

**UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN WEARABLE  
ELECTROENCEPHALOGRAPH  
DEVICES AND SYSTEMS AND  
COMPONENTS THEREOF**

**Investigation No. 337-TA- \_\_\_\_\_**

**COMPLAINT UNDER SECTION 337 OF THE  
TARIFF ACT OF 1930, AS AMENDED**

**Complainant**

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**Proposed Respondents**

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## **TABLE OF CONTENTS**

I.	INTRODUCTION.....	1
II.	PARTIES.....	8
	A. Ceribell.....	8
	B. The Natus Respondents .....	9
III.	BACKGROUND OF THE TECHNOLOGY .....	10
	A. Challenges of Historical EEG Monitoring Lead to Ceribell’s Founding .....	10
	B. Ceribell’s Groundbreaking Innovations in EEG Technology .....	14
	C. Natus Copies Ceribell’s Patented Technology .....	19
IV.	THE TECHNOLOGY AND PRODUCTS AT ISSUE.....	27
V.	THE ASSERTED PATENTS AND NON-TECHNICAL DESCRIPTIONS OF THE INVENTIONS .....	27
	A. U.S. Patent No. 9,820,670 .....	27
	1. Identification of Patent Ownership.....	27
	2. Non-Technical Description of the Invention of the ’0670 Patent .....	28
	3. Foreign or Domestic Counterparts to the ’0670 Patent.....	29
	4. Licensees to the ’0670 Patent .....	30
	B. U.S. Patent No. 12,150,769 .....	30
	1. Identification of Patent Ownership.....	30
	2. Non-Technical Description of the Invention of the ’769 Patent.....	31
	3. Foreign or Domestic Counterparts to the ’769 Patent.....	31
	4. Licensees to the ’769 Patent .....	32
	C. U.S. Patent No. 12,324,670 .....	32
	1. Identification of Patent Ownership.....	32
	2. Non-Technical Description of the Invention of the ’4670 Patent .....	33

3.	Foreign or Domestic Counterparts to the '4670 Patent.....	33
4.	Licensees to the '4670 Patent .....	34
D.	U.S. Patent No. 12,336,826.....	35
1.	Identification of Patent Ownership.....	35
2.	Non-Technical Description of the Invention of the '826 Patent.....	35
3.	Foreign or Domestic Counterparts to the '826 Patent.....	36
4.	Licensees to the '826 Patent .....	37
E.	U.S. Patent No. 10,433,756.....	37
1.	Identification of Patent Ownership.....	37
2.	Non-Technical Description of the Invention of the '756 Patent.....	38
3.	Foreign or Domestic Counterparts to the '756 Patent.....	38
4.	Licensees to the '756 Patent .....	39
F.	U.S. Patent No. 11,357,434.....	39
1.	Identification of Patent Ownership.....	39
2.	Non-Technical Description of the Invention of the '434 Patent.....	40
3.	Foreign or Domestic Counterparts to the '434 Patent.....	40
4.	Licensees to the '434 Patent .....	41
VI.	RESPONDENTS' INFRINGEMENT OF THE ASSERTED PATENTS .....	41
2.	Infringement of the '0670 Patent.....	41
3.	Infringement of the '769 Patent.....	42
4.	Infringement of the '4670 Patent.....	44
5.	Infringement of the '826 Patent.....	45
6.	Infringement of the '756 Patent.....	46
7.	Infringement of the '434 Patent.....	47
VII.	SPECIFIC ACTS OF UNFAIR IMPORTATION AND SALE.....	48

VIII. CLASSIFICATION UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES..... 61

IX. RELATED LITIGATION..... 62

X. THE DOMESTIC INDUSTRY RELATING TO THE ASSERTED PATENTS ..... 62

    B. Technical Prong..... 63

    C. Economic Prong ..... 63

XI. RELIEF REQUESTED ..... 64

## EXHIBIT LIST

<b>Exhibits</b>	<b>Description</b>
1	Copy of U.S. Patent No. 9,820,670
2	Copy of U.S. Patent No. 12,150,769
3	Copy of U.S. Patent No. 12,324,670
4	Copy of U.S. Patent No. 12,336,826
5	Copy of U.S. Patent No. 10,433,756
6	Copy of U.S. Patent No. 11,357,434
7	Certified Copy of USPTO Assignment Records for U.S. Patent No. 9,820,670
8	Certified Copy of USPTO Assignment Records for U.S. Patent No. 12,150,769
9	Certified Copy of USPTO Assignment Records for U.S. Patent No. 12,324,670
10	Certified Copy of USPTO Assignment Records for U.S. Patent No. 12,336,826
11	Certified Copy of USPTO Assignment Records for U.S. Patent No. 10,433,756
12	Certified Copy of USPTO Assignment Records for U.S. Patent No. 11,357,434
13	Infringement Claim Chart for the '0670 Patent
14	Technical Domestic Industry Claim Chart for the '0670 Patent
15	Infringement Claim Chart for the '769 Patent
16	Technical Domestic Industry Claim Chart for the '769 Patent
17	Infringement Claim Chart for the '4670 Patent
18	Technical Domestic Industry Claim Chart for the '4670 Patent
19	Infringement Claim Chart for the '826 Patent
20	Technical Domestic Industry Claim Chart for the '826 Patent
21	Infringement Claim Chart for the '756 Patent
22	Confidential Technical Domestic Industry Claim Chart for the '756 Patent
23	Confidential Technical Domestic Industry Claim Chart for the '756 Patent
24	Infringement Claim Chart for the '434 Patent
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## **APPENDIX LIST**

<b>Appendices</b>	<b>Description</b>
A	Prosecution History of U.S. Patent No. 9,820,670
B	Prosecution History of U.S. Patent No. 12,150,769
C	Prosecution History of U.S. Patent No. 12,324,670
D	Prosecution History of U.S. Patent No. 12,336,826
E	Prosecution History of U.S. Patent No. 10,433,756
F	Prosecution History of U.S. Patent No. 11,357,434

## I. INTRODUCTION

1. Ceribell, Inc. (hereinafter “Ceribell” or “Complainant”) is the pioneering innovator and market leader in the field of rapid point-of-care electroencephalogram (“EEG”) monitoring products for clinical use in acute care settings. After years of groundbreaking research and development, Ceribell revolutionized seizure detection with its patented point-of-care EEG system (the “Ceribell System”). It transformed a clinical challenge that took 1 to 4 hours or more into a life-saving breakthrough<sup>1</sup> that takes only 5 to 10 minutes to set up and is now implemented across 550+ hospitals in the United States.<sup>2</sup> Ceribell’s innovations further gave rise to the Asserted Patents, which Ceribell raises in this action to put a stop to Proposed Respondents’ unlawful infringement.

2. Proposed Respondents Natus Medical Incorporated, Excel-Tech Ltd. (“XLTEK”), and Natus Neurology Incorporated (collectively “Natus” or “Respondents”) are serial copycats with a documented history of willful patent infringement. Rather than innovate, Natus systematically steals. In 2018, a federal jury found Natus willfully infringed another company’s patents on neurological sleep diagnostic technology, leading to a permanent injunction and damages.<sup>3</sup> Now, Natus has struck again—this time targeting Ceribell’s revolutionary technology with a blatant knockoff product that copies critical innovations that Ceribell spent years developing

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<sup>1</sup> Ex. 27, Paul M. Vespa et al., *Evaluating the Clinical Impact of Rapid Response Electroencephalography: The DECIDE Multicenter Prospective Observational Clinical Study*, CRITICAL CARE MED., Sept. 2020.

<sup>2</sup> Ex. 28, Ceribell Q1 2025 10-Q filing; *see also* Ex. 84, BioTech Health X, *CeriBell (CBLL) is a Smart MedTech Play in 2025*, BIOTECH HEALTH X (May 30, 2025), <https://biotechhealthx.com/biotech-news/ceribell-cbll-is-a-smart-medtech-play-in-2025/>.

<sup>3</sup> Ex. 30, Permanent Injunction, Nox Med. Ehf v. Natus Neurology Inc., No. 1:15-cv-00709-RGA (D. Del. June 5, 2018), ECF No. 285; Ex. 31, Final Judgment, Nox Med. Ehf v. Natus Neurology Inc., No. 1:15-cv-00709-RGA (D. Del. Sept. 11, 2018), ECF No. 335.

and patenting. Ceribell’s technology was born out of a clinical need that remained unfulfilled by Natus’ “conventional” EEG technology for decades. Indeed, Ceribell’s technology and very existence are a direct reflection of Natus’ inability or failure to innovate.

3. Ceribell was founded in 2014 to provide neurological care in medical settings such as Intensive Care Units (ICUs) and Emergency Departments (EDs) where conventional EEG approaches, such as Natus’ legacy EEG products, had proven too slow and impractical. EEG monitoring products measure the brain’s electrical activity using electrodes placed on a patient’s scalp to detect and monitor neurological conditions, most notably seizures and “status epilepticus.” Status epilepticus refers to prolonged or repeated seizures without recovery in between, which is a serious neurological emergency that requires urgent recognition and medical intervention. If status epilepticus is not recognized and treated quickly, it can lead to mortality or severe and permanent brain damage. Prompt detection and management of seizures and status epilepticus are crucial for improving patient outcomes. Ceribell’s mission—to make EEG monitoring as fast and routine as checking vital signs—led to the development of a first-of-its-kind rapid, point-of-care EEG system, the Ceribell System, which was launched commercially in 2018. The Ceribell System is cleared by the U.S. Food and Drug Administration (“FDA”) for indicating suspected seizure activity. It is currently utilized in over 550 hospitals in the United States, and has aided in improving neurological care and outcomes for more than 200,000 patients.<sup>4</sup> With the Ceribell System, Ceribell has transformed a once-niche neurodiagnostic tool into a major advancement in frontline intervention, helping to manage and improve patients’ care in hospitals nationwide.<sup>5</sup>

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<sup>4</sup> Ex. 28, Ceribell Q1 2025 10-Q filing.

<sup>5</sup> *Id.*

4. The Ceribell System, shown below, comprises an EEG recording and amplifying device that is used with a single-use electrode headband, configured with 10 integrated electrodes and a novel system for dispensing conductive gel to the measurement sites on a patient. The EEG recording and amplifying device connects to the hospital’s WiFi network and streams EEG data to Ceribell’s web-based EEG portal software, which neurologists can log into and remotely read and interpret the EEG. With these components working together, the Ceribell System provides a seamless, easy-to-use, clinical grade EEG monitoring system to support detection and diagnosis of seizures and other neurological conditions.



**Fig. 1. The Ceribell System, Including Wearable Headband and EEG Recorder**

5. Ceribell’s efforts to innovate and improve patient outcomes in neurological care have not stopped with the launch of the ground-breaking Ceribell System. Since the System’s introduction, Ceribell has devoted significant resources to advancing EEG technology and bringing additional wearable EEG devices to market.<sup>6</sup> As just one example, Ceribell began incorporating artificial intelligence (“AI”) into its product development in 2019—a time when AI was closer to science fiction than the widely implemented technology it is today. Ceribell has

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<sup>6</sup> *Id.*

acted diligently to protect its research by applying for and successfully receiving numerous patents to protect its ongoing innovation efforts.<sup>7</sup>

6. In bringing its new technology to market, Ceribell has gone to great lengths to earn the trust of the medical community. Ceribell has demonstrated—to the satisfaction of a great number of neurologists, emergency physicians, and other critical care practitioners—that its technology reliably offers healthcare providers timely and vital EEG information to support rapid clinical decision-making in acute care settings. To this end, Ceribell invested in clinical studies with renowned medical institutions, including the SAFER-EEG Trial,<sup>8</sup> the DECIDE trial,<sup>9</sup> and the AccuRASE Study,<sup>10</sup> to show the clinical significance and scientific rigor of the Ceribell System. Ceribell continues to invest today in further research and study, as well as in further improvements to its technology and products.

7. Ceribell has earned widespread industry recognition for its role in transforming healthcare, beginning with the technological innovations of its Ceribell System, detailed further below. For example, in 2023, Fast Company recognized Ceribell as one of the top 10 most innovative medical device companies.<sup>11</sup> Additionally, the FDA has granted Ceribell two separate

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<sup>7</sup> Ex. 29, Ceribell 2024 S-1 filing.

<sup>8</sup> Ex. 32, Mariel Kalkach-Aparicio et al., *Seizure Assessment and Forecasting With Efficient Rapid EEG (“SAFER-EEG”)*, NEUROLOGY, July 2024.

<sup>9</sup> Ex. 27, Paul M. Vespa et al., *Evaluating the Clinical Impact of Rapid Response Electroencephalography: The DECIDE Multicenter Prospective Observational Clinical Study*, CRITICAL CARE MED., Sept. 2020.

<sup>10</sup> Ex. 33, Zubeda B. Sheikh et al., *Accuracy of a Rapid Response EEG’s Automated Seizure-Burden Estimator*, NEUROLOGY, Jan. 202.

<sup>11</sup> Ex. 34, *Ceribell Named to Fast Company's 2023 List of the World's Most Innovative Companies*, PR NEWswire (Mar. 2, 2023), <https://www.prnewswire.com/news-releases/ceribell-named-to-fast-companys-2023-list-of-the-worlds-most-innovative-companies-301760414.html>.

Breakthrough Device Designations<sup>12</sup> for its innovative technologies and their transformative nature. This designation is reserved for cutting-edge devices that “provide[] for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions” and are worthy of special consideration by FDA in the regulatory authorization process.<sup>13</sup> Only 128 technologies in total have received “Breakthrough Device Designation” and subsequently garnered FDA marketing authorization in the nearly ten years since the inception of the program.<sup>14</sup>

8. Ceribell’s patent-protected breakthroughs were recognized and subsequently pirated, without license or permission, by Natus. Natus’ latest act of infringement is the “BrainWatch” system—a shameless copy of Ceribell’s patented inventions that Natus rushed to market in May 2025 without testing it in clinical trials. Natus even admitted to the FDA that its copycat device has only “minor” differences from Ceribell’s original, and Natus relies exclusively on Ceribell’s products as “predicate devices” in these regulatory filings.<sup>15</sup> Natus also relies heavily on publications of clinical trial results involving the Ceribell System. Having failed to develop competing technology through legitimate means, Natus chose the path of patent infringement.

9. It is on this basis that Ceribell files this complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“Section 337”), to stop the unlawful importation

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<sup>12</sup> See, e.g., Ex. 35, *Breakthrough Devices Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#authorizations> (last visited June 27, 2025) (identifying Ceribell ESE device, which received FDA 510(k) clearance: K223504).

<sup>13</sup> See Ex. 36, U.S. FOOD & DRUG ADMIN., *BREAKTHROUGH DEVICES PROGRAM, GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF* (Sept. 15, 2023).

<sup>14</sup> Ex. 35, *Breakthrough Devices Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#authorizations> (last visited June 27, 2025).

<sup>15</sup> Ex. 37, Letter from U.S. Food & Drug Admin. to Prithful Bom, Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) (Nov. 19, 2024) (“BrainWatch 510(k)”).

into the United States, the sale for importation into the United States, and/or the sale within the United States after importation of certain wearable EEG devices and systems and components thereof that infringe valid and enforceable United States patents owned by Ceribell.

