ceribell®

EEG Recorder Operator Manual

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Indications for Use

The Ceribell® EEG Recorder is intended to record and store EEG signals, and to present the EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses. The Ceribell EEG Recorder is intended to be used in a professional healthcare facility environment. Additionally, the EEG Recording Viewer Software component of the Ceribell EEG Recorder incorporates a Seizure Detection component that is intended to mark previously acquired sections of EEG recordings in patients greater than or equal to 18 years of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection component provides notifications to the user when detected seizure prevalence is “Frequent”, “Abundant,” or “Continuous” per the definitions of the American Neurophysiology Society Guideline 14. Notifications include an on- screen display on the Ceribell EEG Recorder and the optional sending of an e-mail message. Delays of up to several minutes can occur between the beginning of a seizure and when the Seizure Detection notifications will be shown to a user. The Ceribell EEG Recorder does not provide any diagnostic conclusion about the subject’s condition and Seizure Detection notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Indications for Use (expanded seizure detection population)

The Ceribell Seizure Detection Software is intended to mark previously acquired sections of EEG recordings in patients greater or equal to 1 year of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection Software also provides notifications to the user when detected seizure prevalence is “Frequent”, “Abundant”, or “Continuous, per the definitions of the American Clinical Neurophysiology Society Guideline 14. Delays of up to several minutes can occur between the beginning of a seizure and when the Seizure Section notifications will be shown to a user.

The Ceribell Seizure Detection Software does not provide any diagnostic conclusion about the subject’s condition and Seizure Detection notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Indications for Use (Electrographic Status Epilepticus Monitor)

The Ceribell Status Epilepticus Monitor software is indicated for the diagnosis of Electrographic Status Epilepticus in patients greater than or equal to 18 years of age who are at risk for seizure. The Ceribell Status Epilepticus Monitor software analyzes EEG waveforms and identifies patterns that may be consistent with electrographic status epilepticus as defined in the American Clinical Neurophysiology Society's Guideline 14.

The diagnostic output of the Ceribell Status Epilepticus Monitor is intended to be used as an aid for determining patient treatment in acute-care environments. The device's diagnosis of Electrographic Status Epilepticus provides one input to the clinician that is intended to be used in conjunction with other elements of clinical practice to determine the appropriate treatment course for the patient.

The Ceribell Status Epilepticus Monitor is intended for diagnosis of Electrographic Status Epilepticus only. The device does not substitute for the review of the underlying EEG by a qualified clinician with respect to any other types of pathological EEG patterns. The device is not intended for use in Epilepsy Monitoring Units.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Indications for use (expanded infant seizure detection population)

The Ceribell Infant Seizure Detection Software is intended to mark previously acquired sections of EEG recordings in newborns (defined as preterm or term neonates of 25-44 weeks postmenstrual age) and infants less than 1 year of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection Software also provides notifications to the user when detected seizure prevalence is “Frequent”, “Abundant”, or “Continuous”, per the definitions of the American Clinical Neurophysiology Society Guideline 14. Delays of up to several minutes can occur between the beginning of a seizure and when the Seizure Detection notifications will be shown to a user.

The Ceribell Infant Seizure Detection Software does not provide any diagnostic conclusion about the subject’s condition and Seizure Detection notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Table 1: Clarity is cleared for the following wearable use and patient ages

Patient Age	Wearable	Clarity Type
18 years and up	Headband	Adult Clarity
1 - 17 years	Headband	Pediatric Clarity
25 weeks PMA to 1 year	Headcap	Neonate Clarity

Warnings and Precautions

Warning: The Ceribell EEG Recorder is not defibrillation -proof. Remove the Ceribell EEG Recorder and all accessories from the patient prior to using a defibrillator.

Warning: The Ceribell EEG Recorder is MR Unsafe. Remove the Ceribell EEG Recorder and all accessories from the patient prior to entering an MRI (magnetic resonance imaging) scanning room.

Warning: Only use the included power adapter and micro-USB cable to charge the Ceribell EEG Recorder. Use of other charging devices is not authorized.

Warning: All EEG acquisition functions are automatically disabled when the Ceribell EEG Recorder is plugged into an external power supply or computer. EEG measurements and recordings cannot be taken while the Ceribell EEG Recorder is charging or connected to a computer.

Warning: The Ceribell EEG Recorder does not contain any user-serviceable parts. Contact Ceribell if your device requires service. Do not attempt to open or disassemble the Ceribell EEG Recorder.

Warning: The Ceribell EEG Recorder provides notifications for Seizure Detection that can be used when processing a record during acquisition. These include an on screen display and the optional sending of an email message. Delays of up to several minutes can occur between the beginning of a seizure and when the Ceribell EEG Recorder notifications will be shown to a user.

Warning: The Ceribell EEG Recorder Seizure Detection output cannot be used as a substitute for review of the underlying EEG by a trained expert.

Warning: Do not rely solely on the Seizure Detection output for review of the study. The Seizure Detection output is a tool used to assist the qualified practitioner with the analysis and diagnosis of the patient.

Warning: The Seizure Detection Software only analyzes signals recorded by the Fp1, Fp2, F7, F8, T3, T4, T5, T6, O1 and O2 electrodes.

Warning: The Infant Seizure Detection Software only analyzes signals recorded by the Fp1, Fp2, T3, T4, C3, Cz, C4, O1 and O2 electrodes.

Caution: The Status Epilepticus Monitor is only compatible with the Ceribell Pocket EEG Device and the Ceribell Instant EEG Headband. Users of the Status Epilepticus Monitor must be familiar with the operation of the Ceribell Pocket EEG Device and the Ceribell Instant EEG Headband. Consult the instructions for use for the Pocket EEG Device provided here and the separate instructions for the Ceribell Instant EEG Headband for further information.

Caution: The Status Epilepticus Monitor is intended only to analyze EEG waveforms against the criteria for ESE. The absence of a detection of ESE by the subject device does not preclude the possibility that seizures, other epileptiform patterns, or other pathologies are present in the EEG recording.

Caution: The Ceribell Status Epilepticus Monitor is intended for diagnosis of Electrographic Status Epilepticus only. The device does not substitute for the review of the underlying EEG by a qualified clinician with respect to any other types of pathological EEG Patterns.

Caution: The Status Epilepticus Monitor output has not been tested with patients under 18 years old.

Caution: The Infant Seizure Detection Software is only compatible with the Ceribell Pocket EEG Device and the Ceribell Instant EEG Headcap. Users of the Infant Seizure Detection Software must be familiar with the operation of the Ceribell Pocket EEG Device and the Ceribell Instant EEG Headcap. Consult the instructions for use for the Ceribell Pocket EEG Device and the Ceribell Instant EEG Headcap for further information.

Caution: The absence of a detection of seizure by the Infant Seizure Detection Software does not preclude the possibility that seizures, other epileptiform patterns, or other pathologies are present in the EEG recording.

Quick Start Guide

This section outlines how to quickly power on the device

and start and stop an EEG recording. Refer to the Table of Contents and the rest of the operator manual for additional information.

Step 1: Power On the Ceribell EEG Recorder

Press the power button to turn on the Ceribell EEG Recorder. A blue LED on the side of the touchscreen will illuminate and the Home Screen will appear.

Figure 1: Ceribell EEG Recorder

Step 2A: Enter the Patient Information

A. Press the **RECORD** button on the Home Screen to go to the Patient Info entry pages.

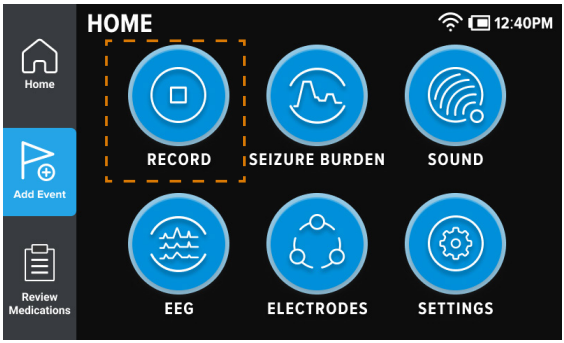


Figure 2: Home Screen

B. Enter the Patient ID and press the **ENTER** button to continue to the next entry page.

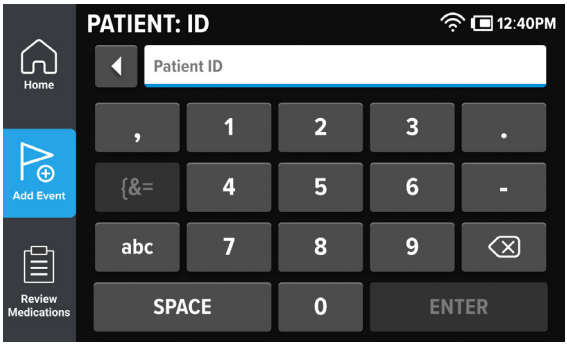


Figure 3: Patient Info: ID Entry Page

C. Enter the Patient First Name and press the **ENTER** button to continue to the next entry page.

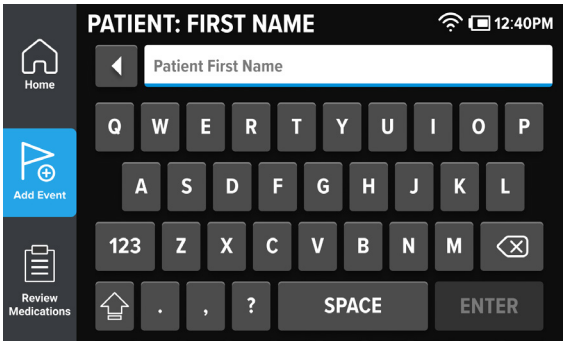


Figure 4: Patient Info: First Name Entry Page

D. Enter the Patient Last Name and press the **ENTER** button to continue to the next entry page.

Figure 5: Patient Info: Last Name Entry Page

E. Enter the Patient Date of Birth (DOB) and press the **ENTER** button to continue to the next entry page.

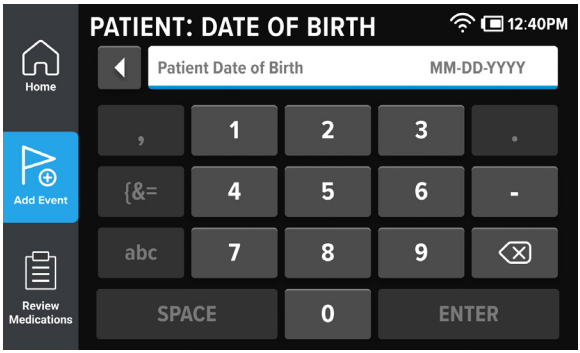


Figure 6: Patient Info: DOB Entry Page

F. Select the appropriate location and press the **NEXT** button to continue to the next entry page.

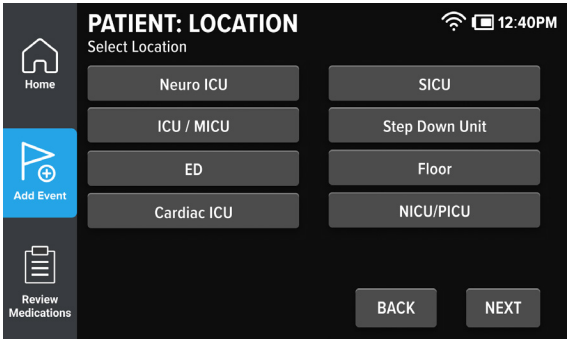


Figure 7: Patient Info: Location Entry Page

G. Select the appropriate Primary Indication (one or more) and press the **NEXT** button to continue to the next entry page. To enter an Other Primary Diagnosis, press the **OTHER** button to continue to the Other Primary Indication entry page.

Note: the options vary based on patient location. For example, choosing NICU will present indications common in the NICU.

