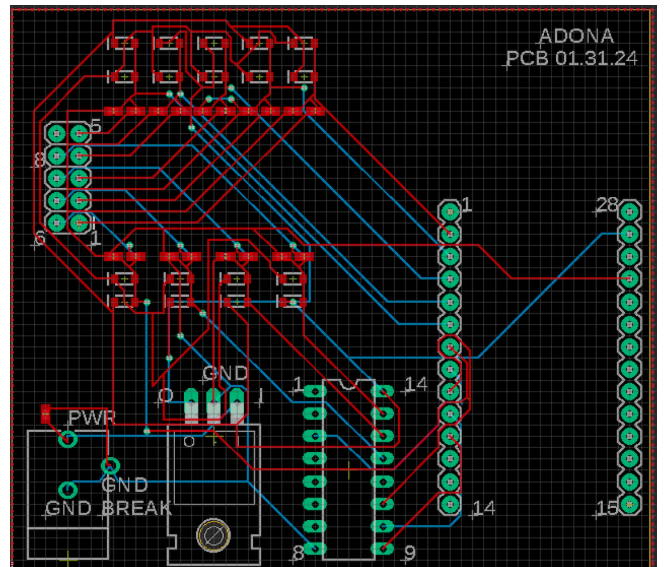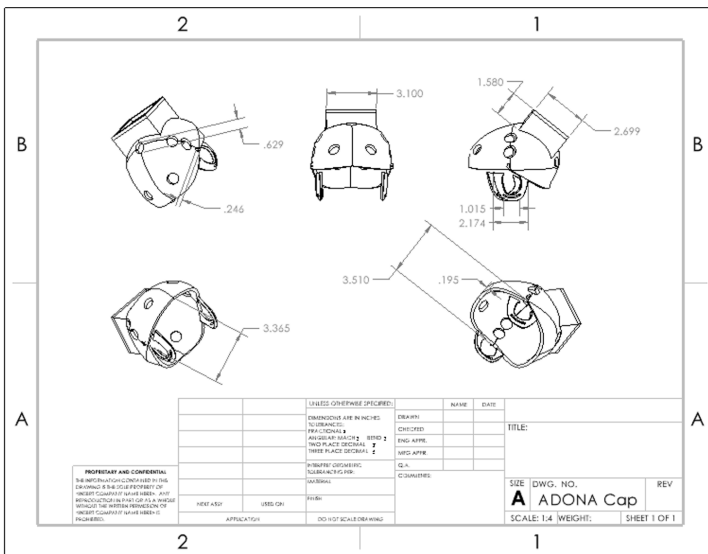

APPENDIX

Mechanical Drawings

Figure 1. ADONA Helmet and ADONA Printed Circuit Board