10. Upon information and belief, Natus has engaged in unfair acts in violation of Section 337 through and in connection with its unlicensed importation into the United States, sale for importation into the United States, and/or its sale within the United States after importation of wearable EEG devices and systems and components thereof (the “Accused Products”) that infringe one or more claims of United States Patent Nos. 9,820,670 (“the ’0670 patent”), 12,150,769 (“the ’769 patent”), 12,324,670 (“the ’4670 patent), 12,336,826 (“the ’826 patent), 10,433,756 (“the ’756 patent”), and 11,357,434 (“the ’434 patent”) (collectively, the “Asserted Patents”).

11. The Asserted Patents can generally be divided into two families. The first patent family comprises the ’769, ’4670, ’826, and ’0670 patents, which share a common specification with one another and claim priority to the same U.S. provisional patent application 62/314,873, filed on March 29, 2016 (the “First Patent Family”). As described *infra*, and in the attached domestic industry claim charts (Exs. 14, 16, 18, and 20) the Ceribell System practices the claims of the First Patent Family. The second patent family comprises the ’756 and ’434 patents, which share a common specification with one another and which claim priority to the same U.S. provisional patent application 62/678,416, filed on May 31, 2018 (the “Second Patent Family”). As described *infra*, and in the attached domestic industry claim charts (Exs. 22, 23, and 25) one or more of Ceribell’s EEG products currently in development practice the claims of the Second Patent Family.

12. Natus infringes, either literally or under the doctrine of equivalents, at least the following claims (independent claims in **bold and underlined**; collectively, the “Asserted Claims”) in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c):

<b>Patent No.</b>	<b>Asserted Claims</b>
9,820,670	<u>1</u> , 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 16, 17, 18, 20, 22, 23, 24, 25, 26, 27, 28
12,150,769	<u>1</u> , 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19
12,324,670	<u>1</u> , 2, 3, 4, 6, 7, 9, 10, 11, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 28, 29
12,336,826	<u>1</u> , 2, 3, 4, 6, 8, 9, 12, 13, 14, 15, 16, 17, 18
10,433,756	<u>1</u> , 2, 3, 4, 5, 7, 8, 10, 11, 12, 15, 16, 17, 18, <u>22</u> , 24, 27
11,357,434	<u>1</u> , 3, 4, 5, 6, 7, 8, 10, 14, 17, 18, 19

13. Discovery may reveal that Natus engaged in other actionable unfair acts in violation of Section 337, including but not limited to infringement of additional claims of the '0670 patent, the '769 patent, the '4670 patent, the '826 patent, the '756 patent, and the '434 patent. Accordingly, Ceribell reserves the right to seek leave to amend the Complaint to assert such claims.

14. As required by 19 U.S.C. § 1337(a)(2) and (3), domestic industry exists and/or is in the process of being established in the United States relating to articles protected by Ceribell’s Asserted Patents. Ceribell’s domestic industry includes significant investment in plant and equipment, significant employment of labor and capital, and substantial investment in the exploitation of the inventions claimed in Ceribell’s Asserted Patents, including through research, design, product development, engineering, product support, manufacturing support, testing, quality assurance, regulatory compliance, clinical affairs, sales, marketing, distribution, warehousing, and technical customer support activities.

15. Natus’ unlicensed and unauthorized use of Ceribell’s technology—including the technology disclosed in the Asserted Patents—to import, sell for importation and/or sell after

importation into the United States wearable EEG devices and systems and components thereof in the United States constitutes an unfair act within the meaning of Section 337.

16. On information and belief, the Accused Products are manufactured and/or sold for importation into the United States, imported into the United States, and/or sold after importation into the United States by or on behalf of Natus.

17. Ceribell seeks as relief a permanent limited exclusion order under 19 U.S.C. § 1337(d) barring from entry into the United States infringing wearable EEG devices and systems and components thereof that are manufactured, sold for importation, and/or imported by or on behalf of Natus. Excluding Natus' infringing products will promote legitimate competition that Natus unfairly sought to circumvent by way of its infringement.

18. Ceribell further seeks as relief permanent cease and desist orders under 19 U.S.C. § 1337(f) prohibiting Natus from marketing, distributing, selling, offering for sale, warehousing inventory for distribution, and otherwise transferring or bringing into the United States wearable EEG devices and systems and components thereof that violate Section 337.

19. Ceribell further seeks as relief a bond, for the 60-day Presidential Review Period pursuant to 19 U.S.C. § 1337(j), for the importation of Natus' wearable EEG devices and systems and components thereof that infringe one or more claims of the Asserted Patents.

## **II. PARTIES**

### **A. Ceribell**

20. Ceribell is a corporation organized and existing pursuant to the laws of the State of Delaware and has its principal place of business at 360 N Pastoria Ave., Sunnyvale, CA 94085. Since its founding in 2014, Ceribell has grown substantially, starting from just 3 full-time employees based in the United States in its first year, launching its first, EEG market-shifting

product in the middle of 2018, and eventually growing into a company with nearly 300 full-time employees based in the United States.<sup>16</sup>

21. Ceribell has made substantial investments in domestic activities in the United States including, engineering, design, data collection and analysis, support for patients and clinicians, research, and development to bring devices to market that make continuous EEG monitoring and seizure detection and diagnosis more accessible, more accurate, and more convenient. These investments are detailed in the accompanying declaration of Ceribell’s Chief Technology Officer, Raymond Woo (the “Woo Declaration”). *See Ex. 26.*

**B. The Natus Respondents**

22. Respondent Natus Medical Incorporated is a Delaware corporation with a principal place of business at 3150 Pleasant View Rd., Middleton, WI 53562. On information and belief, Respondent Natus Medical Incorporated designs the Accused Products that are sold for importation into the United States, imported into the United States, and/or sold within the United States after importation.

23. Respondent Excel Tech Ltd. (“XLTEK”) is a Canadian corporation with a principal place of business at 2568 Bristol Circle, Oakville, Ontario, L6H 5S1, Canada. On information and belief, Respondent Natus Medical Incorporated acquired XLTEK in 2007, and XLTEK operates today as a division, subsidiary of, or the d/b/a name for Respondent Natus Medical Incorporated. Respondent XLTEK is the FDA registered Specification Developer for the Accused Products that are sold for importation into the United States, imported into the United States, and/or sold within the United States after importation. On information and belief, Respondent XLTEK manufactures the EEG recorder for the Accused Products. Further, on information and belief, Respondent

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<sup>16</sup> Ex. 29, Ceribell 2024 S-1 filing.

XLTEK, is the publisher of Natus' user manual, which instructs users on how to use the Accused Products.<sup>17</sup>

24. Respondent Natus Neurology Incorporated is a Delaware corporation with a principal place of business at 3150 Pleasant View Rd., Middleton, WI 53562. On information and belief, Natus Neurology Incorporated operates today as a division or subsidiary of Respondent Natus Medical Incorporated. On information and belief, Respondent Natus Neurology Incorporated designs hardware and software for the Accused Products that are sold for importation into the United States, imported into the United States, and/or sold within the United States after importation.

25. On information and belief, the Natus Respondents design, develop, test, import into the United States, offer for sale, and sell in the United States after importation infringing wearable EEG devices and systems and components thereof, including devices sold under the tradename BrainWatch.<sup>18</sup> The BrainWatch devices were formally launched in the United States on May 20, 2025.<sup>19</sup>

### **III. BACKGROUND OF THE TECHNOLOGY**

#### **A. Challenges of Historical EEG Monitoring Lead to Ceribell's Founding**

26. Seizures are sudden, uncontrolled electrical disturbances in the brain that can affect behavior, movements, emotions, and consciousness. In intensive care settings, over 90% of

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<sup>17</sup> See Ex. 38 at 2, NATUS MEDICAL INC. DBA EXCEL-TECH LTD. (XLTEK), 046994 REV 08 BRAINWATCH SYSTEM USER MANUAL (2025) ("Publisher's Notice").

<sup>18</sup> See, e.g., Ex. 85, Trademark/Service Mark Application Serial No. 98304107 (filed Dec. 07, 2023).

<sup>19</sup> Ex. 39, Natus Medical Inc., Natus Medical Inc., *Natus Announces Entry into Point-of-Care EEG with Launch of BrainWatch*, PR Newswire (May 20, 2025), <https://www.prnewswire.com/news-releases/natus-announces-entry-into-point-of-care-eeeg-with-launch-of-brainwatch-302460438.html>.

seizures are non-convulsive, *i.e.*, there are no visible symptoms, and detection is only possible through EEG.<sup>20</sup> Seizures—especially prolonged seizures—in the ICU are considered neurological emergencies, as for every minute these hidden seizures go untreated, brain tissue is at risk of harm. Prolonged non-convulsive seizures can evade diagnosis, extend hospital stays, increase the risk of complications, cause permanent brain damage, and even lead to death.<sup>21</sup>

27. Guidelines promulgated by the Neurocritical Care Society recommend the initiation of EEG monitoring within 60 minutes of seizure suspicion, especially when non-convulsive seizures are suspected.<sup>22</sup> However, meeting the “within 60 minutes” guideline was nearly impossible with conventional EEG systems. Those systems typically required a specially trained technician to carefully apply 20 or more individual electrodes at specific locations on the patient’s head: a time-consuming and challenging exercise prone to frequent failure.<sup>23</sup> In many hospitals, EEG technicians are only onsite during working hours, Monday to Friday, leaving significant gaps for 24/7 coverage. These challenges have worsened in recent years due to a shortage of EEG technicians and neurologists,<sup>24</sup> making reliable and on-demand EEG monitoring unpredictable and unavailable in all but the most top-tier, well-funded academic medical centers.

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<sup>20</sup> Ex. 40, J. Claassen et al., *Detection of Electrographic Seizures with Continuous EEG Monitoring in Critically Ill Patients*, 62 NEUROLOGY 1743 (2004).

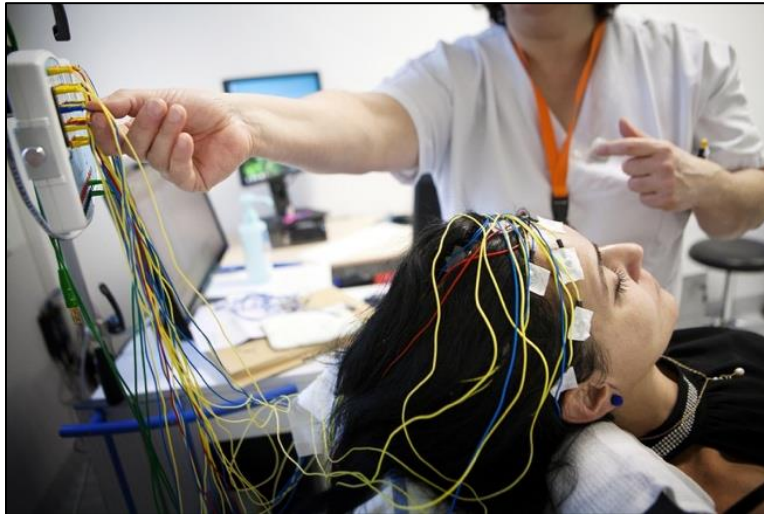
<sup>21</sup> Ex. 41, O. Mecarelli et al., *EEG Patterns and Epileptic Seizures in Acute Phase Stroke*, 31 CEREBROVASC. DISEASES 191 (2011).

<sup>22</sup> Ex. 42, Gretchen M. Brophy et al., *Guidelines for the Evaluation and Management of Status Epilepticus*, NEUROCRITICAL CARE SOC’Y, Apr. 2012.

<sup>23</sup> Ex. 43, Patrick Ledwidge, et al., *Recommendations for Developing an EEG Laboratory at a Primarily Undergraduate Institution*, J. UNDERGRADUATE NEUROSCIENCE EDUC., Fall 2018; see also Ex. 29 at 96, Ceribell 2024 S-1 Filing.

<sup>24</sup> Ex. 44, Timothy M. Dall et al., *Supply and Demand Analysis of the Current and Future US Neurology Workforce*, 81 NEUROLOGY 470 (2013).

Multiple studies show that the delay in availability of conventional EEG is regularly hours and often days, leading to suboptimal patient management.<sup>25</sup>



**Fig. 2. Conventional EEG System Being Operated on a Patient**

28. This gap—between the need for rapid brain monitoring in point-of-care settings such as ICUs, urgent care clinics, and emergency rooms, and the challenge of conventional EEG access in those settings—was a fundamental problem that Ceribell was founded to address. Ceribell was co-founded by Dr. Josef Parvizi, M.D., Ph.D., Chris Chafe, D.M.A, and Jane Chao, Ph.D. They recognized that the EEG monitoring products offered by legacy EEG companies such as Natus were not meeting patients’ needs in these medical settings, as they cannot be deployed or interpreted quickly enough to meet the needs of patients. As a physician, Dr. Parvizi saw that he and his colleagues were unable to make appropriate clinical decisions for their patients, who suffered from delayed or suboptimal treatment regimens due to the lack of readily available EEG

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<sup>25</sup> See, e.g., Ex. 32, Mariel Kalkach-Aparicio et al., *Seizure Assessment and Forecasting With Efficient Rapid EEG (“SAFER-EEG”)*, NEUROLOGY, July 2024; Ex. 45, Shaurya Taran et al., *Educational Initiatives and Implementation of Electroencephalography into the Acute Care Environment: A Protocol of a Systematic Review*, SYSTEMATIC REVIEWS, 2020; Ex. 46, Norah M.K. Wright et al., *Evaluating the Utility of Rapid Response EEG in Emergency Care*, EMERGENCY MED. J., 2021.

monitoring. The three co-founders started Ceribell to solve this problem by developing a rapidly deployable, bedside EEG monitoring tool that eventually became the Ceribell System.

29. Ceribell's early years were not easy. The founding team members worked hard to turn their idea into a prototype that became a marketable product. Ceribell's founders labored tirelessly, including for nearly two years with minimal or no pay, to try to find investors who shared their vision.

30. Raising capital was particularly challenging for Ceribell. The lack of historical innovation in the EEG market made it an unfamiliar investment for venture capitalists. Through their relentless efforts, Ceribell's co-founders were eventually able to raise \$1 million in seed funding to develop their vision, and subsequently secured a \$9 million investment to build a product ready for commercialization. In the medical device market, this represented a very modest investment for a new company. New devices, even from established manufacturers, typically require tens of millions of dollars to bring to market. During this period, the majority of Ceribell's early employees took significant salary cuts compared to their previous jobs. They made this sacrifice because they believed in the co-founders' vision of enabling better patient care through rapid bedside EEG.

31. Building the technology itself was highly challenging. Other companies, both before and after Ceribell, have tried to make EEG easier and quicker to set up, but none have overcome the core technical barriers. Examples of previous attempts at point-of-care EEG systems that were not successful include the StatNet EEG electrode headband, developed by BioSignal Group, and the EEG-NOW system, developed by Encephalodynamics. EEG is a complex and weak signal (~1,000 times weaker than the cardiac electrical signal) and is highly sensitive to noise, motion and interference. Furthermore, the scalp is often covered with hair and shaped

irregularly, making it more difficult to reliably acquire high-quality signals. This is why, historically, a well-trained EEG technician is required to take special care in setting up an EEG, typically 20-30 minutes per EEG. Developing a device that allowed any nurse or non-EEG specialist to set up an EEG much more quickly was unthinkable, before Ceribell.