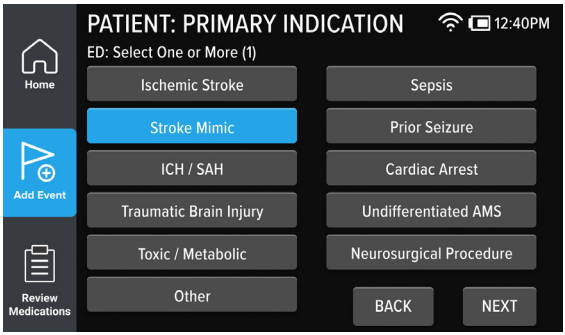


Figure 8: Patient Info: Primary Indication Entry Page

H. Enter the Other Primary Indication and press the **ENTER** button to continue to the next entry page.

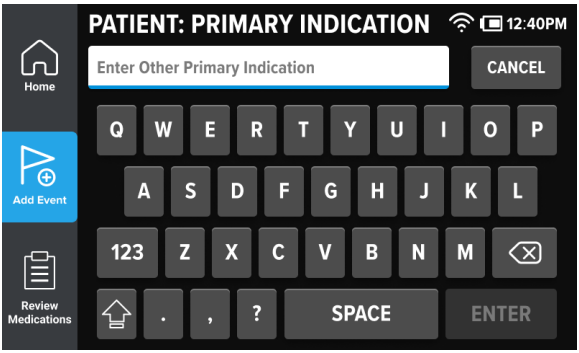


Figure 9: Patient Info: Other Primary Indication Entry Page

I. Enter the Ordering Physician Name and press the **ENTER** button to continue to the Confirm Patient Info page.

Figure 10: Patient Info: Ordering Physician Entry Page

J. Verify that the entered patient information is correct and press the **CONFIRM** button to continue.

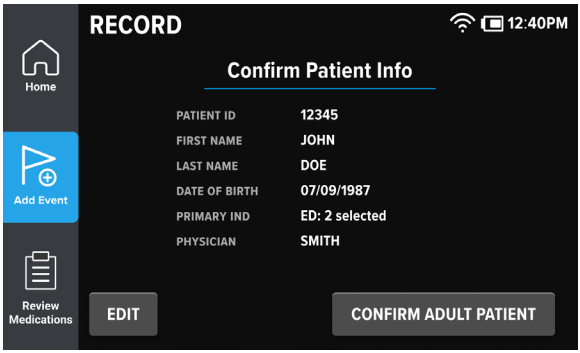


Figure 11: Confirm Patient Info Page

*Note: If any incorrect patient information has been entered, press the **BACK** button to edit the incorrect information.*

Step 2B: Select Order

A. If EMR integration is enabled, patient and order details are automatically retrieved from the EMR.

Press the **RECORD** button on the Home Screen to go to the Orders in Last 24 Hours page.

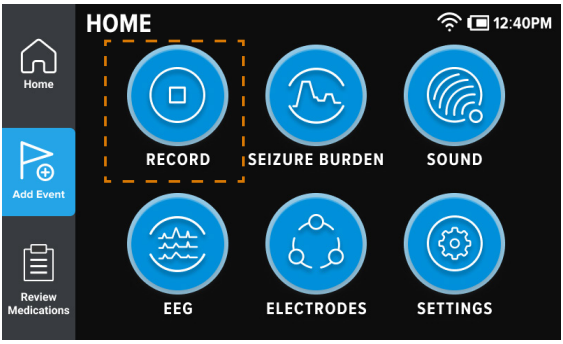


Figure 12: Home Screen

B. Select the patient from the list of active Ceribell orders and press the **CONFIRM** button to continue.

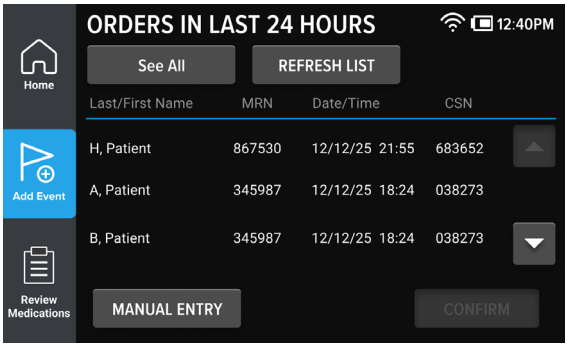


Figure 13: Orders in Last 24 Hours Page

C. To view additional orders, press **SEE ALL** to display orders from the past 7 days. To update the list, press **REFRESH**.

Use the Up and Down arrow buttons to navigate through additional names.

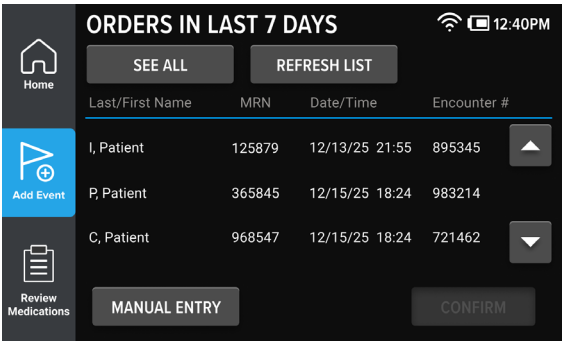


Figure 14: See All Orders Page

D. Select the desired order and press **CONFIRM**.

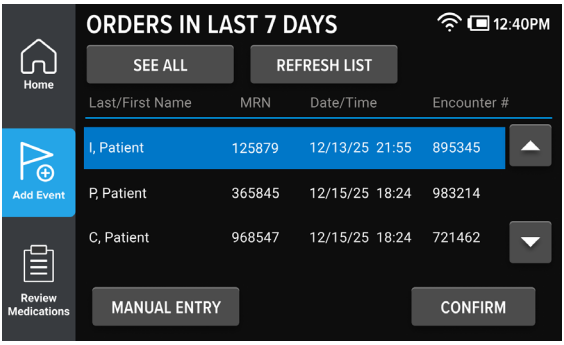


Figure 15: Select and Confirm Order Page

E. Verify that the entered patient information is correct and press the **CONFIRM** button to continue

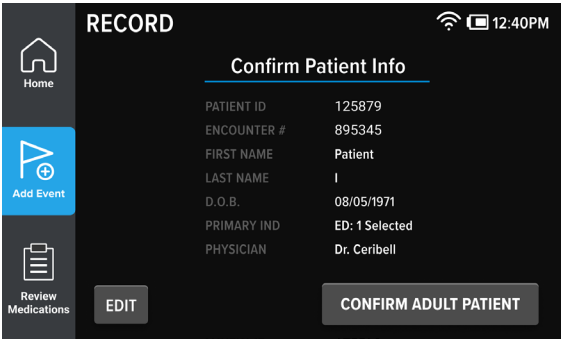


Figure 16: Confirm Patient info Page

*Note: If any incorrect patient information has been entered, press the **EDIT** button to edit the incorrect information.*

Step 3: Connect the Ceribell Instant EEG Device

A. Plug the Ceribell EEG Headband, Headcap or other EEG electrodes into the connector labeled “Headband” on the side of the Ceribell EEG Recorder.

Figure 17: Please Connect a Wearable to Continue Page

B. Set up the device, and adjust the electrodes until a green indication is shown for each electrode on the Check Electrode Connections page.

C. Press the **RECORD** button to begin recording.

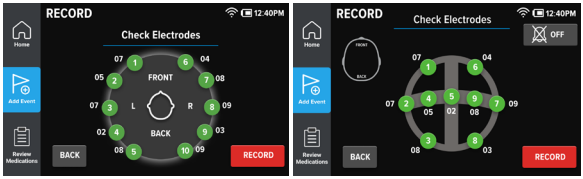


Figure 18: Check Electrode Connections Page – headband (left), headcap (right)

Note: The Check Electrode Connections page shows the status of each electrode. A red indication means that the electrode connection is poor, which will result in noisy EEG signals. A green indication means that the electrode connection is good. A yellow indication means that the electrode connection is acceptable. Try to ensure that all the electrodes are shown as green prior to starting a recording.

Step 4: Listen to EEG Waveforms

A. Press the **SOUND** button on the Home Screen or the Brain Stethoscope button next to the speaker to go to the Sound page.

Note: the sound button is not available with the EEG headcap.

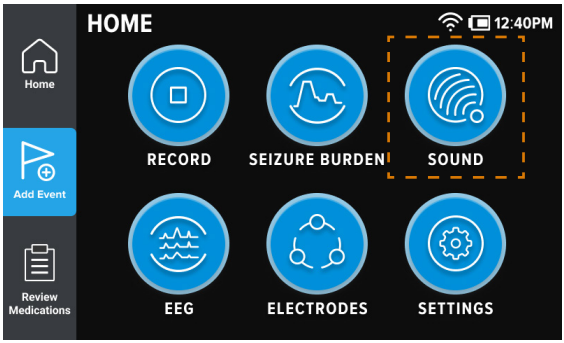


Figure 19: Home Screen

Figure 20: Ceribell EEG Recorder

B. Press the **L** or **R** button on the Sound page to switch between the left and right hemispheres.

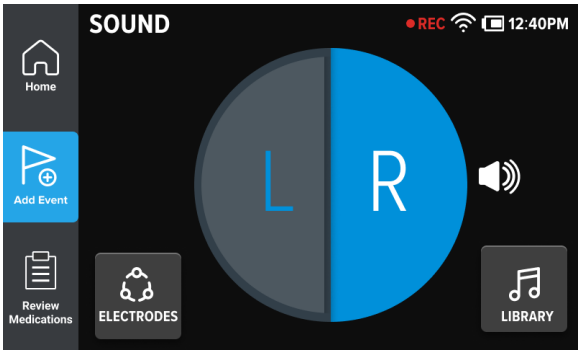


Figure 21: Sound Page

Note: When listening to the left hemisphere, electrode channel 3-4 is used. When listening to the right hemisphere, electrode channel 8- 9 is used. To adjust the volume, press the volume up and down buttons located next to the power button.

Step 5: View Seizure Burden

A. Press the **SEIZURE BURDEN** button on the Home Screen to go to the *Seizure Burden* page.

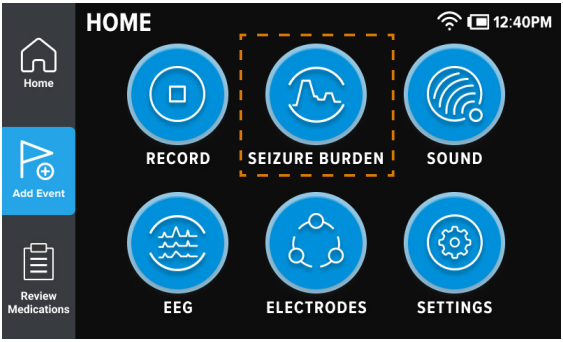


Figure 22: Home Screen

B. The *Seizure Burden* page displays the Seizure Burden plot for the recording.Use the left and right arrow buttons beneath the plot to navigate through the recording. Navigation is available once the recording duration exceeds approximately 70 minutes.

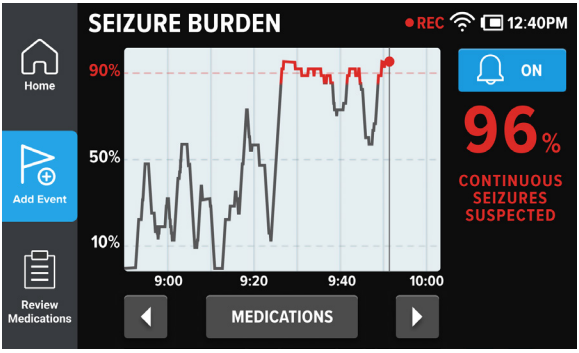


Figure 23: Seizure Burden Page

Note: The Seizure Burden plot displays the percentage of detected seizures over a five minute period. WiFi must be enabled. Data upload begins approximately 15–20 seconds after connection.

Step 6: Stop the EEG Recording

A. Press the **RECORD** button on the Home Screen to go to the *Record* page, and press the **STOP RECORDING** button to stop recording.

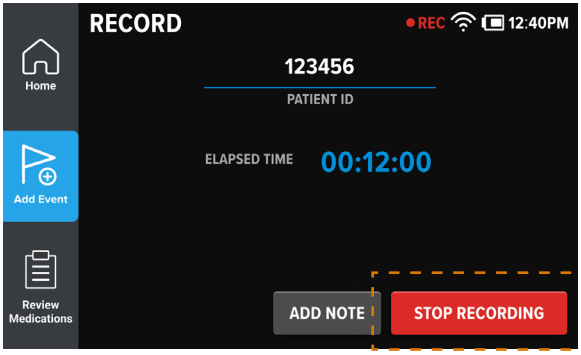


Figure 24: Record Page

B. When the Survey is enabled, pressing the **STOP RECORDING** button opens the survey question pages. The recording continues until the survey is completed or skipped..

Select an answer choice and press **NEXT** to move through the questions. Use **BACK** to review previous responses.

Press **SKIP SURVEY AND STOP RECORDING** to return to the Recording Complete Page.

Figure 25:Post-Recording Survey Anti-Seizure Medications Avoided

C. After the final question, press **SUBMIT SURVEY AND STOP RECORDING** to submit the survey. The system then returns to the Recording Complete Page.

Figure 26: Post-Recording Survey Overall Experience

D. The patient can be disconnected once the *Recording Complete* page displays. Press the **DONE** button to finish.

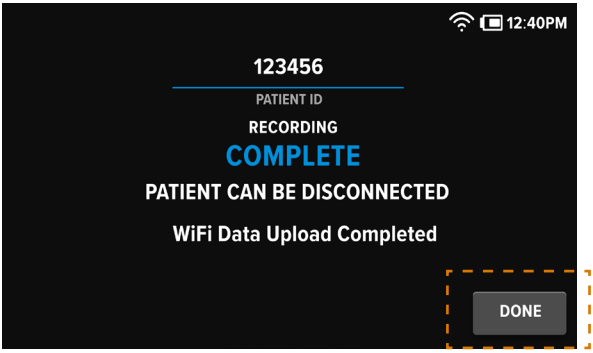


Figure 27: Recording Complete Page

Note: It may take a few moments for the recording data to be saved; however, the patient can still be disconnected.

System Overview

The Ceribell EEG Recorder is a portable EEG monitoring system that displays 8 channels of EEG. 10 patients electrodes (5 left, 5 right) are required to form 8 channels when the Ceribell Instant EEG Headband is connected. When the Ceribell EEG Headcap is connected, 9 electrodes form 8 channels on the device and 12 channels in the Ceribell EEG Portal. The Ceribell EEG Recorder can be used with any EEG electrodes

EEG Headband:
Electrodes 1-5 should be used for the patient's left hemisphere, with channel 1 at the front of the patient's head and Electrode 5 at the back of the patient's head. Electrodes 6-10 should be used for the patient's right hemisphere, with Electrode 6 at the front of the patient's head and Electrode 10 at the back of the patient's head.

EEG Headcap:
Slide the headcap down to just above the ears, with cable at the back of the head. Electrodes 1 and 6 will be at the front of the patient's head, and electrodes 3 and 8 will be at the back of the patient's head.

Contact Ceribell for technical specifications of the connector used to connect electrodes to the Ceribell EEG Recorder. When connected to patient electrodes, the Ceribell EEG Recorder can be used to view or listen to EEG signals in real time. The operator can listen to EEG signals by using the Brain Stethoscope® function. Either the left or the right hemisphere can be listened to.

The Ceribell EEG Recorder can be used to record EEG sessions. Recorded sessions can later be reviewed on a computer using the Ceribell EEG Portal. EEG recording is transferred to the Ceribell EEG Portal in real time via WiFi. The recording can be transferred to a computer using a Micro-USB cable only after the recording has been completed.

System Components

- Ceribell EEG Recorder assembly (Ceribell part number SA-00039): portable, battery-powered, 8-channel EEG monitoring system.

- Ceribell EEG Portal (Ceribell part number SW-00001): portal that is used to view EEG recordings on a computer. The Ceribell EEG Portal can only be used to view EEG recordings from the Ceribell EEG Recorder. The Ceribell EEG Portal includes a Seizure Detection software module that assists qualified users in reviewing and annotating EEG by marking previously acquired sections of EEG that may correspond to electrographic seizures.

- Ceribell Mount Clip (Ceribell part number SA-00051): a mount clip for securing the Ceribell EEG Recorder to a hospital bed rail, IV pole, or equivalent.

- Ceribell Charging Station (Ceribell part number SA-00040): a base station used to both charge and provide easy access to the Ceribell EEG Recorder.

- Power adapter (Ceribell part number SA-00003): 100-240 V ac power adapter used to charge the Ceribell EEG Recorder. Only use the included power adapter to charge the Ceribell EEG Recorder.

- Micro-USB cable (Ceribell part number EC-00095): cable used to connect the Ceribell EEG Recorder to the power adapter for charging and to a computer for transferring EEG recording files. Only use the included micro-USB cable to connect the Ceribell EEG Recorder to the power adapter or a computer. When the Ceribell EEG Recorder is connected to the power adapter or a computer, all EEG acquisition functions are automatically disabled.

System Description

The Ceribell EEG Recorder has a 4-inch touchscreen display as its primary interface. The Ceribell EEG Recorder also has a power button, a Brain Stethoscope button, and volume up and down buttons. The power button turns the device on and off. When the device is on, the power button also toggles the display on and off. The Brain Stethoscope button turns the Brain Stethoscope function on and off, and the volume up and down buttons control the volume of the EEG waveform sound.

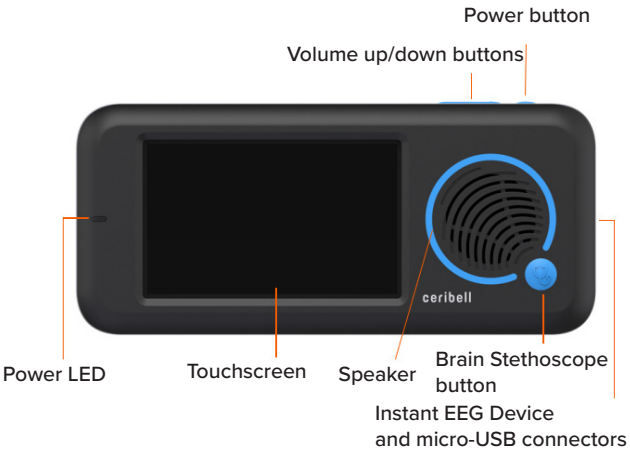


Figure 28: Ceribell EEG Recorder

On the left side of the touchscreen display, a blue LED illuminates whenever the device is powered on. On the right side of the device are instant EEG device and micro-USB connectors.

The Instant EEG electrode device plugs into the wearable connector. The micro-USB cable plugs into the micro-USB connector for charging the device and transferring EEG recording files.

Charging the Battery

To charge the battery, connect the Ceribell EEG Recorder to an external power supply using either the Ceribell Charging Station or the micro-USB cable and power adapter.

When the Ceribell EEG Recorder is plugged into a power source and powered on, the device will indicate that it is "Charging" and EEG acquisition features have been disabled.

Figure 29: Device Charging: Charging Page

The Ceribell EEG Recorder will indicate "Ready to Record" when it has charged sufficiently to complete a minimum of 2 hours of recording.

Figure 30: Device Charging: Ready to Record Page

The Ceribell EEG Recorder will indicate “Charging Complete” when it has fully charged.

Figure 31: Device Charging: Charging Complete Page

You can check the battery status by unplugging the Ceribell EEG Recorder, turning it on, and looking at the battery status icon in the status bar. When 20% of the battery is remaining, a Low Battery Warning page will appear.

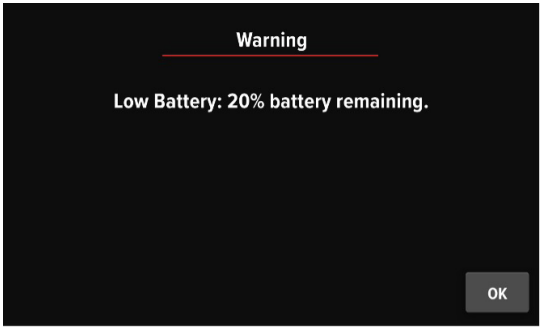


Figure 32: Low Battery Warning Page

Warning: Only use the included power adapter or micro -USB cable to charge the Ceribell EEG Recorder. Use of other charging devices is not authorized.

Warning: All EEG acquisition functions are automatically disabled when the Ceribell EEG Recorder is plugged into an external power supply or computer. EEG measurements and recordings cannot be taken while the Ceribell EEG Recorder is charging or connected to a computer.

Powering On and Off the Ceribell EEG Recorder

To turn on the Ceribell EEG Recorder, press and release the power button. To turn off the Ceribell EEG Recorder, press the power button and hold for 3 seconds. A message will appear on the touch-screen display to confirm that you would like to power off the device. Press the **POWER OFF** button on the display, and the system will power off.

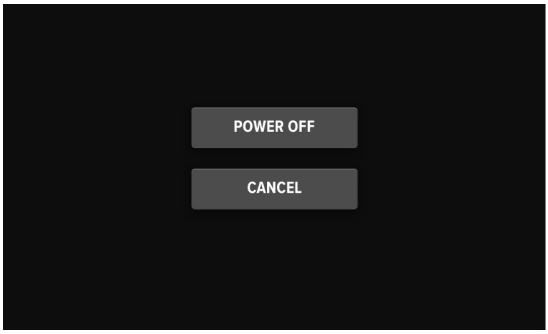


Figure 33: Power Off Confirmation Page

Note: When the device is on, pressing the power button toggles the touchscreen display on and off.

When no battery is remaining, the Ceribell EEG Recorder will automatically save an in-progress recording before powering off.

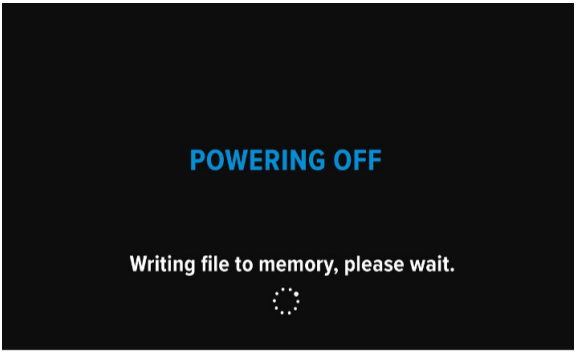


Figure 34: Powering Off Page

Ceribell EEG Recorder Software

Home Screen

The Home Screen provides access to entering patient information; starting a recording; listening to and displaying EEG signals; monitoring electrode connection status, WiFi status, and battery level; and adjusting system settings. The blue **HOME** button provides easy access to the Home Screen from any system page. Similarly, the orange **ADD EVENT**"button provides quick access to tag an event during recording from any system page. The **REVIEW MEDICATIONS** button provides access to medication list.

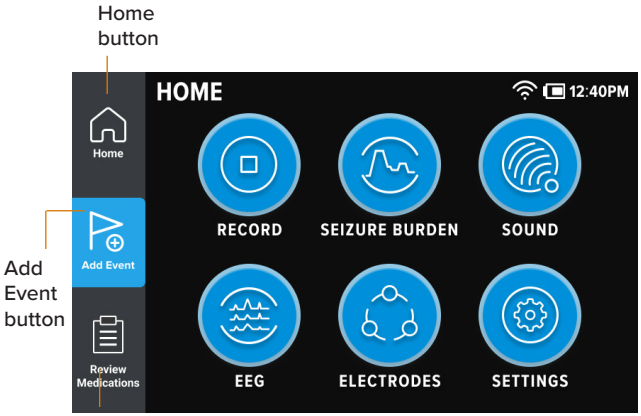


Figure 35: Home Screen

Starting an EEG Recording

Before starting an EEG recording using the Ceribell EEG Recorder, you must first enter the patient information. Press the **RECORD** button on the Home Screen to go to the *Patient Info* entry pages.