32. Despite the challenges, Ceribell has successfully developed the technology that allows non-specialist setup of EEG in 5 to 10 minutes, greatly expanding the number of patients who benefit from EEG monitoring and creating a brand-new market that had been ignored for decades by EEG incumbents like Natus: the market for point-of-care EEG monitoring.

### **B. Ceribell's Groundbreaking Innovations in EEG Technology**

33. The Ceribell System was specifically designed to address the limitations of conventional EEG recognized by Ceribell's co-founders, and to improve clinical outcomes of critically ill patients at high risk of otherwise undetectable seizures.<sup>26</sup> The Ceribell System represents a first-of-its-kind technology that integrates reliable highly portable hardware with proprietary AI-powered algorithms to deliver precise seizure detection and assessment in minutes rather than hours or days.<sup>27</sup>

34. The Ceribell System's hardware consists of a novel and highly effective disposable, flexible headband embedded with 10 EEG electrodes and a pocket-sized, battery-operated recording and amplifying device that captures and wirelessly transmits EEG data to a secure cloud portal. Once recorded, EEG signals are streamed live to a web-based portal, enabling caretakers

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<sup>26</sup> Ex. 47 at 1, 2, 89, and 98, Ceribell S-1 Filing, Form S-1/A (2024).

<sup>27</sup> *Id.*

to remotely monitor brain activity from any internet-connected device and eliminating delays tied to on-site technologist support and neurologist availability for interpretation.<sup>28</sup>

35. The Ceribell System is intuitive, easy to use, and allows frontline clinicians and nurses (not just those with specialized EEG training) to initiate EEG monitoring and receive support within minutes, dramatically accelerating diagnosis and treatment compared to conventional EEG workflows. Ceribell's Clarity™ AI-powered algorithms aid in the rapid diagnosis and measurement of seizures in critical care settings by assessing seizure burden (*i.e.*, the amount of seizure activity within a set time window) from continuously monitored EEG data outputs.

36. In addition to offering a portable and easily deployable EEG solution, the Ceribell System delivers a highly accurate, diagnostic-quality EEG signal using just an 8-channel headband.<sup>29</sup> By contrast, conventional EEG systems typically require 19 or even 32 channels, comprising 20 and 33 electrodes, respectively.<sup>30 31</sup> The high-quality EEG data output of the Ceribell System—the product of rigorous clinical testing that upended traditional expectations about EEG monitoring—is readily comparable to more complex measurement systems. Together with its streamlined setup and rapid implementation, the Ceribell System provides an efficient and accessible solution for critical care environments, enabling timely neurological assessment without

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<sup>28</sup> *Id.*

<sup>29</sup> Ex. 48, M. Brandon Westover et al., *Diagnostic Value of Electroencephalography with Ten Electrodes in Critically Ill Patients*, 33 NEUROCRITICAL CARE 479 (2020).

<sup>30</sup> *Id.*

<sup>31</sup> Ex. 49, Kapil Gururangan et al., *Diagnostic Utility of Eight-Channel EEG for Detecting Generalized or Hemispheric Seizures and Rhythmic Periodic Patterns*, 3 CLINICAL NEUROPHYSIOLOGY PRACTICE 65 (2018).

the delays associated with conventional EEG systems.<sup>32</sup> Front and center to the benefits of the Ceribell System is its novel headband design, which streamlines the EEG setup process for rapid deployment in acute care settings. The headband's electrode assemblies are engineered to ensure precise placement, efficient gel delivery to the skin surface, and optimal signal acquisition, reducing setup errors and improving data reliability. This intuitive design not only enhances ease of use for non-specialists, it also maximizes accuracy in seizure detection.<sup>33</sup>

37. The Ceribell System stands out from conventional EEG systems not only due to its streamlined setup, but also its highly accurate data output. The Ceribell System, including its algorithms, has been proven to reliably detect seizures in critically ill patients.<sup>34</sup>

38. Through Ceribell's significant clinical testing investments and partnership with medical institutions, Ceribell supported rigorous clinical testing and validation studies, confirming for the healthcare community that Ceribell's EEG monitoring solution performed at least as well as, if not better than, conventional EEG in hospital ICUs. The Ceribell System has been evaluated in numerous studies at leading medical institutions, resulting in a large number of published peer-reviewed articles documenting its effectiveness and accuracy in EEG monitoring and seizure detection. A detailed overview of at least 10 such studies can be found on Ceribell's website: <https://ceribell.com/evidence/clinical-studies/>.

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<sup>32</sup> *Id.*

<sup>33</sup> Ex. 50, Marian P. LaMonte, *Ceribell EEG Shortens Seizure Diagnosis and Workforce Time and is Useful for COVID Isolation*, 2021 *EPILEPSIA OPEN* 331.

<sup>34</sup> See, e.g., Ex. 51, Baharan Kamousi et al., *Comparing the Quality of Signals Recorded with a Rapid Response EEG and Conventional Clinical EEG Systems*, 4 *CLINICAL NEUROPHYSIOLOGY PRACTICE* 69 (2019); Ex. 27, Paul M. Vespa et al., *Evaluating the Clinical Impact of Rapid Response Electroencephalography: The DECIDE Multicenter Prospective Observational Clinical Study*, *CRITICAL CARE MED.*, Sept. 2020; Ex. 33, Zubeda B. Sheikh et al., *Accuracy of a Rapid Response EEG's Automated Seizure-Burden Estimator*, *NEUROLOGY*, Jan. 2025.

39. For instance, the SAFER-EEG Trial (Seizure Assessment and Forecasting With Efficient Rapid-EEG) was a retrospective, multi-center study, involving over 1,000 patients, that compared the Ceribell System with conventional EEG in acutely ill patients at risk for seizures.<sup>35</sup> The SAFER-EEG trial demonstrated that the Ceribell System performed at least as well as conventional EEG at forecasting in-hospital seizure risk, significantly reduced the time to EEG acquisition (a median time of 5.9 hours compared to 25.3 hours with conventional EEG), and led to better neurological outcomes for 18% more patients compared to conventional EEG.<sup>36</sup> Indeed, the published, peer-reviewed results of the multicenter study demonstrated that the Ceribell System “outperforms conventional EEG across various outcomes.”<sup>37</sup>

40. As another example, the DECIDE Study (Diagnostic Evaluation of Ceribell Rapid Response EEG) was a prospective, multicenter observational study conducted across five academic hospitals in the United States.<sup>38</sup> The DECIDE Study demonstrated that the Ceribell System improved diagnostic accuracy, increasing non-specialist physicians’ sensitivity for seizure detection from 77.8% with clinical judgment alone to 100% when using the Ceribell System, and specificity from 63.9% to 89% with the addition of Ceribell EEG data.<sup>39</sup> These findings indicate that the Ceribell System enhances both the ability to correctly identify patients experiencing

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<sup>35</sup> Ex. 32, Mariel Kalkach-Aparicio et al., *Seizure Assessment and Forecasting With Efficient Rapid EEG (“SAFER-EEG”)*, NEUROLOGY, July 2024

<sup>36</sup> *Id.*

<sup>37</sup> Ex. 52, Marco Meglio, *Ceribell Point-of-Care EEG Platform Outperforms Conventional EEG Across Various Outcomes in Mutlicenter Study*, NEUROLOGYLIVE (Aug. 10, 2024), <https://www.neurologylive.com/view/ceribell-eeg-platform-outperforms-conventional-eeg-across-various-outcomes>

<sup>38</sup> Ex. 27, Paul M. Vespa et al., *Evaluating the Clinical Impact of Rapid Response Electroencephalography: The DECIDE Multicenter Prospective Observational Clinical Study*, CRITICAL CARE MED., Sept. 2020.

<sup>39</sup> *Id.*

seizures (“sensitivity”) and the ability to correctly identify those not experiencing seizures (“specificity”). The study also showed that the Ceribell System enhanced physician confidence in diagnostic and treatment decisions and that it significantly reduced the time to EEG acquisition compared to conventional EEG.<sup>40</sup>

41. These advancements in EEG monitoring technology, made possible by the groundbreaking Ceribell System, are driven by innovations protected under Ceribell’s United States patent portfolio. As a result of Ceribell’s extensive investments in research and development and its commitment to intellectual property, Ceribell possesses a substantial patent portfolio. Over the years, the United States Patent and Trademark Office (“USPTO”) has granted Ceribell a number of United States patents covering its inventions, including but not limited to those identified as Asserted Patents.

42. The demonstrable benefits of the Ceribell System have been touted by many neurologists and other medical practitioners. Testimonials available on Ceribell’s website describe the Ceribell System as “ma[king] a huge difference as far as timing and being able to rapidly assess and treat appropriately,”<sup>41</sup> with one neurologist describing Ceribell’s EEG technology as “chang[ing] our culture as far as how we manage patients with seizures, how we manage patients neurologically, and doing it in a way that doesn’t compromise patient care.”<sup>42</sup>

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<sup>40</sup> *Id.*

<sup>41</sup> Ex. 53, CERIBELL, INC., <http://www.ceribell.com> (last visited July 2, 2025) (Testimonial by neurologist Margo Block, DO).

<sup>42</sup> Ex. 53, CERIBELL, INC., <http://www.ceribell.com> (last visited July 2, 2025) (Testimonial by neurologist Parshaw Dorriz, MD).

43. Ceribell and its groundbreaking Ceribell System have been recognized by several prestigious industry awards<sup>43</sup> and the FDA itself,<sup>44</sup> further validating the innovative and impactful nature of the technology.

44. In short, the Ceribell System has demonstrated great success in the field of neurological monitoring, the technology is improving patient outcomes, and Natus has taken notice of these successes after many years of failing to innovate on its own. The Ceribell System truly represents a revolution in point-of-care brain monitoring. The visionary efforts of Ceribell's co-founders and the sacrifices of Ceribell's early employees have now come to fruition, as Ceribell has built a business that is widely respected by healthcare providers, hospitals, and the investment community as truly innovative and renowned for making a difference in patients' neurological care and health outcomes.

### **C. Natus Copies Ceribell's Patented Technology**

45. Natus is a medical equipment manufacturer founded in 1989. In 2022, after being publicly traded for more than two decades with its stock price stagnating for years, Natus was

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<sup>43</sup> At the 2019 Medical Design Excellence Awards, Ceribell received Gold in the "Testing and Diagnostic Products and Systems" category, Silver in the "NonSurgical Hospital Supplies and Equipment" category, and was awarded overall Best in Show. Ex. 54, Advanced Manufacturing New York, *Winners of the 2019 Medical Design Excellence Awards (MDEAs) Announced at MD&M East*, GLOBENEWSWIRE (June 11, 2019, 6:15 PM), <https://www.globenewswire.com/news-release/2019/06/11/1867283/0/en/Winners-of-the-2019-Medical-Design-Excellence-Awards-MDEAs-Announced-at-MD-M-East.html>. In 2018, Fierce MedTech Fierce 15 awards recognized Ceribell as one of the top 15 emerging medical device companies. Ex. 55, Conor Hale, *FierceMedTech's 2018 Fierce 15*, FIERCE BIOTECH (Feb. 11, 2019, 3:00 AM), <https://www.fiercebiotech.com/special-report/fiercemedtech-s-2018-fierce-15>. And as discussed in Section I *supra*, Ceribell was recently recognized in 2023 by Fast Company as one of the top 10 most innovative medical device companies. Ex. 34, Ceribell, Inc., *Ceribell Named to Fast Company's 2023 List of the World's Most Innovative Companies*, PR NEWSWIRE (Mar. 2, 2023), <https://www.prnewswire.com/news-releases/ceribell-named-to-fast-companys-2023-list-of-the-worlds-most-innovative-companies-301760414.html>.

<sup>44</sup> See *supra* Section I.

acquired by private equity firm, ArchiMed.<sup>45</sup> As part of the acquisition, Natus Medical was split into two companies: Natus Sensory and Natus Neuro.

46. Despite tracing its history in the EEG domain back to 1935 through the acquisition of Grass Technologies—one of the earliest EEG companies<sup>46</sup>—Natus failed to meaningfully grow the market beyond approximately \$350 million.<sup>47</sup> It never meaningfully innovated on the legacy EEG technology, either because it lacked the vision to recognize the significant shortcomings of its products in serving ICU and ED patients, or because it had no incentive to disrupt what had been a consistent and status quo-driven business. Natus offerings remained limited to conventional, legacy EEG solutions of the type that rely on 20 or more electrodes around the head applied by a trained specialist. Until BrainWatch, Natus had never marketed a wearable, point-of-care EEG system.

47. Although Natus had the resources and decades of experience to develop point-of-care EEG products, it was Ceribell that revolutionized the industry through its innovative technologies, proving the existence of an estimated \$2 billion opportunity<sup>48</sup> in the United States alone that Natus now seeks to exploit by piggybacking on Ceribell's efforts. On information and belief, rather than undertake the substantial investment of time and resources required to

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<sup>45</sup> Ex. 56, Andrea Park, *Natus Medical to Go Private in \$1.2B Private Equity Acquisition Deal*, FIERCE BIOTECH (Apr. 18, 2022, 10:15 AM), <https://www.fiercebiotech.com/medtech/natus-medical-go-private-12b-private-equity-acquisition-deal>.

<sup>46</sup> Ex. 57, *Natus to Acquire Grass Technologies Product Group from Astro-Med*, ASTRONOVA (Jan. 7, 2013), <https://www.astronovainc.com/natus-to-acquire-grass-technologies-product-group-from-astro-med/>.

<sup>47</sup> Ex. 58, *U.S. Electroencephalography Devices Market Size, Share & Trends Analysis Report By Product (32-Channel, Multichannel), By Type (Portable Device, Standalone Device), By Application, By End-use, And Segment Forecasts, 2024 – 2030*, GRAND VIEW RSCH., <https://www.grandviewresearch.com/industry-analysis/us-electroencephalography-devices-market-report> (last visited June 27, 2025).

<sup>48</sup> Ex. 59 at 24, Ceribell, Inc., *Corporate Presentation* (May 2025).

independently develop and validate its own system, Natus willfully appropriated and copied Ceribell's proprietary technology after observing the Ceribell System's unprecedented commercial success. This copying led to infringement of Ceribell's Asserted Patents.

48. This is not Natus' first infringement rodeo. Natus is an adjudicated copyist in the industry. In 2015, Natus was sued in the District of Delaware by Nox Medical Ehf. ("Nox Medical") for patent infringement due to its manufacturing, sale, and exportation of XactTrace, a pre-sized single-use biometric belt incorporating a patented connector for use in sleep diagnostic technologies.<sup>49</sup> During the case, discovery revealed that Natus had deliberately copied Nox Medical's commercial product while the patent application was pending, and continued to do so after the patent issued. The Court found Natus "deliberately copied the ideas and design of Plaintiff and continued to produce copied belts after receiving notice of the [] patent's existence."<sup>50</sup>

49. The Nox Medical case was tried to a jury in April 2018. The jury ultimately found Natus to have willfully infringed Nox Medical's patent.<sup>51</sup> The Court subsequently issued a permanent injunction and awarded damages against Natus for its infringement.<sup>52</sup>

50. On information and belief, through the success and accolades achieved by Ceribell after launching the Ceribell System in 2018, Natus and its new owner, ArchiMed, recognized a growing market opportunity for point-of-care EEG technology. With its explosive growth and

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<sup>49</sup> Ex. 60 at 2-3, Complaint for Patent Infringement, Nox Med. Ehf v. Natus Neurology Inc., No. 1:15-cv-00709-RGA (D. Del. Aug. 17, 2015), ECF No. 1.