On each *Patient Info* entry page, enter the requested patient information (Patient ID, Patient First Name, Patient Last Name, etc.), And press the **ENTER** button to continue to the next entry page.

Figure 36: Sample Patient Info Entry Page

After entering all the requested patient information, press the **ENTER** button on the final Patient Info entry page to continue to the *Confirm Patient Info* page.

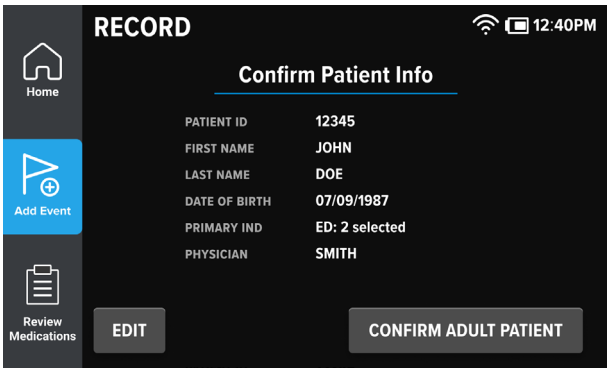


Figure 37: Confirm Patient Info Page

Verify that the entered patient information is correct. If any incorrect patient information has been entered, press the **EDIT** button to edit the incorrect information.

If EMR integration is enabled: Press the **RECORD** button on the Home Screen to go to the Orders in Last 24 Hours page (Figure 38). The Orders in Last 24 Hours page displays a list of active Ceribell orders.

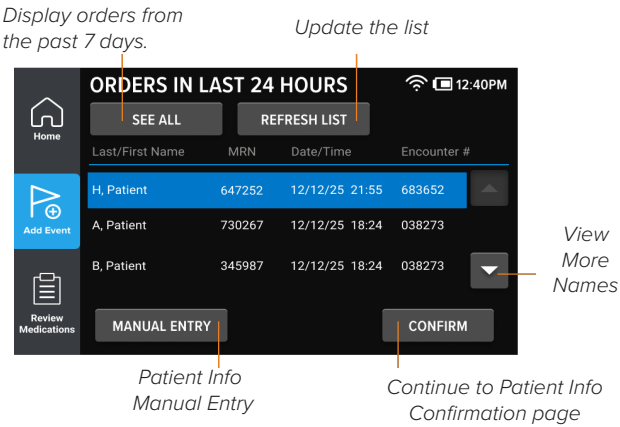


Figure 38: Sample Order Page

After selecting the patient from the active Ceribell orders, press the **CONFIRM** button to continue to the *Confirm Patient Info* page.

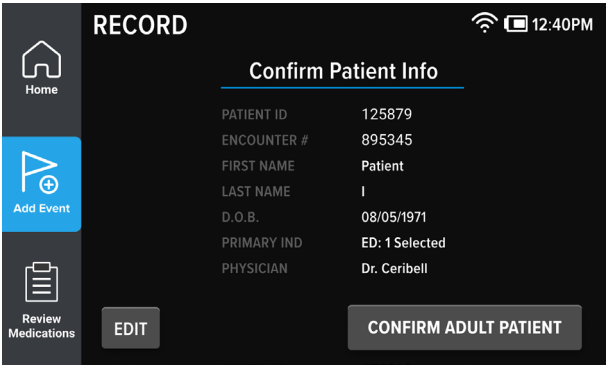


Figure 39: Confirm Patient Info Page

After verifying the patient information, press the **CONFIRM** button to continue to the *Check Electrode Connections* page.

The *Check Electrode Connections* page shows the status of each electrode. A red indication means that the electrode connection is poor, which will result in noisy EEG signals. A green indication means that the electrode connection is good.

A yellow indication means that the electrode connection is acceptable. Try to ensure that all the electrodes are shown as green prior to starting a recording.

Ensure that all the electrodes are shown as green prior to starting a recording.

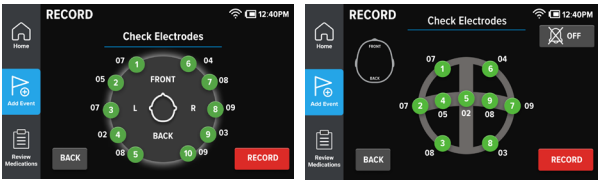


Figure 40: Check Electrode Connections Page – Headband (left), headcap (right)

Note: If an electrode device is not connected, a message will appear prompting you to connect a device.

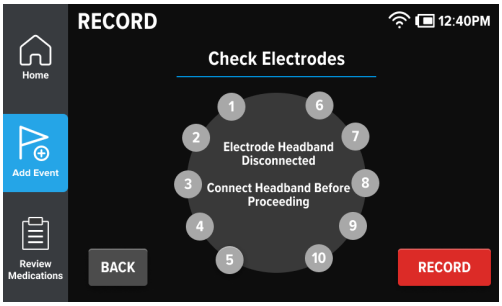


Figure 41: Electrode Headband Disconnected Page

Individual electrodes can be skipped and left red, if desired.

Checking Electrode Connections

To check the quality of the electrode connections during, before, or after a recording, press the **ELECTRODES** button on the Home Screen to go to the Electrodes page.

Note: During EEG recordings, electrode connection quality is checked and updated once every minute. However, when the Electrodes page is open, electrode connection quality is checked and updated once every 10 seconds.

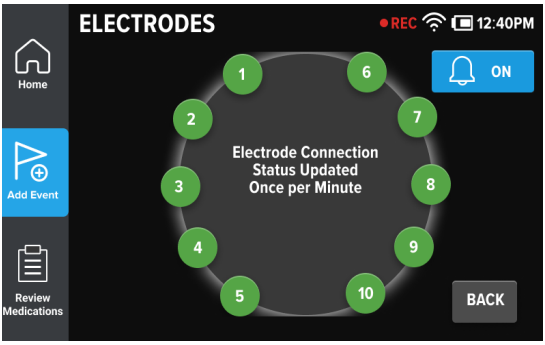


Figure 42: Electrodes Page

If a poor electrode connection is detected, a warning page will appear on the screen. Press the **PAUSE RECORDING AND CHECK ELECTRODES** button to go to the *Check Electrodes* page and adjust the electrodes that are shown in red, or press the **BACK** button to continue without adjusting any electrodes.

Note: If the display is powered off, the display will power on to display this page.

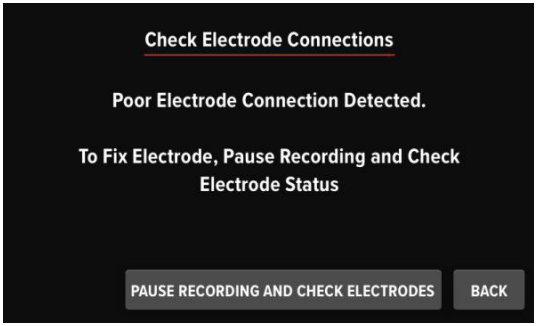


Figure 43: Check Electrode Connections Warning Page

Once an electrode connection has been fixed, press the **RESUME RECORDING** button to resume the recording.

Note: The EEG recording is paused and electrode connection quality is checked and updated every 10 seconds while the Check Electrodes page is open.

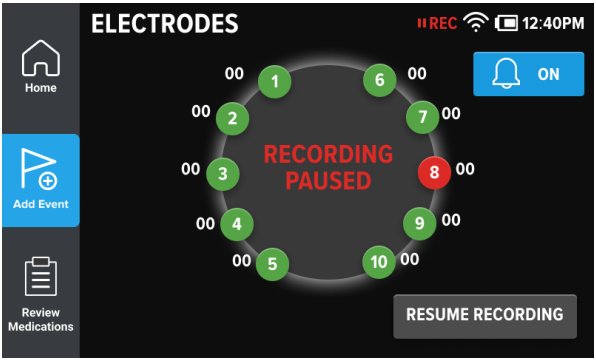


Figure 44: Fix Electrode Connections Page

Electrode Impedance Audible Notifications

To turn on, turn off, or mute audible notifications for Electrode Impedance, for the current recording, press the **NOTIFICATIONS** button on the *Electrodes* page.

Press the **ON**, **OFF**, or **MUTE** buttons to turn on, turn off, or mute notifications for Electrode Impedance.

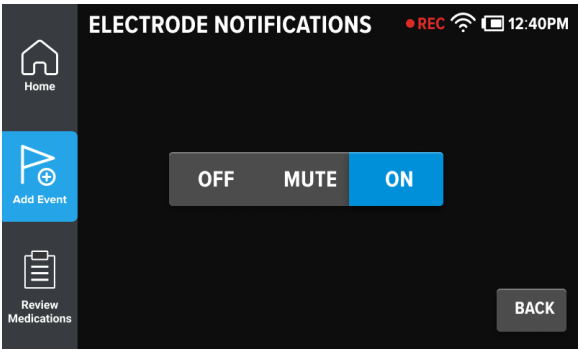


Figure 45: Electrode Impedance Notifications Page

After pressing the **OFF** button for Electrode Impedance notifications, a confirmation page will appear. Press the **OK** button to turn off Electrode Impedance audible notifications.

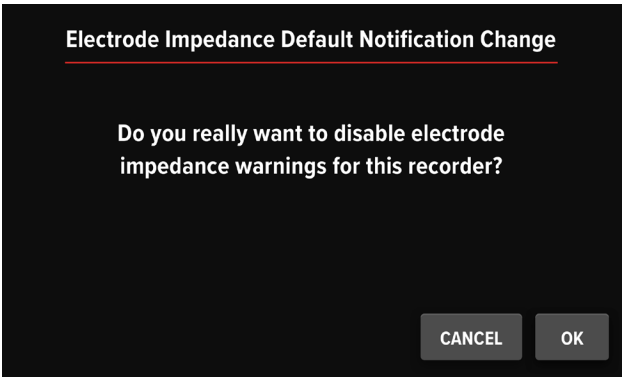


Figure 46: Electrode Impedance Notification Change Page

After pressing the **MUTE** button for Electrode Impedance notifications, a Mute page will appear. Select the desired duration to mute audible Electrode Impedance notifications and press the **DONE** button.

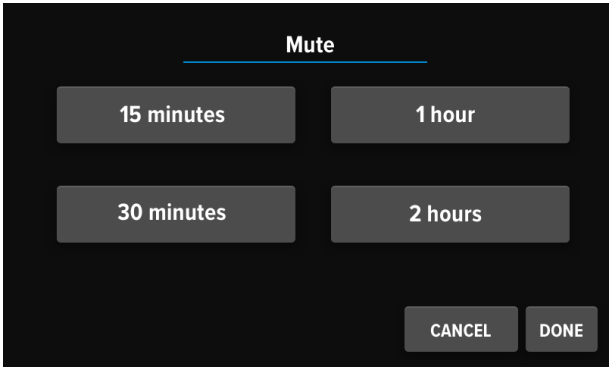


Figure 47: Electrode Impedance Mute Page

Stopping an EEG Recording

To stop an EEG recording, press the **RECORD** button on the Home Screen to go to the Record page, and press the **STOP RECORDING** button.

Figure 48: Recording Complete Page

After stopping the EEG recording, the Recording Complete page displays. Press the **DONE** button to finish the recording and proceed to the Home screen.

Note: It may take a few moments for the recording data to be saved; however, the patient can still be disconnected.

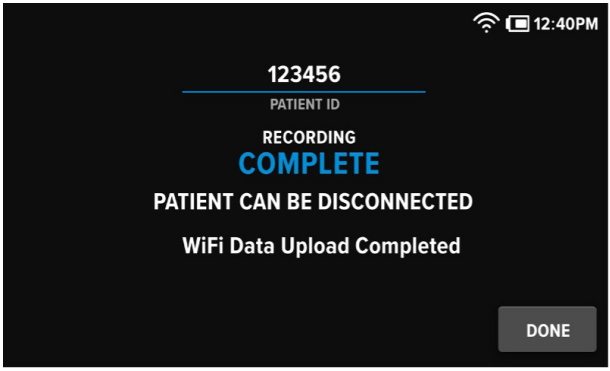


Figure 49: Recording Complete Page

Adding Tags and Notes

During an EEG recording, you can add tags and notes to denote medications, observations, and events that occur during the recording. To tag an event, press the orange "**TAG EVENT**" button on the Home Screen or the **ADD NOTE** button on the Record page to go to the Tag Event page. Select the appropriate Event Tag, and press the **DONE** button.

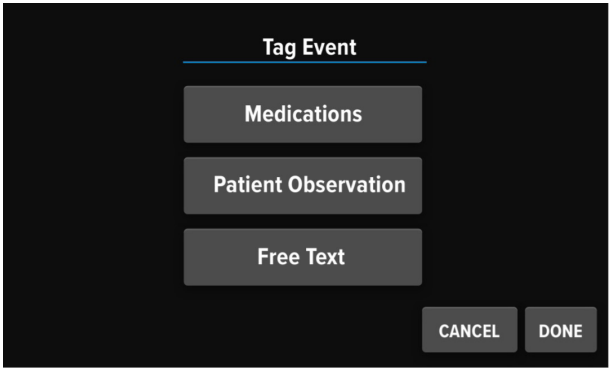


Figure 50: Tag Event Page. Note – event options vary based on patient location chosen.

If the **MEDICATIONS** button was selected, select the appropriate medication tag and press the **DONE** button.

If EMR integration is enabled, medication administration annotations may be automatically created.

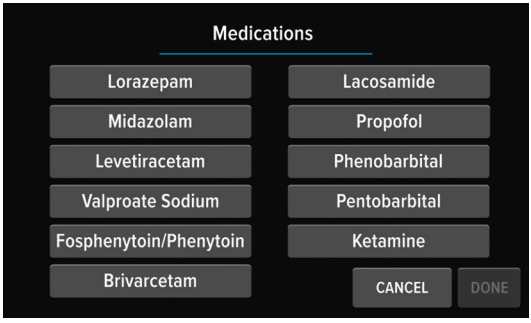


Figure 51: Medications Event Page. Note – medications vary based on patient location chosen.

If the **PATIENT OBSERVATION** button was selected, select the appropriate patient observation tag and press the **DONE** button.

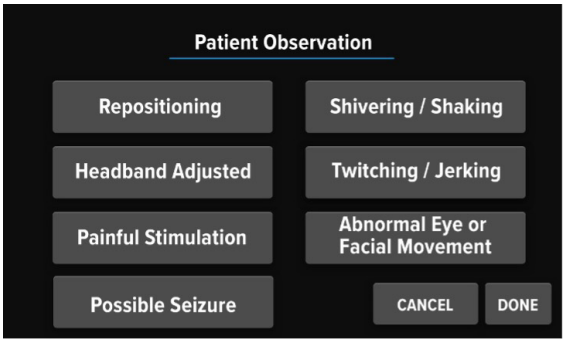


Figure 52: Patient Observation Tag Event Page. Note – patient observations vary by location chosen.

If **FREE TEXT** button was selected, enter the desired note, and press the **ENTER** button.

Viewing EEG Waveforms

EEG waveforms can be viewed only during a recording. To view the EEG waveforms, press the **DISPLAY** button on the Home Screen to go to the EEG Display page. Press the **50µV** or **100µV** button to select the display-unit scale.

Figure 53: EEG Display Page

Listening to EEG Waveforms

To listen to EEG waveforms with the Brain Stethoscope function, press the **SOUND** button on the Home Screen or the Brain Stethoscope button next to the speaker to go to the *Sound* page. To switch between the left and right hemispheres, press the **L** or **R** button on the touchscreen. When listening to the left hemisphere, electrode channel 3-4 is used. When listening to the right hemisphere, electrode channel 8-9 is used. To adjust the volume, press the volume up and down buttons located next to the power button.

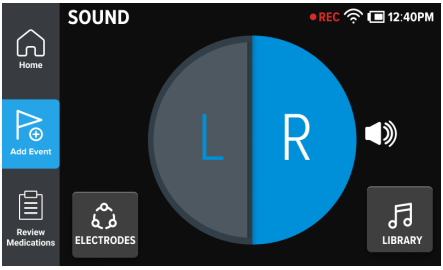


Figure 54: Sound Page

If electrode connection signal quality is poor due to electrode setup or otherwise, a “Noisy Signal” alert will appear at the bottom of the *Sound* page.

Note: the Brain Stethoscope function is not available with the EEG headcap.

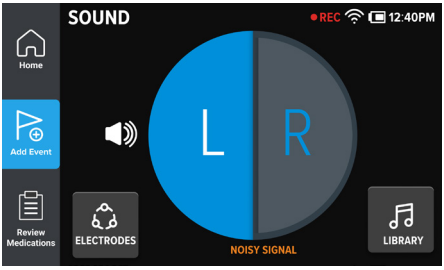


Figure 55: Noisy Signal Alert

A complete analysis of an EEG session must include a visual review of the EEG waveforms per standard procedures. To visually review the EEG waveforms, use the Ceribell EEG Recorder to display the signals in real-time or use the Ceribell EEG Portal to review the signals during and after a recording has been completed.

Listening to Sound Library Samples

To listen to sample EEG waveforms, of either normal EEG waveforms or seizure EEG waveforms, press the **LIBRARY** button on the *Sound* page to go to the *Sound Library* page.

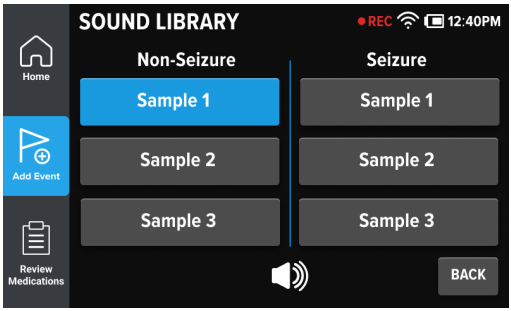


Figure 56: Sound Library Page

Viewing Seizure Burden

During a recording, the Seizure Burden value will be continuously updated while the Ceribell EEG Recorder is connected to WiFi.

To view the Seizure Burden, press the **SEIZURE BURDEN** button on the Home Screen. The Seizure Burden plot displays the percentage of detected seizures over a five minute period. If the recording duration exceeds approximately 70 minutes, use the left and right arrow buttons beneath the plot to navigate through the data.

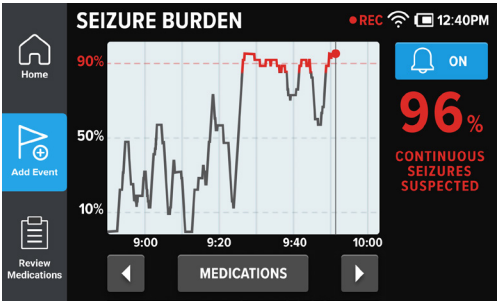


Figure 57: Seizure Burden Page

Continuous Seizure Notifications

During a recording, every time the Seizure Burden reaches 90%, a notification page will appear on the screen and an audible notification will sound, if turned on. Press the **OK** button to dismiss the notification and continue to the *Seizure Burden* page.

Figure 58: *Continuous Seizure Notifications Page*

Electrographic Status Epilepticus Notifications

During a recording of an adult (18 and over) patient, every time the Seizure Burden is above 90% for ≥ 10 continuous minutes or for a total duration of ≥ 20% of any 60-minute period of recording a notification page will appear on the screen and an audible notification will sound, if turned on. Press the **OK** button to dismiss the notification and continue to the *Seizure Burden* page.

Note: ESE alerts are only available for adults.

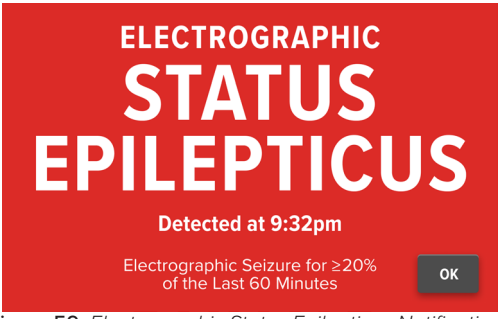


Figure 59: *Electrographic Status Epilepticus Notifications for Seizure ≥ 20% of the Last 60 Minutes*

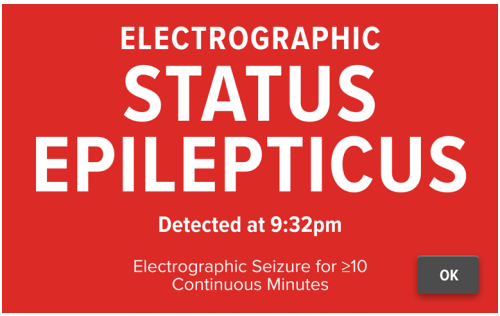


Figure 60: *Electrographic Status Epilepticus Notifications for Seizure ≥ 10 continuous minutes*

Seizure Burden Audible Notifications

To to turn on, turn off, or mute the audible notification settings for Seizure Burden, during a recording, press the **AUDIBLE NOTIFICATIONS** button on the *Seizure Burden* page. Press the **ON**, **OFF**, or **MUTE** buttons to turn on, turn off, or mute the audible notifications for Seizure Burden.

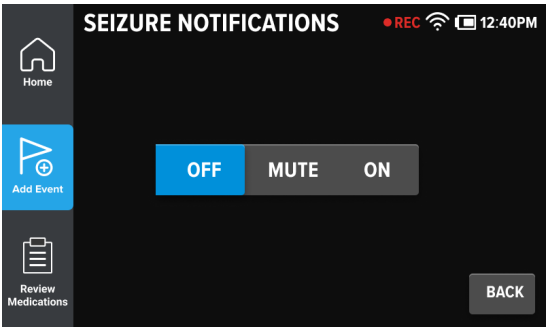


Figure 61: Seizure Burden Notifications Page

After pressing the **OFF** button for Seizure Burden notifications, a confirmation page will appear. Press the **OK** button to turn off Seizure Burden audible notifications.

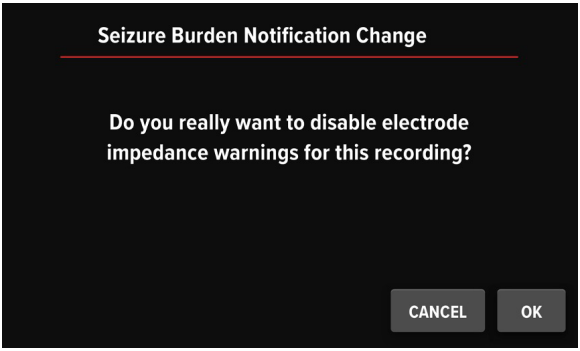


Figure 62: Seizure Burden Notification Change Page

After pressing the **MUTE** button for Seizure Burden notifications, a Mute page will appear. Select the desired duration to mute audible Seizure Burden notifications and press the **DONE** button.

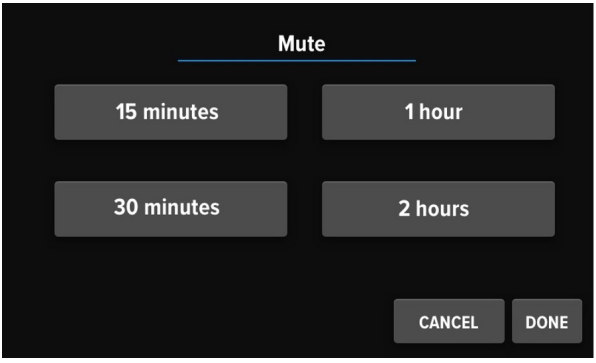


Figure 63: Seizure Burden Mute Page

Transferring EEG Recording Files via USB

Once an EEG recording has been completed, the EEG recording file can be transferred to a computer for review. Plug the Ceribell EEG Recorder into the computer using the micro-USB cable. The Ceribell EEG Recorder will be automatically recognized as a USB storage device, and the EEG recording files can be copied to the computer and uploaded to the Ceribell EEG Portal.