<sup>50</sup> Ex. 61 at 7, Memorandum Opinion, Nox Med. Ehf v. Natus Neurology Inc., No. 1:15-cv-00709-RGA (D. Del. Aug. 27, 2018), ECF No. 329.

<sup>51</sup> Ex. 62 at 30, Final Jury Instructions, Nox Med. Ehf v. Natus Neurology Inc., No. 1:15-cv-00709-RGA (D. Del. May 7, 2018), ECF No. 259; Ex. 63 at 2, Verdict Form, Nox Med. Ehf v. Natus Neurology Inc., No. 1:15-cv-00709-RGA (D. Del. May 7, 2018), ECF No. 262.

<sup>52</sup> Ex. 30, Permanent Injunction, Nox Med. Ehf v. Natus Neurology Inc., No. 1:15-cv-00709-RGA (D. Del. June 5, 2018), ECF No. 285; Ex. 31, Final Judgment, Nox Med. Ehf v. Natus Neurology Inc., No. 1:15-cv-00709-RGA (D. Del. Sept. 11, 2018), ECF No. 335.

strong investor appeal, Ceribell represented the ideal success story that private equity firms like ArchiMed aim to replicate. Natus thus set out to copy the Ceribell System and cash in on the new market that Ceribell had worked so hard to create. Natus did so by copying the product's appearance, its disposable single-use elastic headband design, its electrode configuration and count, its sizing options, and its usage guidelines. Natus also co-opted terminology Ceribell had popularized in the industry, including “point-of-care EEG” and its advantages “when every minute matters” [Natus: “when time matters”]. Most importantly, as demonstrated in the infringement analysis below and the accompanying infringement charts, Natus copied numerous claimed features of Ceribell's patents to launch an infringing product that unfairly competes against Ceribell in the point-of-care EEG market that Ceribell created.

51. Instead of undertaking the extensive efforts required to identify unmet clinical needs, secure investments, innovate breakthrough technologies, develop and train sophisticated AI algorithms, and educate physicians about the clinical benefits of a brand-new approach to an old problem, Natus simply appropriated the fruits of Ceribell's labor.

52. Aiming to capitalize on Ceribell's success, Natus publicized submission of its copycat point-of-care EEG device for FDA clearance on the eve of Ceribell's IPO.<sup>53</sup> On May 20, 2025, Natus announced the commercial launch of its BrainWatch system.<sup>54</sup> As described, the

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<sup>53</sup> Ex. 64, Natus Medical Inc., *Natus Seeks FDA 510(k) Clearance for Its Highly Anticipated Point-of-Care EEG Solution*, PR NEWSWIRE (Oct. 10, 2024, 5:05 PM), <https://www.prnewswire.com/news-releases/natus-seeks-fda-510k-clearance-for-its-highly-anticipated-point-of-care-eeeg-solution-302273441.html>; Ex. 65, *CeriBell, Inc. Announces Closing of Upsized Initial Public Offering and Full Exercise of the Underwriters' Option to Purchase Additional Shares*, NASDAQ (Oct 15, 2024, 5:00 PM), <https://www.nasdaq.com/press-release/ceribell-inc-announces-closing-up-sized-initial-public-offering-and-full-exercise>.

<sup>54</sup> Ex. 39, Natus Medical Inc., *Natus Announces Entry into Point-of-Care EEG with Launch of BrainWatch*, PR Newswire (May 20, 2025), <https://www.prnewswire.com/news-releases/natus-announces-entry-into-point-of-care-eeeg-with-launch-of-brainwatch-302460438.html>.

BrainWatch Point-of-Care EEG System bears a striking resemblance to Ceribell’s product in its appearance, features, and functionality, positioning it as an alternative to the Ceribell System.

53. Natus’ website describes the BrainWatch system as “a wireless, wearable point-of-care EEG system.”<sup>55</sup> It goes on to state: “Designed for ease of use, BrainWatch Point-of-Care EEG enables quick setup by any ED or ICU clinician within minutes. Bedside alerts for suspected continuous seizures empower care teams to make rapid triaging decisions and collaborate with neuro teams effectively.”<sup>56</sup> Natus’ website makes available point-of-care EEG documentation that relies on Ceribell data to validate point-of-care EEG use.<sup>57</sup>

54. On information and belief, Natus has intentionally copied Ceribell’s wearable EEG System and is using Ceribell’s patented technology, as discussed in further detail below and illustrated by the infringement charts attached hereto.

55. On information and belief, Natus was aware of Ceribell’s technology and products during its development of the Accused Products. In November 2024, Natus filed and received 510(k) clearance from the FDA for its BrainWatch technology, expressly naming both the Ceribell Pocket EEG Device (K170363) and Ceribell Instant EEG Headband (K210805) as predicate devices.<sup>58</sup>

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<sup>55</sup> Ex. 66 at 2, *BrainWatch Point-of-Care EEG*, NATUS, [https://natus.com/neuro/brainwatch/?utm\\_campaign=8237573-Neuro%20-%20BrainWatch%20POC%20EEG&utm\\_content=333248891&utm\\_medium=social&utm\\_source=linkedin&hss\\_channel=lcp-863741#n6514d9fe090dcAsdasdfsdkjlfs](https://natus.com/neuro/brainwatch/?utm_campaign=8237573-Neuro%20-%20BrainWatch%20POC%20EEG&utm_content=333248891&utm_medium=social&utm_source=linkedin&hss_channel=lcp-863741#n6514d9fe090dcAsdasdfsdkjlfs) (last visited May 23, 2025).

<sup>56</sup> *Id* at 4.

<sup>57</sup> Ex. 67, Natus Medical Inc., *Building a Bridge Between Neurology and Point-of-Care EEG*, Natus White Paper No. 048302 RevA (2025).

<sup>58</sup> Ex. 37, Letter from U.S. Food & Drug Admin. to Prithful Bom, Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) (Nov. 19, 2024) (“BrainWatch 510(k)”).

56. Appended to the 510(k) clearance summary on pages 10-15 is a table, which Natus submitted to the FDA, comparing the Accused Products to Ceribell. In Natus' own words, any differences between these devices "are minor and do not impact the overall performance or safety[.]"<sup>59</sup>

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<sup>59</sup> *Id.* at 16.

Feature	Subject Device Natus BrainWatch System	Predicate 1 Ceribell Pocket EEG Device, K170363	Predicate 2 Ceribell Instant EEG HeadbandK210805	Comments
Where used	Professional healthcare facility.	Professional healthcare facility	Professional healthcare facility, in the home or clinical research	Same as predicate
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same as predicate
A/D Conversion	24-Bit Delta-Sigma	24-Bit Delta-Sigma	N/A	Same as predicate
Sampling Rate	250 Hz	250 Hz	N/A	Same as predicate
Battery charging power adapter	100-240V AC power adapter	100-240V AC power adapter	N/A	Same as predicate
Bedside Unit-PC Interface	Bedside unit to computer using WiFi	Bedside unit to computer using WiFi or Micro-USB cable	N/A	Similar to predicate but equivalent in safety and effectiveness.  Predicate device has a Micro-USB cable as an alternate option.
WiFi frequency/standard	2.4 GHz IEEE 802.11 b/g/n	2.4 GHz IEEE 802.11 b/g/n	N/A	Same as predicate
Type of Applied Part	BF	BF	N/A	Same as predicate
Type of Patient Contact	Contacts patient scalp	N/A	Contacts patient scalp	Same as predicate
Type of Use	Single use, non-sterile, disposable	N/A	Single use, non-sterile, disposable	Same as predicate
Available Sizes	Small 45-51 cm Medium 50-56 cm Large 55-62 cm	N/A	Small 45-51 cm Medium 50-56 cm Large 55-62 cm	Same as predicate
Number of Electrodes	12 (Locations: Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2, Reference, Ground)	10 (Locations: Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2)	10 (Locations: Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2)	Similar to predicate but equivalent in safety and effectiveness.
Type of Electrodes	Passive Ag/AgCl	N/A	Passive Ag/AgCl	Same as predicate
Conductive Electrolyte Gel	Conductive electrolyte gel is included in sealed gel pods integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using another gel pod.	N/A	Conductive electrolyte gel is included in sealed gel packets integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using a syringe.	Similar to predicate but equivalent in safety and effectiveness. To add additional gel to the subject device, a new, fully filled gel pod can be replaced. For the predicate device, additional gel is applied using a syringe.

**Fig. 3. BrainWatch 510(k) at 10-15 (excerpted) (highlighting added)**

57. As that table shows, the Accused Products identically implement 10 recording electrodes, of the same type, placed in the same locations as on the Ceribell System headband.<sup>60</sup>

<sup>60</sup> *Id.* at 13-14. The Accused Products contain a “reference” electrode and a “ground” electrode not present on the Ceribell System. However, and as noted in the BrainWatch 510(k), the balance

The Accused Products also offer headbands in the same head size range as the Ceribell System headbands: 45-62 cm.<sup>61</sup> And the Accused Products include “sealed gel pods integrated into each electrode assembly” to apply electrolyte gel to the patient’s skin, just like in the Ceribell System.<sup>62</sup>

58. Natus has been directly targeting current Ceribell customers with its copycat system, and encouraging its adoption by providing informational materials that rely on Ceribell’s products and contributions.<sup>63</sup> For example, a white paper entitled “Building a Bridge Between Neurology and Point-of-Care EEG” relies on Ceribell-funded studies showing the need for point-of-care EEG devices and the effects of their implementation in hospitals.<sup>64</sup> Further, the same paper references a study by one of the inventors of Ceribell’s System, demonstrating the rarity of seizures in brain regions not covered by its headband.<sup>65</sup> Tellingly, none of these Natus materials appears to rely on any studies performed by Natus itself. On information and belief, there are no

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of 10 recording electrodes on the Accused Products—Locations: Fp1, F7, T3,T5, O1, Fp2, F8, T4, T6, and O2—are identical to the 10 recording electrode locations in the Ceribell System.

<sup>61</sup> *Id.* at 13.

<sup>62</sup> *Id.* at 14.

<sup>63</sup> Ex. 66, *BrainWatch Point-of-Care EEG*, NATUS, [https://natus.com/neuro/brainwatch/?utm\\_campaign=8237573-Neuro%20-%20BrainWatch%20POC%20EEG&utm\\_content=333248891&utm\\_medium=social&utm\\_source=linkedin&hss\\_channel=lcp-863741#n6514d9fe090dcAsdasdfsdkjlf](https://natus.com/neuro/brainwatch/?utm_campaign=8237573-Neuro%20-%20BrainWatch%20POC%20EEG&utm_content=333248891&utm_medium=social&utm_source=linkedin&hss_channel=lcp-863741#n6514d9fe090dcAsdasdfsdkjlf) (last visited May 23, 2025); Ex. 68, *How Point-of-Care EEG Helps Overcome Many Challenges of Acute Neurology Care*, NATUS, <https://natus.com/insights/how-point-of-care-eeg-helps-overcome-challenges-of-acute-neurology-care/> (last visited May 23, 2025); Ex. 69, *6 Reasons Emergency Departments Should Consider Point-of-Care EEG*, NATUS, <https://natus.com/insights/6-reasons-emergency-departments-should-consider-point-of-care-eeg/> (last visited May 23, 2025).

<sup>64</sup> Ex. 67, Natus Medical Inc., *Building a Bridge Between Neurology and Point-of-Care EEG*, Natus White Paper No. 048302 RevA (2025).

<sup>65</sup> *Id.*

publications reflecting such Natus-supported studies.<sup>66</sup> Natus instead is brazenly free-riding on Ceribell’s hard work in creating the point-of-care EEG market.

#### **IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE**

59. Pursuant to Commission Rules 210.10(b)(1) and 210.12(a)(12), the Accused Products are wearable EEG devices and systems and components thereof including, a wearable electronic headband providing EEG measurement and signal collection, a wireless amplifier that attaches to the headband, an EEG recorder which communicates wirelessly with the headband to provide EEG monitoring and recording functionalities, and an application on the EEG recorder that provides software-based monitoring functionality.<sup>67</sup> These components of the Natus BrainWatch Point-of-Care EEG System comprise the “Accused Products,” which as set forth below infringe one or more claims of the Asserted Patents.<sup>68</sup>

#### **V. THE ASSERTED PATENTS AND NON-TECHNICAL DESCRIPTIONS OF THE INVENTIONS**

##### **A. U.S. Patent No. 9,820,670**

##### **1. Identification of Patent Ownership**

60. U.S. Patent No. 9,820,670 entitled “Methods and Apparatus for Electrode Placement and Tracking,” with named inventors Josef Parvizi, Xingjuan (Jane) Chao, Bradley G. Bachelder, Raymond Woo, Mathew A. Herron, Vahid Saadat, Alexander M. Grant, and Jianchun Yi, issued on November 21, 2017.<sup>69</sup> The ’0670 patent issued from U.S. Patent Application No.

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<sup>66</sup> *Supra*, note 63.

<sup>67</sup> Ex. 38 at 10, NATUS MEDICAL INC. DBA EXCEL-TECH LTD. (XLTEK), 046994 REV 08 BRAINWATCH SYSTEM USER MANUAL (2025) (“System Overview”).

<sup>68</sup> Representative samples of the products at issue are available upon request.

<sup>69</sup> U.S. Patent No. 9,820,670, at [54], [72], and [45].

15/387,381, which was filed on December 21, 2016.<sup>70</sup> The '0670 patent claims priority to U.S. Provisional Application No. 62/314,873, filed on March 29, 2016.<sup>71</sup>

61. The '0670 patent has twenty-eight (28) claims.<sup>72</sup> A copy of the '0670 patent is attached as Exhibit 1.<sup>73</sup> The '0670 patent expires on December 21, 2036.<sup>74</sup>

62. Ceribell owns by assignment the entire right, title, and interest in the '0670 patent. Pursuant to 19 C.F.R. § 210.12(a)(9)(ii), a certified copy of the assignment record for the '0670 patent is attached as Exhibit 7.

63. Pursuant to 19 C.F.R § 210.10(c)(1), a copy of the prosecution history of the '0670 patent is attached as Appendix A.<sup>75</sup>

## **2. Non-Technical Description of the Invention of the '0670 Patent<sup>76</sup>**

64. The '0670 patent is generally directed to electrode assemblies that may be used for EEG measurement purposes, and an electrode carrier system comprising such electrode assemblies.<sup>77</sup> Claim 1, for example, describes an electrode assembly comprising one or more tubular members each having a distribution channel.<sup>78</sup> A conductive fluid or gel may flow through

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<sup>70</sup> *Id.* at [21]-[22].

<sup>71</sup> *Id.* at 1:7-9.

<sup>72</sup> *Id.* at 19:51-22:20.

<sup>73</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>74</sup> 35 U.S.C. § 154(a)(2) (2015).

<sup>75</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>76</sup> Any description of the patented inventions hereinafter is not intended, and should not be understood, to limit the scope of any claim, including during claim construction. Ceribell presents general descriptions regarding the inventions subject to and without waiver of their right to argue that claim terms should be construed in a particular way during claim construction.

<sup>77</sup> U.S. Patent No. 9,820,670, at [57], 1:15-22.

<sup>78</sup> *Id.* at 19:51-66.

the lumens of the tubular members and through the distribution channel to form an electrically conductive path.<sup>79</sup>

### 3. Foreign or Domestic Counterparts to the '0670 Patent

65. Pursuant to 19 C.F.R. § 210.12(a)(9)(v), Ceribell is aware of the following foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '0670 patent.