A warning page will appear when less than 20 hours of recording time memory is remaining.

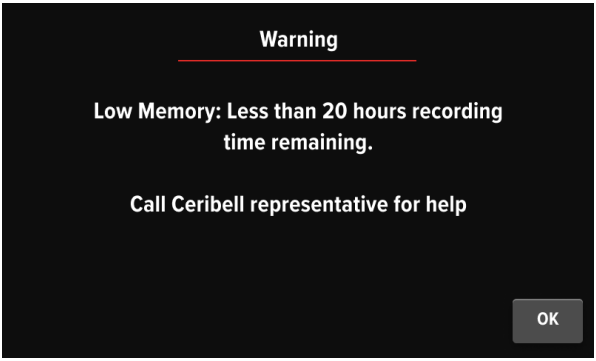


Figure 64: Low Memory Warning Page

Transferring EEG Recording Files via WiFi

EEG recording files can also be transferred using a wireless (WiFi) connection. To enter your WiFi network information, when not recording, press the **SETTINGS** button on the Home Screen to go to the *Settings* page.

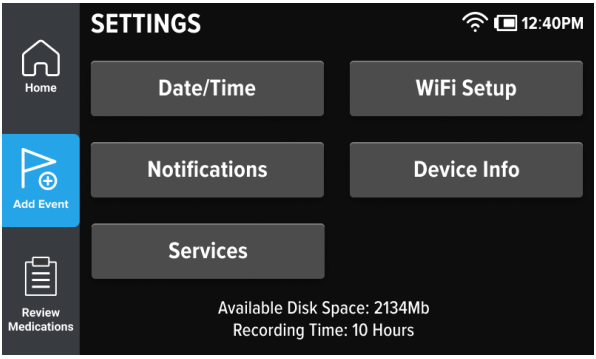


Figure 65: Settings Page

From the Settings page, press the **WIFI SETUP** button to go to the *WiFi Setup* entry page.

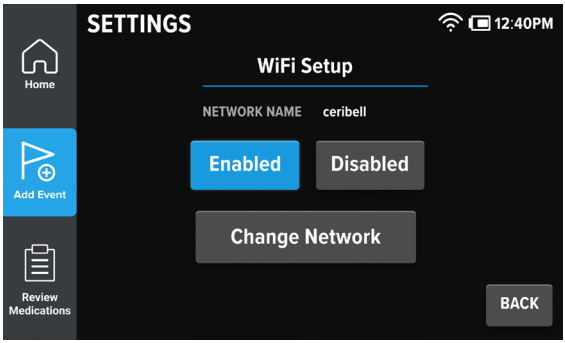


Figure 66: WiFi Setup Entry Page

Press the **ENABLED** button to go to the *Settings: Input Network Name* entry page. If WiFi is already enabled and you would like to change the WiFi network, press the **CHANGE NETWORK** button to go to the *Settings: Input Network Name* entry page.

Enter the network name, and press the **ENTER** button to go to the *Settings: Input Password* entry page. Enter the network password, and press the **ENTER** button.

If a WiFi upload is taking an extended amount of time to complete after a recording has already been completed, press the **STOP UPLOAD** button to continue to the *WiFi Upload Cancellation* page.

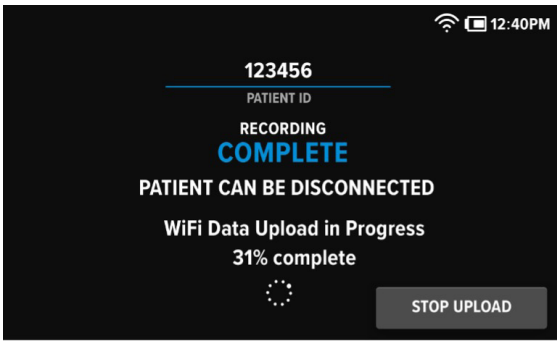


Figure 67: WiFi Upload Status Page

From the *WiFi Upload Cancellation* page, press the **STOP DATA UPLOAD** button to stop the upload.

Note: The percentage of the WiFi upload that has been completed will be available for review on the Ceribell EEG Portal and the remaining percentage of the recording that did not complete can be uploaded using the micro-USB cable and a computer.

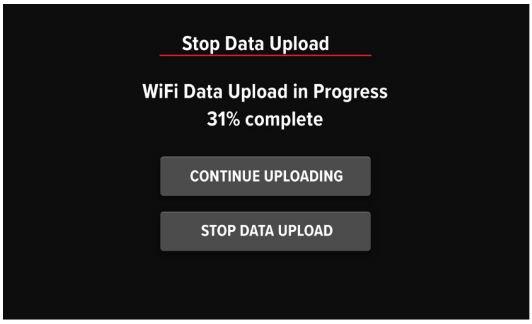


Figure 68: WiFi Upload Cancellation Page

If a WiFi upload did not complete, from either an upload cancellation or error, a warning page will appear and indicate that the recording must be uploaded using the micro-USB cable and a computer.

Figure 69: WiFi Upload Warning Page

Default Audible Notification Settings

To adjust the default audible notification settings for the Seizure Burden and Electrode Impedance, when not recording, press the **SETTINGS** button on the Home Screen to go to the *Settings* page.

From the *Settings* page, press the **NOTIFICATIONS** button to go to the *Notifications* page.

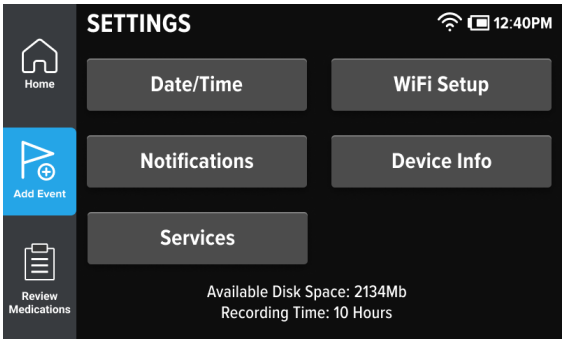


Figure 70: Settings Page

Press the **ON** or **OFF** buttons to turn on or turn off the default audible notifications for either the Seizure Burden and the Electrode Impedance.

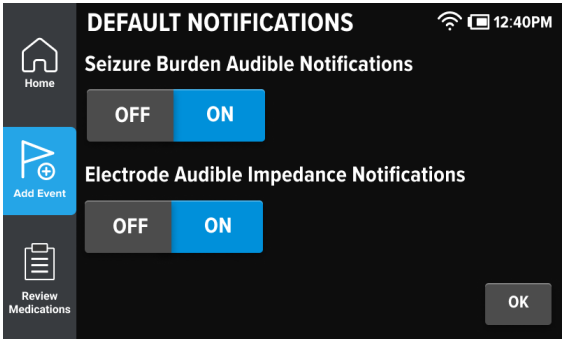


Figure 71: Default Audible Notifications Page

After pressing the **OFF** button for Seizure Burden notifications, a confirmation page will appear. Press the **OK** button to turn off default Seizure Burden audible notifications.

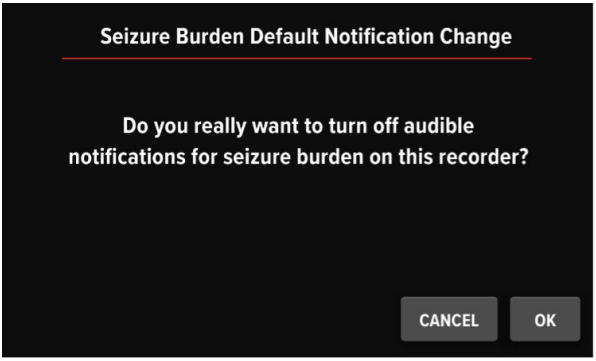


Figure 72: Seizure Burden Default Notification Change Page

After pressing the **OFF** button for the Electrode Impedance, a message will appear on the touchscreen display to confirm that you would like to turn off default Electrode Impedance notifications.

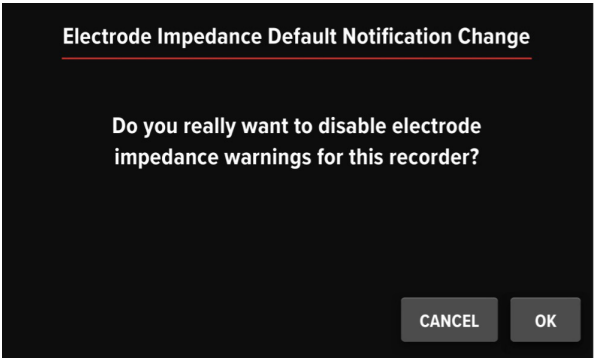


Figure 73: Electrode Impedance Default Notification Change Page

Setting Date/Time

To set the date and time, when not recording, press the **SETTINGS** button on the Home Screen to go to the *Settings* page.

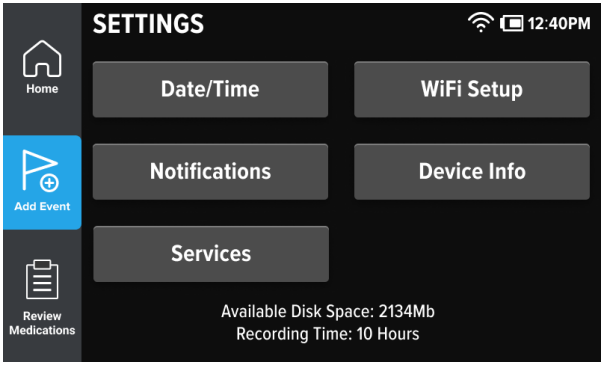


Figure 74: Settings Page

From the Settings page, press the **DATE/TIME** button to go to the *Date/Time* entry page.

Device Info

To view device information, press the **SETTINGS** button on the Home Screen to go to the *Settings* page. From the Settings page, press the **DEVICE INFO** button to go to the *Device Info* page.

Figure 75: Device Info Page

Maintenance Services

To format storage or conduct a server test, when not recording, press the **SETTINGS** button on the Home Screen to go to the *Settings* page.

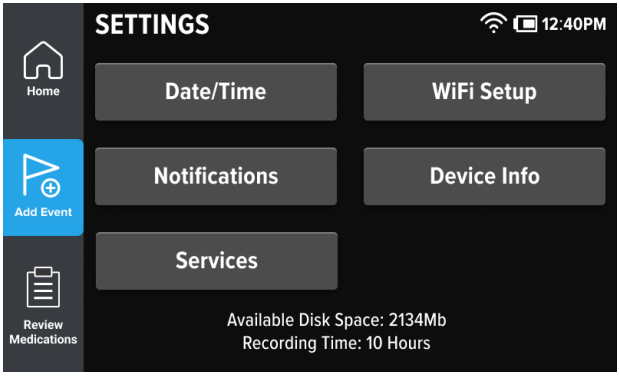


Figure 76: Settings Page

From the *Settings* page, press the **SERVICES** button to go to the *Storage Maintenance* page. Press the **CANCEL** button to return to the *Settings* page.

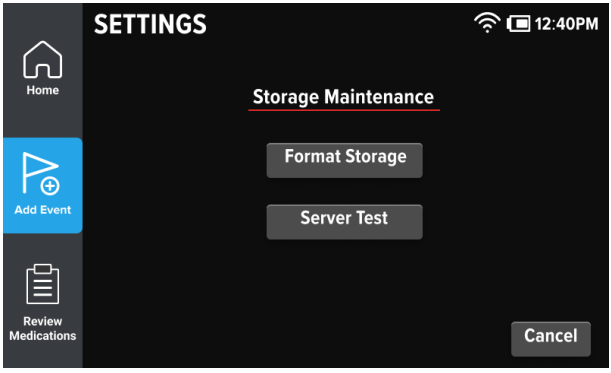


Figure 77: Storage Maintenance Page

Ceribell EEG Portal

The Ceribell EEG Portal is used to review EEG recordings obtained using the Ceribell EEG Recorder. The Ceribell EEG Portal is only compatible with EEG recordings made with the Ceribell EEG Recorder. The portal cannot be used to view EEG recordings made with other EEG devices.