<b>Publication/Patent No.</b>	<b>Application No.</b>	<b>Jurisdiction(s)</b>	<b>Status</b>
3 435 859	17 776 445.3	Belgium	Registered
ZL 201780033456X	201780033456X	China	Registered
CN 115944300	202310028766X	China	Allowed
3 435 859	17 776 445.3	European Patent Office	Registered
4 230 128	23 170 663.1	European Patent Office	Pending
3 435 859	17 776 445.3	France	Registered
3 435 859	17 776 445.3	Germany	Registered
40091508	42023080464	Hong Kong	Pending
3 435 859	17 776 445.3	Italy	Registered
7104631	2018-551938	Japan	Registered
7498226	2022-107639	Japan	Registered
2024-109942	2024-088099	Japan	Pending
WO 2017/172742	PCT/US2017/024505	PCT	Expired
3 435 859	17 776 445.3	Spain	Registered
3 435 859	17 776 445.3	Switzerland	Registered
3 435 859	17 776 445.3	United Kingdom	Registered
	62/314,873	US	Expired
	18/787,979	US	Pending
	19/213,887	US	Pending

66. Ceribell is not aware of any additional foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '0670 patent.

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<sup>79</sup> *Id.*

#### **4. Licensees to the '0670 Patent**

67. Pursuant to 19 C.F.R. § 210.12(a)(9)(iii), Ceribell does not currently have any licensees of the '0670 patent.

#### **B. U.S. Patent No. 12,150,769**

##### **1. Identification of Patent Ownership**

68. U.S. Patent No. 12,150,769 entitled “Methods and Apparatus for Electrode Placement and Tracking,” with named inventors Josef Parvizi, Xingjuan (Jane) Chao, Bradley G. Bachelder, Raymond Woo, Mathew A. Herron, Vahid Saadat, Alexander M. Grant, and Jianchun Yi, issued on November 26, 2024.<sup>80</sup> The '769 patent issued from U.S. Patent Application No. 17/089,586, which was filed on November 4, 2020.<sup>81</sup> The '769 patent claims priority to U.S. Provisional Application No. 62/314,873, filed on March 29, 2016.<sup>82</sup>

69. The '769 patent has nineteen (19) claims.<sup>83</sup> A copy of the '769 patent is attached as Exhibit 2.<sup>84</sup> The '769 patent expires on May 1, 2039.<sup>85</sup>

70. Ceribell owns by assignment the entire right, title, and interest in the '769 patent. Pursuant to 19 C.F.R. § 210.12(a)(9)(ii), a certified copy of the assignment record for the '769 patent is attached as Exhibit 8.

71. Pursuant to 19 C.F.R § 210.10(c)(1), a copy of the prosecution history of the '769 patent is attached as Appendix B.<sup>86</sup>

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<sup>80</sup> U.S. Patent No. 12,150,769, at [54], [72], and [45].

<sup>81</sup> *Id.* at [21]-[22].

<sup>82</sup> *Id.* at 1:7-14.

<sup>83</sup> *Id.* at 21:16-22:44.

<sup>84</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>85</sup> 35 U.S.C. § 154(b) (2015).

<sup>86</sup> A certified copy has been ordered and will be provided by complainant in due course.

## 2. Non-Technical Description of the Invention of the '769 Patent

72. The '769 patent is generally directed to a method of measuring electrical signals from a subject, which may be used for EEG measurement purposes.<sup>87</sup> Claim 1, for example, recites such a method, including the steps of positioning an electrode assembly with prongs adjacent skin of the subject, preparing a surface of the skin of the subject using the electrode assembly, and dispensing a conductive fluid or gel through a vertical passageway, a horizontal passageway, a lumen, and a channel or slot to reach the skin surface.<sup>88</sup>

## 3. Foreign or Domestic Counterparts to the '769 Patent

73. Pursuant to 19 C.F.R. § 210.12(a)(9)(v), Ceribell is aware of the following foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '769 patent.

<b>Publication/Patent No.</b>	<b>Application No.</b>	<b>Jurisdiction(s)</b>	<b>Status</b>
3 435 859	17 776 445.3	Belgium	Registered
ZL 201780033456X	201780033456X	China	Registered
CN 115944300	202310028766X	China	Allowed
3 435 859	17 776 445.3	European Patent Office	Registered
4 230 128	23 170 663.1	European Patent Office	Pending
3 435 859	17 776 445.3	France	Registered
3 435 859	17 776 445.3	Germany	Registered
40091508	42023080464	Hong Kong	Pending
3 435 859	17 776 445.3	Italy	Registered
7104631	2018-551938	Japan	Registered
7498226	2022-107639	Japan	Registered
2024-109942	2024-088099	Japan	Pending
WO 2017/172742	PCT/US2017/024505	PCT	Expired
3 435 859	17 776 445.3	Spain	Registered
3 435 859	17 776 445.3	Switzerland	Registered

<sup>87</sup> U.S. Patent No. 12,150,769, at [57], 1:20-27.

<sup>88</sup> *Id.* at 21:17-32.

3 435 859	17 776 445.3	United Kingdom	Registered
	62/314,873	US	Expired
	18/787,979	US	Pending
	19/213,887	US	Pending

74. Ceribell is not aware of any additional foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '769 patent.

#### **4. Licensees to the '769 Patent**

75. Pursuant to 19 C.F.R. § 210.12(a)(9)(iii), Ceribell does not currently have any licensees of the '769 patent.

### **C. U.S. Patent No. 12,324,670**

#### **1. Identification of Patent Ownership**

76. U.S. Patent No. 12,324,670 entitled “Methods and Apparatus for Electrode Placement and Tracking,” with named inventors Josef Parvizi, Xingjuan (Jane) Chao, Bradley G. Bachelder, Raymond Woo, Mathew A. Herron, Vahid Saadat, Alexander M. Grant, and Jianchun Yi, issued on June 10, 2025.<sup>89</sup> The '4670 patent issued from U.S. Patent Application No. 17/564,131, which was filed on December 28, 2021.<sup>90</sup> The '4670 patent claims priority to U.S. Provisional Application No. 62/314,873, filed on March 29, 2016.<sup>91</sup>

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<sup>89</sup> U.S. Patent No. 12,324,670, at [54], [72], and [45].

<sup>90</sup> *Id.* at [21]-[22].

<sup>91</sup> *Id.* at 1:7-15.

77. The '4670 patent has thirty (30) claims.<sup>92</sup> A copy of the '4670 patent is attached as Exhibit 3.<sup>93</sup> The '4670 patent expires on January 22, 2037.<sup>94</sup>

78. Ceribell owns by assignment the entire right, title, and interest in the '4670 patent. Pursuant to 19 C.F.R. § 210.12(a)(9)(ii), a certified copy of the assignment record for the '4670 patent is attached as Exhibit 9.

79. Pursuant to 19 C.F.R § 210.10(c)(1), a copy of the prosecution history of the '4670 patent is attached as Appendix C.<sup>95</sup>

## **2. Non-Technical Description of the Invention of the '4670 Patent**

80. The '4670 patent is generally directed to electrode assemblies that may be used for EEG measurement purposes, an electrode carrier system comprising such electrode assemblies, and method for measuring EEG signals using such electrode assemblies.<sup>96</sup> Claim 1, for example, describes an electrode assembly comprising one or more members having a vertical lumen.<sup>97</sup> A conductive fluid or gel may flow through the vertical lumen through a horizontal passageway directly connected to the vertical lumen.<sup>98</sup>

## **3. Foreign or Domestic Counterparts to the '4670 Patent**

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<sup>92</sup> *Id.* at 21:17-22:62.

<sup>93</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>94</sup> 35 U.S.C. § 154(b) (2015).

<sup>95</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>96</sup> U.S. Patent No. 12,324,670, at [57], 1:21-28.

<sup>97</sup> *Id.* at 21:17-27.

<sup>98</sup> *Id.*

81. Pursuant to 19 C.F.R. § 210.12(a)(9)(v), Ceribell is aware of the following foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '4670 patent.

<b>Publication/Patent No.</b>	<b>Application No.</b>	<b>Jurisdiction(s)</b>	<b>Status</b>
3 435 859	17 776 445.3	Belgium	Registered
ZL 201780033456X	201780033456X	China	Registered
CN 115944300	202310028766X	China	Allowed
3 435 859	17 776 445.3	European Patent Office	Registered
4 230 128	23 170 663.1	European Patent Office	Pending
3 435 859	17 776 445.3	France	Registered
3 435 859	17 776 445.3	Germany	Registered
40091508	42023080464	Hong Kong	Pending
3 435 859	17 776 445.3	Italy	Registered
7104631	2018-551938	Japan	Registered
7498226	2022-107639	Japan	Registered
2024-109942	2024-088099	Japan	Pending
WO 2017/172742	PCT/US2017/024505	PCT	Expired
3 435 859	17 776 445.3	Spain	Registered
3 435 859	17 776 445.3	Switzerland	Registered
3 435 859	17 776 445.3	United Kingdom	Registered
	62/314,873	US	Expired
	18/787,979	US	Pending
	19/213,887	US	Pending

82. Ceribell is not aware of any additional foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '4670 patent.

#### **4. Licensees to the '4670 Patent**

83. Pursuant to 19 C.F.R. § 210.12(a)(9)(iii), Ceribell does not currently have any licensees of the '4670 patent.

**D. U.S. Patent No. 12,336,826**

**1. Identification of Patent Ownership**

84. U.S. Patent No. 12,336,826 entitled “Methods and apparatus for electrode placement and tracking” with named inventors Josef Parvizi, Xingjuan (Jane) Chao, Bradley G. Bachelder, Raymond Woo, Mathew A. Herron, Vahid Saadat, Alexander M. Grant, and Jianchun Yi, issued on June 24, 2025.<sup>99</sup> The ’826 Patent issued from U.S. Patent Application No. 17/564,135, which was filed on December 28, 2021.<sup>100</sup> The ’826 Patent claims priority to U.S. Provisional Application No. 62/314,873, filed on March 29, 2016.<sup>101</sup>

85. The ’826 Patent has eighteen (18) claims.<sup>102</sup> A copy of the ’826 Patent is attached as Exhibit 4.<sup>103</sup> The ’826 Patent expires on February 22, 2037.<sup>104</sup>

86. Ceribell owns by assignment the entire right, title, and interest in the ’826 Patent. Pursuant to 19 C.F.R. § 210.12(a)(9)(ii), a certified copy of the assignment record for the ’826 Patent is attached as Exhibit 10.

87. Pursuant to 19 C.F.R § 210.10(c)(1), a copy of the prosecution history of the ’826 Patent is attached as Appendix D.<sup>105</sup>

**2. Non-Technical Description of the Invention of the ’826 Patent**

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<sup>99</sup> U.S. Patent No. 12,336,826, at [54], [72], and [45].

<sup>100</sup> *Id.* at [21]-[22].

<sup>101</sup> *Id.* at 1:7-15.

<sup>102</sup> *Id.* at 21:12-22:38.

<sup>103</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>104</sup> 35 U.S.C. § 154(b) (2015).

<sup>105</sup> A certified copy has been ordered and will be provided by complainant in due course.

88. The '826 patent is generally directed to a headband containing electrode assemblies that may be used in EEG measurement devices.<sup>106</sup> Claim 1, for example, describes a plurality of electrodes that may be distributed over a backing of the headband.<sup>107</sup> One or more of these electrodes contain an elongate member and are configured to deliver an electrically conductive fluid or gel, while another one or more of the electrodes of the headband are configured without an elongate member.<sup>108</sup>

### 3. Foreign or Domestic Counterparts to the '826 Patent

89. Pursuant to 19 C.F.R. § 210.12(a)(9)(v), Ceribell is aware of the following foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '826 Patent.

<b>Publication/Patent No.</b>	<b>Application No.</b>	<b>Jurisdiction(s)</b>	<b>Status</b>
3 435 859	17 776 445.3	Belgium	Registered
ZL 201780033456X	201780033456X	China	Registered
CN 115944300	202310028766X	China	Allowed
3 435 859	17 776 445.3	European Patent Office	Registered
4 230 128	23 170 663.1	European Patent Office	Pending
3 435 859	17 776 445.3	France	Registered
3 435 859	17 776 445.3	Germany	Registered
40091508	42023080464	Hong Kong	Pending
3 435 859	17 776 445.3	Italy	Registered
7104631	2018-551938	Japan	Registered
7498226	2022-107639	Japan	Registered
2024-109942	2024-088099	Japan	Pending
WO 2017/172742	PCT/US2017/024505	PCT	Expired
3 435 859	17 776 445.3	Spain	Registered
3 435 859	17 776 445.3	Switzerland	Registered

<sup>106</sup> U.S. Patent No. 12,336,826, at [57], 1:21-28.

<sup>107</sup> *Id.* at 21:12-32.

<sup>108</sup> *Id.*

3 435 859	17 776 445.3	United Kingdom	Registered
	62/314,873	US	Expired
	18/787,979	US	Pending
	19/213,887	US	Pending

90. Ceribell is not aware of any additional foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '826 patent.

#### **4. Licensees to the '826 Patent**

91. Pursuant to 19 C.F.R. § 210.12(a)(9)(iii), Ceribell does not currently have any licensees of the '826 Patent.

#### **E. U.S. Patent No. 10,433,756**

##### **1. Identification of Patent Ownership**

92. U.S. Patent No. 10,433,756 entitled “Adjustable Geometry Wearable Electrodes,” with named inventors Bradley G. Bachelder and Xingjuan (Jane) Chao, issued on October 8, 2019.<sup>109</sup> The '756 Patent issued from U.S. Patent Application No. 16/017,568, which was filed on June 25, 2018.<sup>110</sup> The '756 Patent claims priority to U.S. Provisional Application No. 62/678,416, filed on May 31, 2018.<sup>111</sup>

93. The '756 Patent has twenty-nine (29) claims.<sup>112</sup> A copy of the '756 Patent is attached as Exhibit 5.<sup>113</sup> The '756 Patent expires on June 25, 2038.<sup>114</sup>

<sup>109</sup> U.S. Patent No. 10,433,756, at [54], [72], and [45].

<sup>110</sup> *Id.* at [21]-[22].

<sup>111</sup> *Id.* at 1:6-15.

<sup>112</sup> *Id.* at 24:48-26:53.

<sup>113</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>114</sup> 35 U.S.C. § 154(a)(2) (2015).

94. Ceribell owns by assignment the entire right, title, and interest in the '756 Patent. Pursuant to 19 C.F.R. § 210.12(a)(9)(ii), a certified copy of the assignment record for the '756 Patent is attached as Exhibit 11.

95. Pursuant to 19 C.F.R § 210.10(c)(1), a copy of the prosecution history of the '756 Patent is attached as Appendix E.<sup>115</sup>

## 2. Non-Technical Description of the Invention of the '756 Patent

96. The '756 patent is generally directed to electrode assemblies that may be used in EEG measurement devices.<sup>116</sup> Claim 1, for example, describes an electrode assembly comprising an electrode body with an opening to dispense conductive fluid or gel onto the patient's skin.<sup>117</sup> The electrode body is partially adjustable, collapsible, or compressible towards the skin of the patient, such that the contact area with the patient increases in response to force towards the skin.<sup>118</sup>

## 3. Foreign or Domestic Counterparts to the '756 Patent

97. Pursuant to 19 C.F.R. § 210.12(a)(9)(v), Ceribell is aware of the following foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '756 Patent.