If EMR Integrated, the EEG Portal will also display applicable patient notes, reports, and medications administered from the EMR

The Ceribell EEG Portal uses a web browser interface. The computer running the Ceribell EEG Portal should meet the following requirements:

- Operating System: Windows 10 or greater; Mac OS X 13 or greater

Web browser: Mozilla Firefox, Microsoft Internet Explorer, Microsoft Edge, Safari, or Google Chrome

Logging Into the Ceribell EEG Portal

The Ceribell EEG Portal (https://eeg.ceribell.com/login) requires a username and password to log in. Contact Ceribell for initial setup of the The Ceribell EEG Portal.

To log into the Ceribell EEG Portal, enter your username and password, and then click the **LOG IN** button.

Figure 78: Ceribell EEG Portal - Login

Viewing EEG Recordings

After logging into the Ceribell EEG Portal, the Recordings page displays a list of the currently uploaded EEG recording files. The EEG recording list can be filtered by patient name, medical ID, organization, review status, or scan date

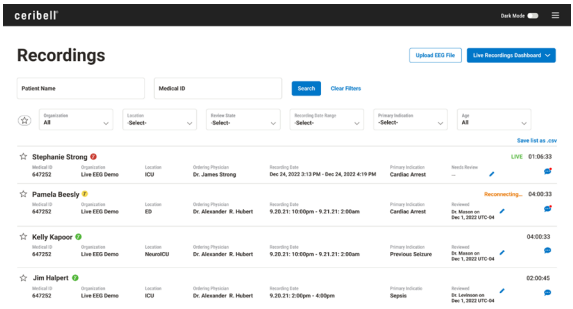


Figure 79: Ceribell EEG Portal - Recordings Page

Click on the desired EEG recording row to go to the EEG Scan page. The EEG Scan page displays the 8 channels of EEG waveform data recorded from the Ceribell EEG Recorder when the Instant EEG device is used, and 12 channels of EEG waveform data when the EEG headcap is used.

Figure 80: Ceribell EEG Portal - EEG Scan Page (headband)

Note: Click the Recordings *button in the upper left corner of the screen to return to the Recordings page.*

Scaling and Filter Options

When viewing EEG recordings, select the horizontal scale using the “Display” dropdown menu. Various display options between 1 second and 60 seconds per page can be selected.

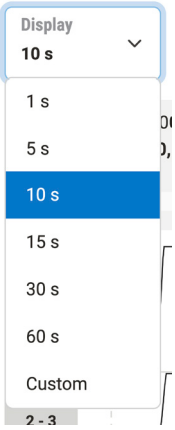


Figure 81: EEG Scan Page - Horizontal Scale Options

Select the vertical scale using the “Scale” dropdown menu. Various scale options between 10 µV and 500 µV can be selected.

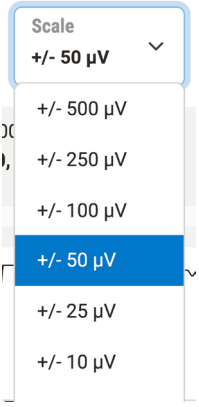


Figure 82: EEG Scan Page - Vertical Scale Options

If desired, select a high pass filter using the “High Pass” drop-down menu. Various high pass filter options between 0.1 Hz and 1 Hz are available.

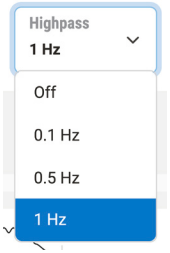


Figure 83: EEG Scan Page - High Pass Filter Options

If desired, select a low pass filter using the “Low Pass” drop-down menu. Various low pass filter options between 15 Hz and 100 Hz are available.

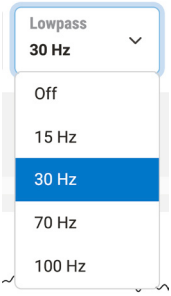


Figure 84: EEG Scan Page - Low Pass Filter Options

If desired, select the notch from the “Notch”filter.

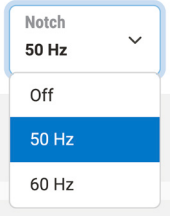


Figure 85: EEG Scan Page - Notch Filter button

Navigation

To navigate the EEG recording, use the recording navigation buttons

 Navigates the EEG recording one page backward

 Navigates the EEG recording one second backward

 Starts the EEG recording playback

 Navigates the EEG recording one second forward

 Navigates the EEG recording one page forward

Changes the EEG recording playback speed

To navigate the EEG recording using keyboard shortcut keys, the following functions are available:

Table 2: Ceribell EEG Portal Shortcut Keys

Shortcut Key	***Function***
Spacebar	Toggles the EEG recording playback
Up Arrow	Decreases the value of the voltage scale
Down Arrow	Increases the value of the voltage scale
Left Arrow	Moves the EEG recording backward one display page
Right Arrow	Moves the EEG recording forward one display page

Viewing the Seizure Burden

The Seizure Burden plot is displayed along the bottom of an EEG recording. The Seizure Burden plot shows the seizure burden value through the course of the entire recording.

Clicking on a particular point in the Seizure Burden plot will seek to the corresponding point in the EEG recording. Vertical markers on the Seizure Burden plot show when the seizure burden value has crossed the 10% (Frequent), 50% (Abundant), and 90% (Continuous) thresholds.

Figure 86: *EEG Scan Page - Seizure Burden*

Click anywhere in the seizure burden plot to view the position in the EEG recording that corresponds to the seizure burden

Figure 87: EEG Scan Page - Seizure Burden Flag

To hide the Seizure Burden plot, click the **MINIMIZE** button.

Figure 88: EEG Scan Page - Hide Seizure Burden Plot

To view a full-screen plot of the Seizure Burden for an EEG recording, click on the **EXPAND** button.

Figure 89: Full-screen Plot of Seizure Burden Page

To return to the EEG recording, click the **VIEW EEG** button.

Figure 90: EEG Scan Page - Return from Full-Screen button

To provide feedback on the Clarity algorithm, select the Thumbs Up or Thumbs Down button.

Figure 91: EEG Scan Page - Agree with Clarity

Annotating an EEG

To annotate an EEG recording, right-click anywhere on the EEG recording and enter the desired annotation. Press the **INSERT** button to save the annotation.

To annotate a specific segment of the EEG, such as seizure-like activity, you may also create an epoch annotation. To create an epoch annotation, click Start Epoch at the desired starting point in the EEG trace. The start point will be displayed on the timeline. Click again to mark the end point of the epoch. The selected time range will be highlighted, and an annotation window will appear for entering comments or details about the event.

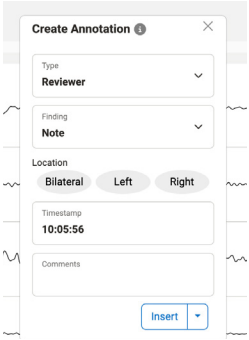


Figure 92: EEG Scan Page - Annotating an EEG Scan

To view a list of tags and notes added during the recording, click the **ANNOTATION LIST** button. Click on the annotation filter buttons to sort tags and notes. Click the **ANNOTATION LIST** buton again to close the list.

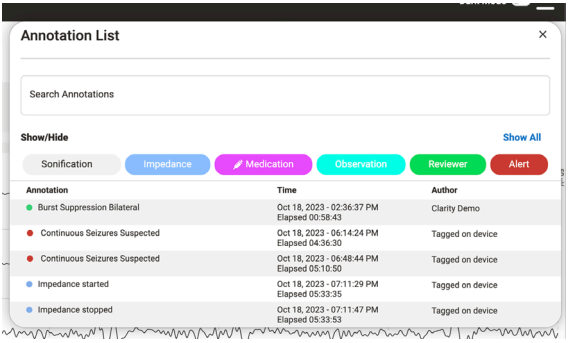


Figure 93: EEG Scan Page - Annotation List Button

Smart EEG Reports

The Ceribell Portal allows users to review EEG data and generate procedure reports that summarize patient demographics, recording information, EEG findings, and clinical impressions.

To generate a report, click the **GENERATE REPORT** button. The report is automatically populated with patient and recording information, including start and end times, diagnostic recording duration, and EEG description.

Figure 94: EEG Scan Page - GENERATE REPORT Button

Enter the *Clinical History* to provide relevant background on the patient's condition or indication for monitoring. Add General Notes as needed to document additional observations or context.

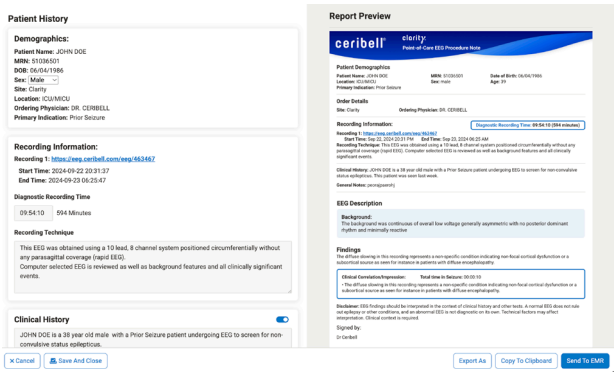


Figure 95: Smart EEG Reports Page

If EMR integration is enabled, pull up applicable EMR notes, reports, and medications administered by selecting the **EMR notes, reports, and medications** button.

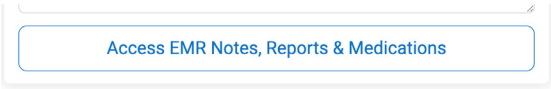


Figure 96: Smart EEG Reports Page - Access EMR Notes, Reports & Medications Button

Under *Medications*, the system automatically displays all medications administered during the EEG recording as captured from the EMR integration or manual device annotations.

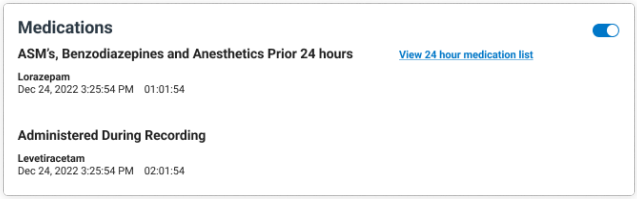


Figure 97: Smart EEG Reports Page - Medications

In the *EEG Description* section, select the appropriate parameters to describe background activity, including continuity, amplitude, symmetry, variability, posterior dominant rhythm, and reactivity. The descriptive summary automatically updates based on the selected values

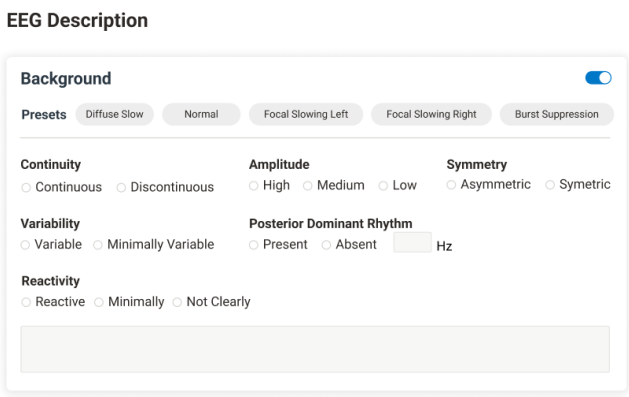


Figure 98: Smart EEG Reports Page - EEG Description

Under *Findings*, select or enter the relevant EEG findings. Findings and corresponding Impressions/Clinical Correlations are generated automatically when a finding is selected. The user may modify or delete these entries as needed.

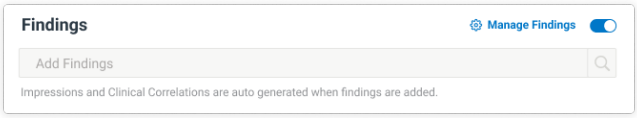


Figure 99: Smart EEG Reports Page - Findings

A Disclaimer statement appears at the end of the report, providing guidance on interpretation within the clinical context.