Publication/Patent No.	Application No.	Jurisdiction(s)	Status
ZL 2019800506796	201980050679.6	China	Registered
3 801 240	19 810 869.8	European Patent Office	Pending
40050166	62021038974.3	Hong Kong	Pending
7319304	2020-566728	Japan	Registered
WO 2019/231897	PCT/US2019/034149	PCT	Expired
	62/678,416	US	Expired

<sup>115</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>116</sup> U.S. Patent No. 10,433,756, at [57], 1:18-38, 8:55-9:6.

<sup>117</sup> *Id.* at 24:48-61.

<sup>118</sup> *Id.*

2023/0000416	17/836,969	US	Pending
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98. Ceribell is not aware of any additional foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '756 patent.

#### **4. Licensees to the '756 Patent**

99. Pursuant to 19 C.F.R. § 210.12(a)(9)(iii), Ceribell does not currently have any licensees of the '756 Patent.

### **F. U.S. Patent No. 11,357,434**

#### **1. Identification of Patent Ownership**

100. U.S. Patent No. 11,357,434 entitled “Adjustable Geometry Wearable Electrodes,” with named inventors Bradley G. Bachelder and Xingjuan (Jane) Chao, issued on June 14, 2022.<sup>119</sup> The '434 Patent issued from U.S. Patent Application No. 16/410,297, which was filed on May 13, 2019.<sup>120</sup> The '434 Patent claims priority to U.S. Provisional Application No. 62/678,416, filed on May 31, 2018.<sup>121</sup>

101. The '434 Patent has twenty-two (22) claims.<sup>122</sup> A copy of the '434 Patent is attached as Exhibit 6.<sup>123</sup> The '434 Patent expires on June 25, 2038.<sup>124</sup>

102. Ceribell owns by assignment the entire right, title, and interest in the '434 Patent. Pursuant to 19 C.F.R. § 210.12(a)(9)(ii), a certified copy of the assignment record for the '434 Patent is attached as Exhibit 12.

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<sup>119</sup> U.S. Patent No. 11,357,434 at [54], [72], and [45].

<sup>120</sup> *Id.* at [21]-[22].

<sup>121</sup> *Id.* at 1:6-10.

<sup>122</sup> *Id.* at 25:10-26:45.

<sup>123</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>124</sup> 35 U.S.C. § 154(a)(2) (2015).

103. Pursuant to 19 C.F.R § 210.10(c)(1), a copy of the prosecution history of the '434 Patent is attached as Appendix F.<sup>125</sup>

## 2. Non-Technical Description of the Invention of the '434 Patent

104. The '434 patent is generally directed to electrode assemblies that may be used in EEG measurement devices.<sup>126</sup> Claim 1, for example, describes an electrode assembly having a skin preparing surface comprising plurality of elongate elements.<sup>127</sup> The electrode assembly also has an adaptor that allows an external dispenser to couple.<sup>128</sup> The external dispenser is moveable about a central axis to clear one or more of skin or hair of the subject with the skin preparing surface.<sup>129</sup>

## 3. Foreign or Domestic Counterparts to the '434 Patent

105. Pursuant to 19 C.F.R. § 210.12(a)(9)(v), Ceribell is aware of the following foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '434 Patent.

Publication/Patent No.	Application No.	Jurisdiction(s)	Status
ZL 2019800506796	201980050679.6	China	Registered
3 801 240	19 810 869.8	European Patent Office	Pending
40050166	62021038974.3	Hong Kong	Pending
7319304	2020-566728	Japan	Registered
WO 2019/231897	PCT/US2019/034149	PCT	Expired
	62/678,416	US	Expired
2023/0000416	17/836,969	US	Pending

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<sup>125</sup> A certified copy has been ordered and will be provided by complainant in due course.

<sup>126</sup> U.S. Patent No. 11,357,434 at [57], 1:22-43, 9:17-35.

<sup>127</sup> *Id.* at 25:11-25.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

106. Ceribell is not aware of any additional foreign patents and foreign or domestic patent applications (including those that have been denied, abandoned, or withdrawn) that correspond to the '434 patent.

#### **4. Licensees to the '434 Patent**

107. Pursuant to 19 C.F.R. § 210.12(a)(9)(iii), Ceribell does not currently have any licensees of the '434 Patent.

### **VI. RESPONDENTS' INFRINGEMENT OF THE ASSERTED PATENTS**

108. On information and belief, Natus has engaged in unlawful and unfair acts including the sale for importation into the United States, the importation into the United States, and/or the sale within the United States after importation of the accused wearable EEG devices and systems and components thereof that infringe, directly or indirectly, literally or under the doctrine of equivalents, at least the Asserted Claims of the Asserted Patents.

#### **2. Infringement of the '0670 Patent**

109. Natus infringes, either literally or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 16, 17, 18, 20, 22, 23, 24, 25, 26, 27, 28 of the '0670 patent by importing the Accused Products, selling the Accused Products for importation, and/or selling the Accused Products within the United States after importation. Pursuant to 19 C.F.R. § 210.12(a)(9)(viii), a claim chart demonstrating how the Accused Products infringe independent claim 1 of the '0670 patent is attached hereto as Exhibit 13.

110. On information and belief, Natus also knowingly induces the infringement of at least claims 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 16, 17, 18, 20, 22, 23, 24, 25, 26, 27, 28 of the '0670 patent by others, based on the importation, sale for importation, and/or selling after importation into the United States the Accused Products. On information and belief, Natus has had knowledge of the '0670 patent, and its infringement of that patent since July 7, 2025. Natus intends and

induces its customers and end-users, *e.g.*, hospitals, clinicians, and other patient caregivers, to directly infringe in the United States at least one of the Asserted Claims of the '0670 patent at least by providing instructions indicating how to use the Accused Products and informing its customers in its advertisements relating to the Accused Products, such as in Natus' User Manual concerning the use and operation of the Accused Products, available at its website.<sup>130</sup> Natus' User Manual details the specific instructions for operating the Accused Products, including a step-by-step visual and written guide.<sup>131</sup>

111. On information and belief, Natus contributes to infringement of at least claims 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 16, 17, 18, 20, 22, 23, 24, 25, 26, 27, 28 of the '0670 patent by importing, selling for importation, and/or selling after importation into the United States the Accused Products and components, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the '0670 patent. On information and belief, the Accused Products are known by Natus to be especially made or especially adapted for use in the infringement of the '0670 patent.

### **3. Infringement of the '769 Patent**

112. Natus infringes, either literally or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 of the '769 patent by importing the Accused Products, selling the Accused Products for importation, and/or selling the Accused Products within the United States after importation. Pursuant to 19 C.F.R. § 210.12(a)(9)(viii), a claim chart demonstrating how the Accused Products infringe independent claim 1 of the '769 patent is attached hereto as Exhibit 15.

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<sup>130</sup> *See* Ex. 38.

<sup>131</sup> *Id.* at 33-38.

113. On information and belief, Natus also knowingly induces the infringement of at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 of the '769 patent by others, based on the importation, sale for importation, and/or selling after importation into the United States the Accused Products. On information and belief, Natus has had knowledge of the '769 patent, and its infringement of that patent since July 7, 2025. Natus intends and induces its customers and end-users, *e.g.*, hospitals, clinicians, and other patient caregivers, to directly infringe in the United States at least one of the Asserted Claims of the '769 patent at least by providing instructions indicating how to use the Accused Products and informing its customers in its advertisements relating to the Accused Products, such as in Natus' User Manual concerning the use and operation of the Accused Products, available at its website.<sup>132</sup> Natus' User Manual details the specific instructions for operating the Accused Products, including a step-by-step visual and written guide.<sup>133</sup>

114. On information and belief, Natus contributes to infringement of at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 of the '769 patent by importing, selling for importation, and/or selling after importation into the United States the Accused Products and components, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the '769 patent. On information and belief, the Accused Products are known by Natus to be especially made or especially adapted for use in the infringement of the '769 patent.

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<sup>132</sup> *See* Ex. 38.

<sup>133</sup> *Id.* at 33-38.

#### 4. Infringement of the '4670 Patent

115. Natus infringes, either literally or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 6, 7, 9, 10, 11, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 28, 29 of the '4670 patent by importing the Accused Products, selling the Accused Products for importation, and/or selling the Accused Products within the United States after importation. Pursuant to 19 C.F.R. § 210.12(a)(9)(viii), a claim chart demonstrating how the Accused Products infringe independent claim 1 of the '4670 patent is attached hereto as Exhibit 17.

116. On information and belief, Natus also knowingly induces the infringement of at least claims 1, 2, 3, 4, 6, 7, 9, 10, 11, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 28, 29 of the '4670 patent by others, based on the importation, sale for importation, and/or selling after importation into the United States the Accused Products. On information and belief, Natus has had knowledge of the '4670 patent, and its infringement of that patent since July 7, 2025. Natus intends and induces its customers and end-users, *e.g.*, hospitals, clinicians, and other patient caregivers, to directly infringe in the United States at least one of the Asserted Claims of the '4670 patent at least by providing instructions indicating how to use the Accused Products and informing its customers in its advertisements relating to the Accused Products, such as in Natus' User Manual concerning the use and operation of the Accused Products, available at its website.<sup>134</sup> Natus' User Manual details the specific instructions for operating the Accused Products, including a step-by-step visual and written guide.<sup>135</sup>

117. On information and belief, Natus contributes to infringement of at least claims 1, 2, 3, 4, 6, 7, 9, 10, 11, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 28, 29 of the '4670 patent by

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<sup>134</sup> See Ex. 38.

<sup>135</sup> *Id.* at 33-38.

importing, selling for importation, and/or selling after importation into the United States the Accused Products and components, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the '4670 patent. On information and belief, the Accused Products are known by Natus to be especially made or especially adapted for use in the infringement of the '4670 patent.

## **5. Infringement of the '826 Patent**

118. Natus infringes, either literally or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 6, 8, 9, 12, 13, 14, 15, 16, 17, 18 of the '826 patent by importing the Accused Products, selling the Accused Products for importation, and/or selling the Accused Products within the United States after importation. Pursuant to 19 C.F.R. § 210.12(a)(9)(viii), a claim chart demonstrating how the Accused Products infringe independent claim 1 of the '826 patent is attached hereto as Exhibit 19.

119. On information and belief, Natus also knowingly induces the infringement of at least claims 1, 2, 3, 4, 6, 8, 9, 12, 13, 14, 15, 16, 17, 18 of the '826 patent by others, based on the importation, sale for importation, and/or selling after importation into the United States the Accused Products. On information and belief, Natus has had knowledge of the '826 patent, and its infringement of that patent since July 7, 2025. Natus intends and induces its customers and end-users, *e.g.*, hospitals, clinicians, and other patient caregivers, to directly infringe in the United States at least one of the Asserted Claims of the '826 patent at least by providing instructions indicating how to use the Accused Products and informing its customers in its advertisements relating to the Accused Products, such as in Natus' User Manual concerning the use and operation of the Accused Products, available at its website.<sup>136</sup> Natus' User Manual details the specific

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<sup>136</sup> See Ex. 38.

instructions for operating the Accused Products, including a step-by-step visual and written guide.<sup>137</sup>

120. On information and belief, Natus contributes to infringement of at least claims 1, 2, 3, 4, 6, 8, 9, 12, 13, 14, 15, 16, 17, 18 of the '826 patent by importing, selling for importation, and/or selling after importation into the United States the Accused Products and components, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the '826 patent. On information and belief, the Accused Products are known by Natus to be especially made or especially adapted for use in the infringement of the '826 patent.

#### **6. Infringement of the '756 Patent**

121. Natus infringes, either literally or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 5, 7, 8, 10, 11, 12, 15, 16, 17, 18, 22, 24, 27 of the '756 patent by importing the Accused Products, selling the Accused Products for importation, and/or selling the Accused Products within the United States after importation. Pursuant to 19 C.F.R. § 210.12(a)(9)(viii), a claim chart demonstrating how the Accused Products infringe independent claim 1 and 22 of the '756 patent is attached hereto as Exhibit 21.

122. On information and belief, Natus also knowingly induces the infringement of at least claims 1, 2, 3, 4, 5, 7, 8, 10, 11, 12, 15, 16, 17, 18, 22, 24, 27 of the '756 patent by others, based on the importation, sale for importation, and/or selling after importation into the United States the Accused Products. On information and belief, Natus has had knowledge of the '756 patent, and its infringement of that patent since July 7, 2025. Natus intends and induces its customers and end-users, *e.g.*, hospitals, clinicians, and other patient caregivers, to directly infringe in the United States at least one of the Asserted Claims of the '756 patent at least by providing

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<sup>137</sup> *Id.* at 33-38.

instructions indicating how to use the Accused Products and informing its customers in its advertisements relating to the Accused Products, such as in Natus' User Manual concerning the use and operation of the Accused Products, available at its website.<sup>138</sup> Natus' User Manual details the specific instructions for operating the Accused Products, including a step-by-step visual and written guide.<sup>139</sup>

123. On information and belief, Natus contributes to infringement of at least claims 1, 2, 3, 4, 5, 7, 8, 10, 11, 12, 15, 16, 17, 18, 22, 24, 27 of the '756 patent by importing, selling for importation, and/or selling after importation into the United States the Accused Products and components, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the '756 patent. On information and belief, the Accused Products are known by Natus to be especially made or especially adapted for use in the infringement of the '756 patent.

#### **7. Infringement of the '434 Patent**

124. Natus infringes, either literally or under the doctrine of equivalents, at least claims 1, 3, 4, 5, 6, 7, 8, 10, 14, 17, 18, 19 of the '434 patent by importing the Accused Products, selling the Accused Products for importation, and/or selling the Accused Products within the United States after importation. Pursuant to 19 C.F.R. § 210.12(a)(9)(viii), a claim chart demonstrating how the Accused Products infringe independent claim 1 of the '434 patent is attached hereto as Exhibit 24.

125. On information and belief, Natus also knowingly induces the infringement of at least claims 1, 3, 4, 5, 6, 7, 8, 10, 14, 17, 18, 19 of the '434 patent by others, based on the importation, sale for importation, and/or selling after importation into the United States the

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<sup>138</sup> See Ex. 38.

<sup>139</sup> *Id.* at 33-38.

Accused Products. On information and belief, Natus has had knowledge of the '434 patent, and its infringement of that patent since July 7, 2025. Natus intends and induces its customers and end-users, *e.g.*, hospitals, clinicians, and other patient caregivers, to directly infringe in the United States at least one of the Asserted Claims of the '434 patent at least by providing instructions indicating how to use the Accused Products and informing its customers in its advertisements relating to the Accused Products, such as in Natus' User Manual concerning the use and operation of the Accused Products, available at its website.<sup>140</sup> Natus' User Manual details the specific instructions for operating the Accused Products, including a step-by-step visual and written guide.<sup>141</sup>

126. On information and belief, Natus contributes to infringement of at least claims 1, 3, 4, 5, 6, 7, 8, 10, 14, 17, 18, 19 of the '434 patent by importing, selling for importation, and/or selling after importation into the United States the Accused Products and components, which are not suitable for substantial non-infringing use and which embody a material part of the invention described in the '434 patent. On information and belief, the Accused Products are known by Natus to be especially made or especially adapted for use in the infringement of the '434 patent.

## **VII. SPECIFIC ACTS OF UNFAIR IMPORTATION AND SALE**

127. On information and belief, Natus has imported, sold for importation, and/or sold after importation, and will continue importing, selling for importation, and/or selling within the United States after importation the Accused Products in violation of Section 337.

128. In connection with the BrainWatch 510(k), Natus affirmatively identified in its Establishment Registration and Device Listing that "BOI(VIETNAM) COMPANY LIMITED" is

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<sup>140</sup> *See* Ex. 38.

<sup>141</sup> *Id.* at 33-38.

the “Contract Manufacturer” of the “Natus Headband & Electrode,” which as discussed above constitutes a key component of the Accused Products:

<b>Establishment Registration &amp; Device Listing</b>		
<a href="#">FDA Home</a>	<a href="#">Medical Devices</a>	<a href="#">Databases</a>
<a href="#">New Search</a>	<a href="#">Back To Search Results</a>	
<b>Proprietary Name:</b>	Natus Headband & Electrode	
<b>Classification Name:</b>	ELECTRODE, CUTANEOUS	
<b>Product Code:</b>	<a href="#">GXY</a>	
<b>Device Class:</b>	2	
<b>Regulation Number:</b>	<a href="#">882.1320</a>	
<b>Medical Specialty:</b>	Neurology	
<b>Registered Establishment Name:</b>	<a href="#">BOI(VIETNAM) COMPANY LIMITED</a>	
<b>Registered Establishment Number:</b>	3030978471	
<b>Premarket Submission Number:</b>	<a href="#">K242930</a>	
<b>Owner/Operator:</b>	<a href="#">BOI(Vietnam) Company Limited</a>	
<b>Owner/Operator Number:</b>	10062197	
<b>Establishment Operations:</b>	Contract Manufacturer	

Page Last Updated: [06/30/2025](#)

**Fig. 4. Establishment Registration & Device Listing**<sup>142</sup>

<sup>142</sup> Ex. 70, *Establishment Registration & Device Listing*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm?lid=940827&lpcd=GXY> (last updated June 30, 2025) (annotations added).

**Establishment Registration & Device Listing**

FDA Home Medical Devices Databases

New Search Back To Search Results

<b>Proprietary Name:</b>	Natus Headband & Electrode
<b>Classification Name:</b>	REDUCED- MONTAGE STANDARD ELECTROENCEPHALOGRAPH
<b>Product Code:</b>	<a href="#">OMC</a>
<b>Device Class:</b>	2
<b>Regulation Number:</b>	<a href="#">882.1400</a>
<b>Medical Specialty:</b>	Neurology
<b>Registered Establishment Name:</b>	<a href="#">BOI(VIETNAM) COMPANY LIMITED</a>
<b>Registered Establishment Number:</b>	3030978471
<b>Premarket Submission Number:</b>	<a href="#">K242930</a>
<b>Owner/Operator:</b>	<a href="#">BOI(Vietnam) Company Limited</a>
<b>Owner/Operator Number:</b>	10062197
<b>Establishment Operations:</b>	Contract Manufacturer

Page Last Updated: [06/30/2025](#)

**Fig. 5. Establishment Registration & Device Listing**<sup>143</sup>

129. On information and belief, BOI(VIETNAM) COMPANY LIMITED is a medical equipment manufacturer located in Bac Giang Province, Vietnam, and this company manufacturers at least a portion of the Accused Products.

<sup>143</sup> Ex. 71, *Establishment Registration & Device Listing*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm?lid=940827&lpcd=OMC> (last updated June 30, 2025) (annotations added).

# Establishment Registration & Device Listing

FDA Home Medical Devices Databases

[New Search](#) [Back To Search Results](#)

**Establishment:**  
BOI(VIETNAM) COMPANY LIMITED  
Lot CN-16 Viet Han Industrial Park, Tang Tien Ward  
Viet Yen Bac Giang, VN 26000  
**Registration Number:** 3030978471  
**FEI Number\*:** 3030978471  
**Status:** Active  
**Date Of Registration Status:** 2025

**Owner/Operator:**  
[BOI\(Vietnam\) Company Limited](#)  
Lot CN-16 Viet Han Industrial Park, Tang Tien Ward  
Viet Yen, Bac Giang VN 26000  
**Owner/Operator Number:** [10062197](#)

**Official Correspondent:**  
Sum Wing Lee  
Lot CN-16 Viet Han Industrial Park, Tang Tien Ward  
Viet Yen, Bac Giang VN 26000  
**Phone:** 84-020-46250388

**US Agent:**  
Peter Tam  
PETER TAM-ENGINEERING CONSULTANT  
11217 Black Fire Opal Dr  
Las Vegas, NV US 89138  
**Phone:** 949 4000888 Ext  
**Email:** PTIUSA@EARTHLINK.NET

\* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 06/30/2025

**Fig. 6. Establishment Registration & Device Listing**<sup>144</sup>

130. A figure included in the BrainWatch user manual illustrating a label on the “Natus BrainWatch Tablet” (*i.e.*, the EEG recorder) identifies Canada as the country in which the Natus BrainWatch EEG recorder is manufactured:

<sup>144</sup> Ex. 72, *Establishment Registration & Device Listing*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=327521> (last updated June 30, 2025) (annotations added).



**Fig. 7. BrainWatch User Manual<sup>145</sup>**

131. On information and belief, at least as of June 2025, ongoing clinical trial programs within the United States utilize the Accused Products. This shows that the Accused Products were imported sometime before that date. For instance, Natus reposted a June LinkedIn post by the Neurology Consultants of Dallas regarding their first use of “the BrainWatch Point-of-Care EEG System,” the Accused Products.

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<sup>145</sup> Ex. 38 at 32 (annotations added) (illustrating “CA” as the Alpha-2 code under ISO 3166-1).



Natus Neuro reposted this



### Neurology Consultants of Dallas

305 followers

2w • 🌐

🎉 We're excited to share a major milestone at [Neurology Consultants of Dallas!](#)

Our team successfully completed our [first use of the BrainWatch Point-of-Care EEG system](#) by @NatusNeuro, and we're proud to be part of the innovation shaping the future of neurodiagnostics.

Advancing neurological care means embracing forward-thinking tools that help us better serve our patients — and this is just one of many ways we're staying ahead.

💡 A special thank you to Dr. Mohamed Shabana, Dr. Puneet Gupta, and the dedicated NCD Neuro Testing Center team who continue to lead with excellence and vision.

Here's to continued progress and patient-centered innovation!

[#NeuroInnovation](#) [#BrainWatch](#) [#Neurology](#) [#HealthcareTechnology](#)  
[#PatientCare](#) [#NeurologyConsultantsofDallas](#) [#WearableTech](#) [#NeuroDiagnostics](#)



### Jeff Rexford • 3rd+

District Sales Manager at Natus Neuro

2w • 🌐

🎉 Exciting Milestone! 🧠 ⭐

@NatusNeuro are proud to share that [Neurological Consultants of Dallas](#) successfully completed their [first usage of the BrainWatch Point-of-Care EEG system](#) — and the experience has been nothing short of impressive. The small, wearable, and wireless design of BrainWatch delivers high-quality EEG signals. Even more powerful is its ability to perform re-montaging after the study, which enhances visualization — a game changer for clinical and diagnostic workflows.

💡 Congratulations to this amazing team for continuing to lead at the forefront of EEG technology to bring innovative tools to their patients and stay ahead with cutting-edge neurodiagnostic solutions.

[#NeuroInnovation](#) [#EEG](#) [#AES](#) [#BrainWatch](#) [#Neurology](#)  
[#HealthcareTechnology](#) [#PatientCare](#) [#WearableTech](#) [#NeuroDiagnostics](#)  
[Natus Neuro](#) [Puneet Gupta](#) [#DrShabana](#) [#NeurologyConsultantsofDallas](#)



**Fig. 8. LinkedIn Post reposted by Natus Neuro<sup>146</sup>**

<sup>146</sup> Ex. 73 at 11-12, 59, Neurology Consultants of Dallas, (LinkedIn, June 4, 2025), [https://www.linkedin.com/posts/neurology-consultants-of-dallas-p.a\\_neuroinnovation-eeg-aes-](https://www.linkedin.com/posts/neurology-consultants-of-dallas-p.a_neuroinnovation-eeg-aes-)

132. On information and belief, the Accused Products were present in the United States at least at the American Association of Critical-Care Nurses' 2025 National Teaching Institute & Critical Care Exposition (AACN NTI 2025) that took place May 19, 2025 to May 21, 2025 in New Orleans, LA.<sup>147</sup> For instance, posted by Rachel Malloy, a Clinical Application Manager at Natus, shows that the Accused Products were present at the AACN NTI 2025.

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[activity-7336229266746953729-wXb8/?utm\\_source=share&utm\\_medium=member\\_desktop&rcm=ACoAADS0mNcBypIWschNSNPW-TVw5UpqhK\\_9IW5](https://www.linkedin.com/feed/update/urn:li:activity-7336229266746953729-wXb8/?utm_source=share&utm_medium=member_desktop&rcm=ACoAADS0mNcBypIWschNSNPW-TVw5UpqhK_9IW5) (reposted by Natus Neuro) (annotations added).

<sup>147</sup> Ex. 74, *NTI 2025 New Orleans*, NTI, <https://www.aacn.org/conferences-and-events/nti> (last visited June 27, 2025).



**Fig. 9. LinkedIn Post by Rachel Malloy (Clinical Application Manager at Natus)<sup>148</sup>**

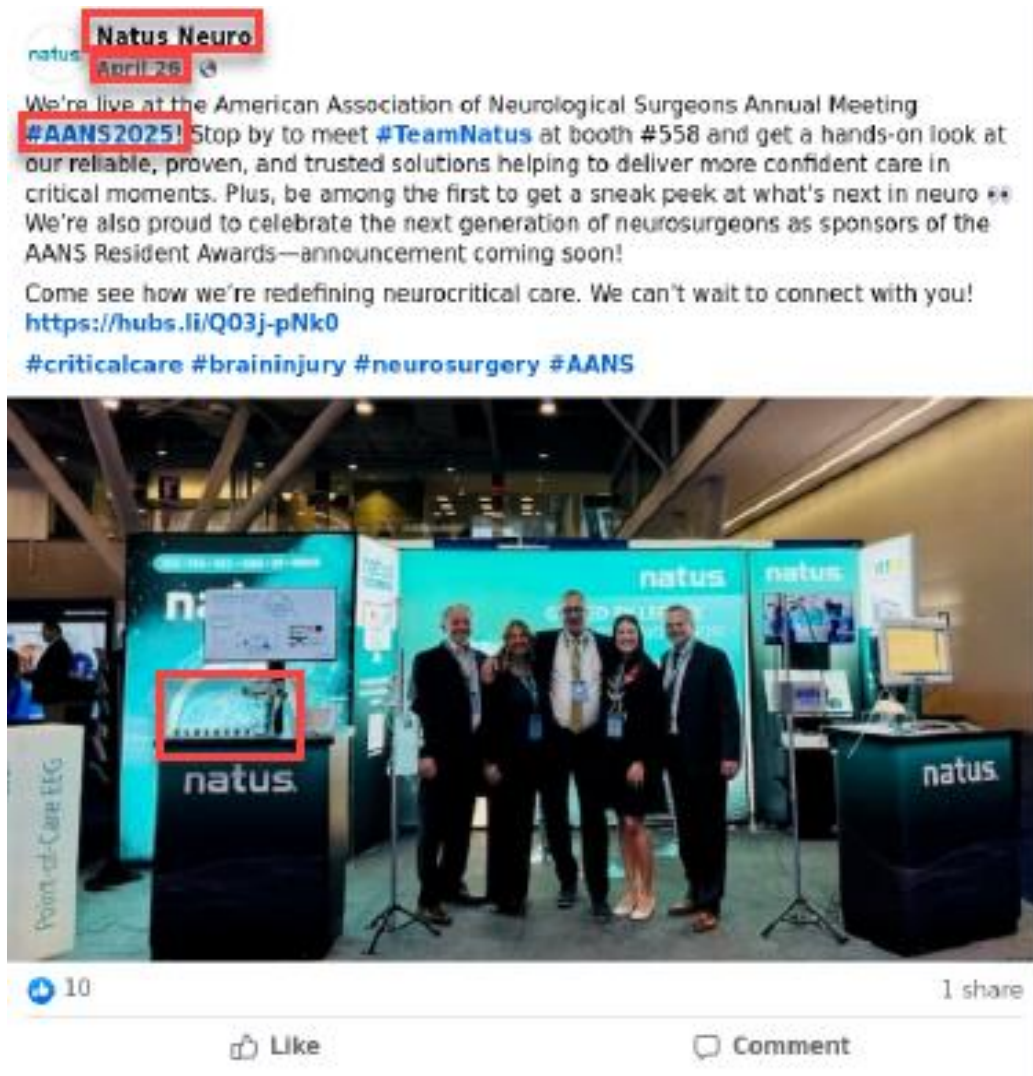
<sup>148</sup> Ex. 75 at 2, 4, Rachel Malloy, LINKEDIN, at 0:10 (May 20, 2025), [https://www.linkedin.com/posts/rachel-malloy-rn\\_poceeg-brainwatch-activity-](https://www.linkedin.com/posts/rachel-malloy-rn_poceeg-brainwatch-activity-)

133. On information and belief, the Accused products were present in the United States at least at the American Association of Neurological Surgeons Annual Meeting (AANS2025) that took place April 25, 2025 to April 28, 2025 in Boston, MA.<sup>149</sup> For instance, Natus' Facebook post shows that the Accused Products were present at the AANS2025.

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[7330672726145196032-mFbM?utm\\_source=share&utm\\_medium=member\\_desktop&rcm=ACoAADYc2YoBNq8vzGKVToeE8pBLCtValLy6nDk](https://www.facebook.com/natusinc/posts/7330672726145196032-mFbM?utm_source=share&utm_medium=member_desktop&rcm=ACoAADYc2YoBNq8vzGKVToeE8pBLCtValLy6nDk) (annotations added).

<sup>149</sup> Ex. 76, *Meeting Dates*, AM. ASS'N OF NEUROLOGICAL SURGEONS, <https://www.aans.org/annual-meeting/meeting-dates/> (last visited June 27, 2025).



**Fig. 10. Facebook Post by Natus Neuro<sup>150</sup>**

134. On information and belief, the Accused products were present in the United States at least at the American Academy of Neurology 2025 Annual Meeting (AANAM 2025) that took place April 5, 2025 to April 9, 2025 in San Diego, CA.<sup>151</sup> For instance, Natus reposted a LinkedIn

<sup>150</sup> Ex. 77, Natus Neuro, FACEBOOK (Apr. 26, 2025), <https://www.facebook.com/natusneuro/posts/pfbid02peVJatb7R8BDcgWBucufH8HTuhzp2ggXeuwZ1A498x7Lja2yGhRcJiFtbUUAtyn5l> (annotations added).

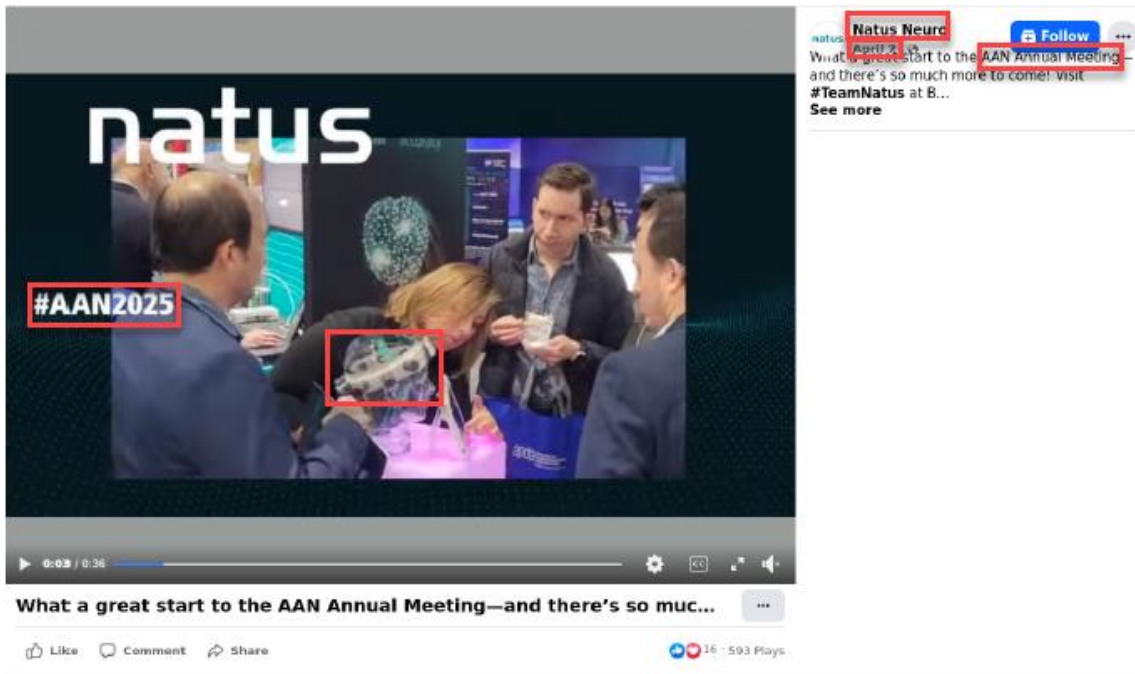
<sup>151</sup> Ex. 78, 2025 AAN Annual Meeting Archive, AM. ACAD. OF NEUROLOGY, <https://www.aan.com/events/2025-annual-meeting> (last visited July 6, 2025).

post showing that the Accused Products were present at the AANAM 2025. Natus also made a Facebook post showing the same.

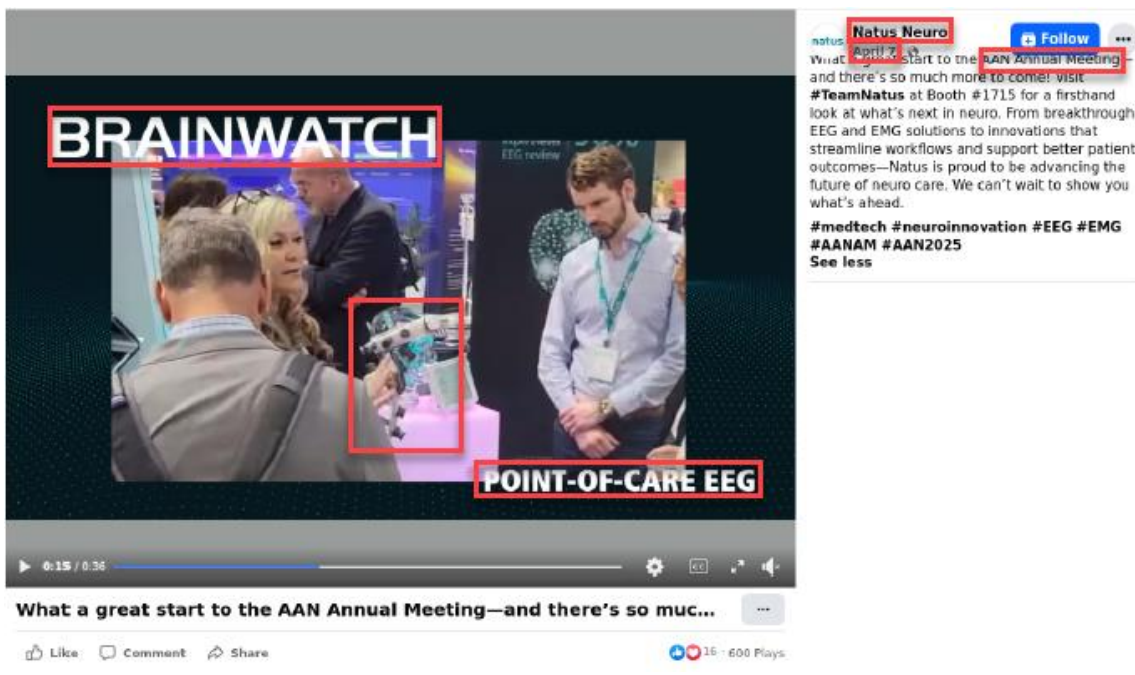


**Fig. 11. LinkedIn Post reposted by Natus Neuro<sup>152</sup>**

<sup>152</sup> Ex. 73 at 51, 56, Kristina Malloy, LINKEDIN (Apr. 6, 2025), available at [https://www.linkedin.com/posts/kristina-malloy-800b0935\\_aanam-teamnatus-eeg-ugcPost-7314722866917236736-PJGN?utm\\_source=share&utm\\_medium=member\\_desktop&rcm=ACoAADS0mNcBypIWschN\\_SNPW-TVw5UpqhK\\_9IWw](https://www.linkedin.com/posts/kristina-malloy-800b0935_aanam-teamnatus-eeg-ugcPost-7314722866917236736-PJGN?utm_source=share&utm_medium=member_desktop&rcm=ACoAADS0mNcBypIWschN_SNPW-TVw5UpqhK_9IWw) (reposted by Natus Neuro) (annotations added).



**Fig. 12. Facebook Post by Natus Neuro<sup>153</sup>**

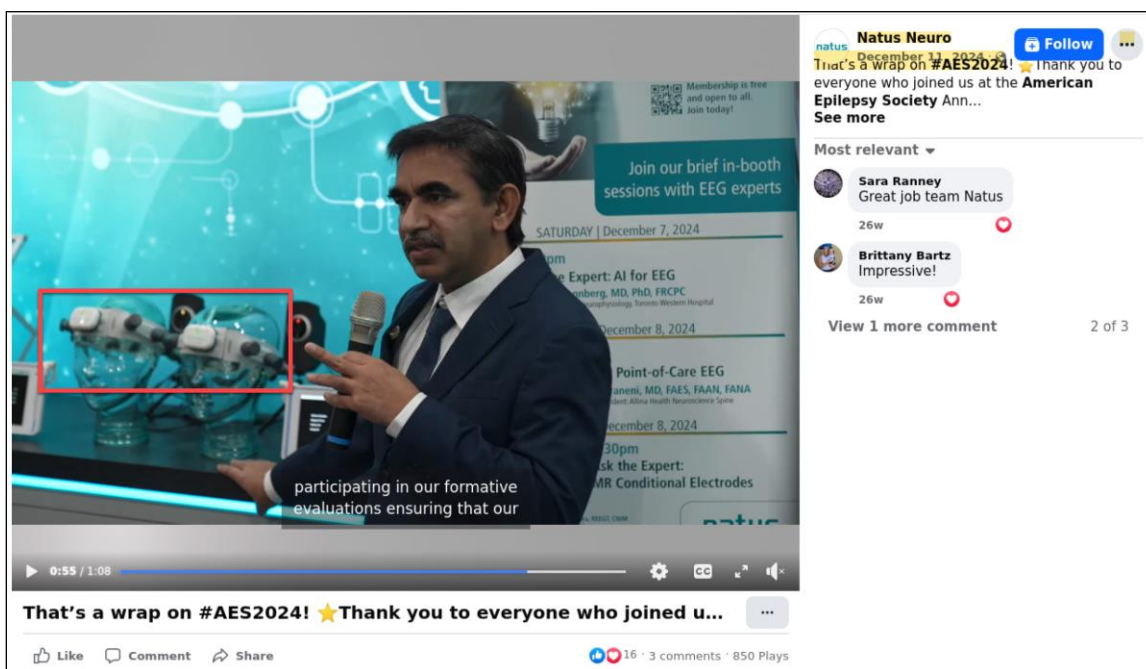


**Fig. 13. Facebook Post by Natus Neuro<sup>154</sup>**

<sup>153</sup> Ex. 79, Natus Neuro, FACEBOOK (Apr. 7, 2025), <https://www.facebook.com/natusneuro/videos/1405012634011406/> at 0:03 (annotations added).

<sup>154</sup> Ex. 80, Natus Neuro, FACEBOOK, at 0:15 (Apr. 7, 2025), <https://www.facebook.com/natusneuro/videos/1405012634011406/> (annotations added).

135. On information and belief, the Accused Products were present in the United States at least at the American Epilepsy Society 2024 Annual Meeting (AES 2024) that took place December 6, 2024 to December 10, 2024 in Los Angeles, CA.<sup>155</sup> For instance, Natus' Facebook post shows that the Accused Products were present at the AES 2024.



**Fig. 14. Facebook Post by Natus Neuro<sup>156</sup>**

136. The FDA Establishment Registration and Device Listing database, current as of June 30, 2025, indicates that the cutaneous electrodes (EEG electrode headband) portion of the Accused Products are manufactured in Vietnam. On information and belief, the Accused Products were imported through at least June 30, 2025.

### **VIII. CLASSIFICATION UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES**

<sup>155</sup> Ex. 81, *AES 2024 Annual Meeting*, AM. EPILEPSY SOC'Y, <https://web.archive.org/web/20241127181357/https://www.aesnet.org/AES-annual-meeting> (last visited June 27, 2025),

<sup>156</sup> Ex. 82, Natus Neuro, FACEBOOK, at 0:55 (Dec. 11, 2024), <https://www.facebook.com/natusneuro/videos/thats-a-wrap-on-aes2024-thank-you-to-everyone-who-joined-us-at-the-american-epil/1007183608114217/> (annotations added).

137. The Accused Products are classified at least under the following subheadings of the Harmonized Tariff Schedule of the United States: 9018.19.95.35 (Electroencephalographs (EEG) and electromyographs (EMG)).<sup>157</sup> This classification is exemplary in nature and not intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

#### **IX. RELATED LITIGATION**

138. Ceribell filed a complaint in the District of Delaware on July 7, 2025, asserting the same patents asserted here. *See Ceribell, Inc. v. Natus Medical Incorporated, et al.*, (D. Del.).

139. Aside from the above-mentioned parallel district court matter, Ceribell has not previously litigated the asserted patents before any other court or agency.

#### **X. THE DOMESTIC INDUSTRY RELATING TO THE ASSERTED PATENTS**

140. An industry as required by Section 337(a)(2) and defined by Section 337(a)(3)(A)-(C) exists and/or is in the process of being established in the United States relating to the Asserted Patents and Ceribell's products and components thereof protected by the Asserted Patents.

141. As described below and in the accompanying declaration at Confidential Exhibit 26, Ceribell researches, designs, and develops wearable EEG devices and systems and components thereof in the United States that practice the claims of each of the Asserted Patents ("Domestic Industry Products").

142. As further described in Confidential Exhibit 26, Ceribell is currently developing new wearable EEG devices and systems and components thereof that practice certain claims of one or more of the Asserted Patents.

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<sup>157</sup> Ex. 83 at XVIII 90-18, U.S. INT'L TRADE COMM'N, HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES REVISION 14 (2025).

**B. Technical Prong**

143. The Domestic Industry Products include the Ceribell System (described above) and new EEG monitoring systems under development. Claim charts demonstrating that the Domestic Industry Products practice at least one claim of each Asserted Patent are attached as Exhibits 14, 16, 18, 20, 22, 23 and 25.<sup>158</sup>

**C. Economic Prong**

144. There is a domestic industry as defined under 19 U.S.C. § 1337(a)(3)(A), (B), and/or (C), comprising continuing significant investments made in the United States by Ceribell in plant and equipment and employment of labor and capital, and continuing substantial investment in exploitation of the Asserted Patents. *See Woo Declaration, pp. 5-7.*

145. Ceribell has made and continues to make significant investments in plant and equipment directed to the Domestic Industry Products in the United States. Those investments in plant and equipment are dedicated to research, design, development, engineering, product support, manufacturing support, testing, and various customer support activities focused on the Domestic Industry Products. *See Woo Declaration, p. 5.*

146. Ceribell also has made and continues to make significant investments in labor and capital directed to the Domestic Industry Products in the United States. Those investments in labor and capital are dedicated to research, design, development, engineering, product support, manufacturing support, testing, and various customer support activities focused on the Domestic Industry Products. *See Woo Declaration, pp. 5-6.*

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<sup>158</sup> The Domestic Industry Products practice additional claims of the Asserted Patents, and Ceribell may establish the technical prong of the domestic industry requirement through claims other than those used in these exhibits.

147. Ceribell further engages in exploitation of the Asserted Patents through its substantial domestic investments in research and development and engineering activities in the United States. These activities include, among other things, research and development and engineering and design tied to the claimed technology implemented in the Asserted Patents. *See* Woo Declaration, pp. 6-7. These activities have occurred in the past and are ongoing with respect to prior and current versions of the Domestic Industry Products as well as future products under development. *Id.*

148. In addition to the existing domestic industry, a domestic industry in new products that practice the Asserted Patents in the United States is in the process of being established under 19 U.S.C. § 1337(a)(3)(A), (B), and/or (C). Specifically, this “in the process” domestic industry relates to Ceribell’s additional EEG products currently in development which practice the Asserted Patents. *See* Woo Declaration, p. 2. Ceribell has taken necessary tangible steps to establish this new domestic industry in the United States through significant investments in research, development, and regulatory activities. *See* Woo Declaration, p. 2. These investments represent concrete steps demonstrating Ceribell’s commitment to establishing a domestic industry for additional EEG products practicing the Asserted Patents. As a result of these steps, there is a significant likelihood that this new domestic industry will be established in the future. *Id.*

**XI. RELIEF REQUESTED**

149. Complainant respectfully requests that the Commission:

(a) Institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to Natus’ violations of that section arising from the importation into the United States, sale for importation, and/or the sale within the United States after importation of certain wearable EEG devices and systems and components thereof that infringe one or more claims of the Asserted Patents;



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*Counsel for Ceribell, Inc.*

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN WEARABLE  
ELECTROENCEPHALOGRAM  
DEVICES AND SYSTEMS AND  
COMPONENTS THEREOF**


**Investigation No. 337-TA- \_\_\_\_\_**

**VERIFICATION OF COMPLAINT**

I, Raymond Woo, am the Chief Technology Officer of Ceribell, Inc. and I am authorized to execute this verification on behalf of Complainant. I have read the Complaint and am aware of its contents. To the best of my knowledge, information, and belief and based upon a reasonable inquiry under the circumstances, I hereby certify that:

1. The allegations contained in the Complaint are well grounded in fact and have evidentiary support, or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;
2. The claims and other legal contentions set forth in the Complaint are warranted by existing laws or by a good faith, non-frivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law; and
3. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

Dated July 7, 2025

  
\_\_\_\_\_  
Raymond Woo