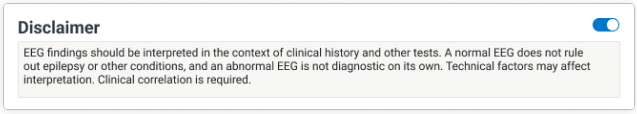


Figure 100: Smart EEG Reports Page - Disclaimer

Enter your Signature in the designated field. The signature can be saved as a default for future reports.

Figure 101: Smart EEG Reports Page - Signature

To include specific waveform segments, select the desired images from the EEG display, then select the + **ADD** button to attach the screenshots to the report.

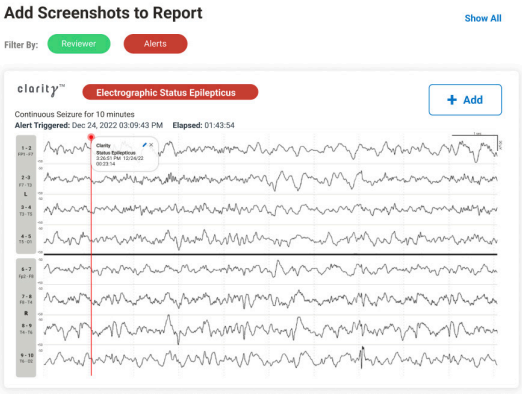


Figure 102: Smart EEG Reports Page - Add Screenshots to Report

When the report is complete, select **EXPORT AS**, **COPY TO CLIPBOARD**, OR **SEND TO EMR** to finalize and share the report

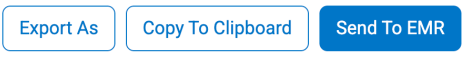


Figure 103: Smart EEG Reports Page - Export As, Copy to Clipboard, and Send to EMR Buttons

Custom Notifications

The Notifications Center in the Ceribell Portal allows users to manage alerts and customize notification preferences for EEG monitoring activity. Users can view notification history, adjust notification settings, and create shift-based schedules for tailored alert delivery.

To open the Notifications Center, select the bell icon in the navigation panel. Three tabs are available: History, Schedule, and Settings.

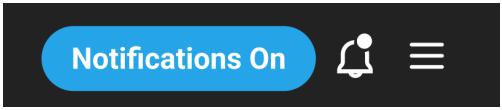


Figure 104: Notification Button

The History tab provides a record of recent system-generated notifications. Entries are displayed in reverse chronological order (most recent first) and include the associated event type and time of occurrence. Selecting a notification navigates to the corresponding case.

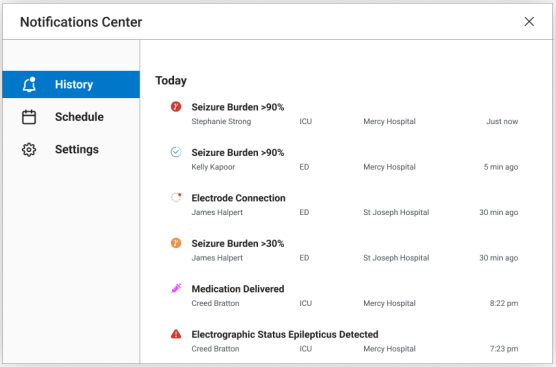


Figure 105: Notification Center - History

The Schedule tab allows users to create or manage notification schedules. Users can define a Basic Schedule or an Advanced Schedule

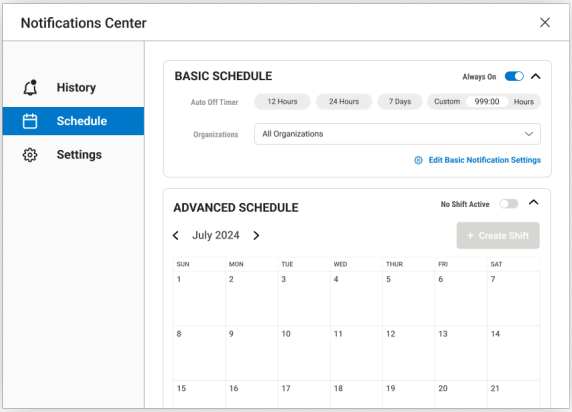


Figure 106: Notification Center - Schedule

The Basic Schedule allows users to set an Auto Off Timer (12 hours, 24 hours, 7 days, or custom) and choose the organization(s) for which notifications apply.

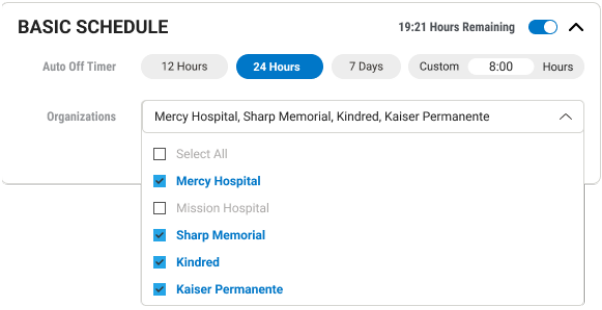


Figure 107: Notification Center - Schedule: Basic Schedule

The Advanced Schedule provides calendar-based scheduling. Select + **CREATE SHIFT** to create a custom shift by specifying dates, days of the week, and time ranges.

Each shift can be labeled (e.g., Night Shift or Weekend Coverage) and applied to selected notification profiles.

Shifts are color coded and appear on the calendar for easy visualization and can be edited or deleted as needed.

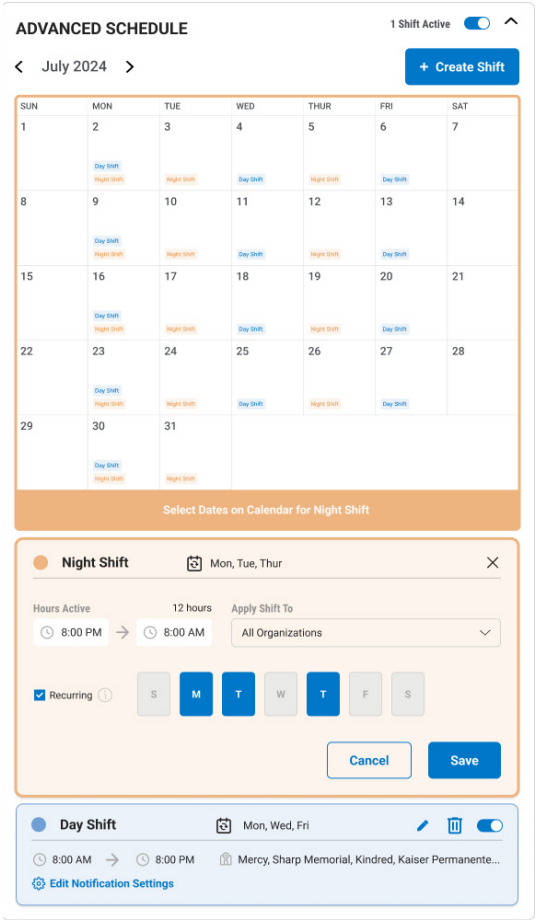


Figure 108: Notification Center - Schedule: Advanced Schedule

The Settings tab allows users to view and modify contact information and notification preferences. Users may enable notifications by phone or email under Contact Methods. Each method can be toggled on or off as needed.

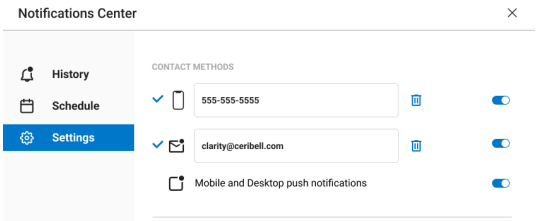


Figure 109: Notification Center - Settings: Contact Methods

Under Notification Types, users can select which alerts to receive. Shifts created in Calendar are selectable here to apply different notification thresholds for each.

Notifications can be turned on or off individually using the toggle switches beside each option. To return all settings to the original configuration, select Reset to Default.

When any change is made the **SAVE SETTING** button becomes active

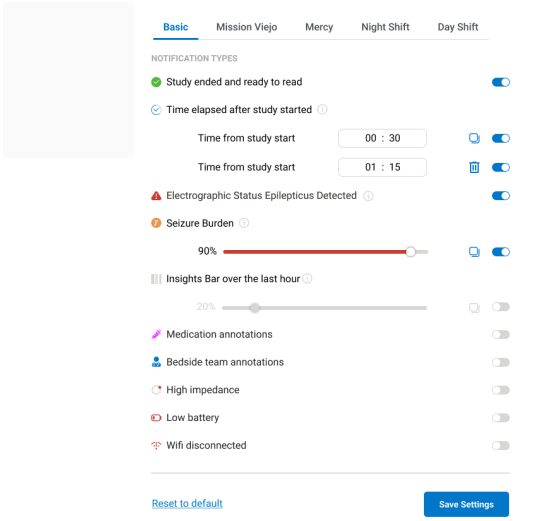


Figure 110: Notification Center - Settings: Notification Types

Additional Options

The **NEEDS REVIEW** button in the upper right indicates that the recording has not been reviewed. After confirmation, the button changes to **REVIEWED**, and the status on the Recordings page changes from “Needs Review” to “Reviewed”. To unmark a recording as reviewed, click on the **REVIEWED** button.

Figure 111: EEG Scan Page - NOT REVIEWED Button

To download the source file for the EEG recording, click the **MENU** button in the upper right corner of the screen, and then click the **DOWNLOAD RECORDING RAW DATA** button.

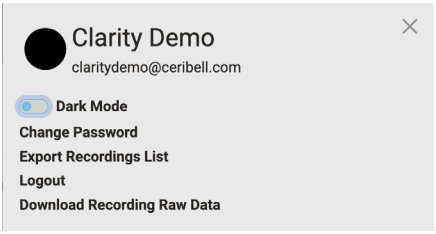


Figure 112: EEG Recording - Download Recording Raw Data

To send feedback regarding the Ceribell EEG Portal, click the **MENU** button in the upper right corner of the screen, complete the feedback form, and then click the **SUBMIT** button

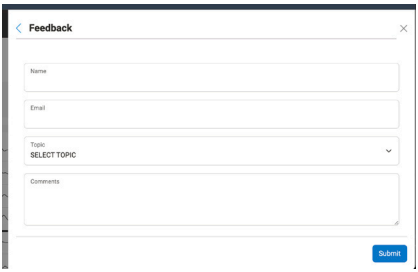


Figure 113: Ceribell EEG Portal - Send Feedback

Logging Out of the Ceribell EEG Portal

To log out of the Ceribell EEG Portal, click the **MENU** button in the upper right corner of the screen, and then click the **LOG OUT** button.

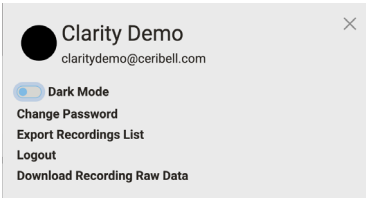


Figure 114: EEG Recording Viewer Logout

The Seizure Detection Module

The Ceribell EEG Portal includes a Seizure Detection module that is intended to mark previously acquired sections of EEG that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection module also provides notifications of detected seizure by displaying an on-screen message on the Ceribell EEG Recorder and the optional sending of an e-mail message.

The software algorithm used by the Seizure Detection module identifies sections of EEG that may correspond to electrographic seizures by going through the following steps:

- The first step consists of preprocessing the incoming waveforms which includes bandpass filtering and segmenting the incoming signals into smaller time epochs.
- In the next step, a machine-learning model analyzes the EEG using a feature-based random forest model and a data driven convolutional neural network to determine the time epochs that may correspond to potential electrographic seizures.
- The last step is combining these epoch by epoch classification results, time-wise and channel-wise, to detect seizure episodes. The algorithm does so by calculating the Seizure Burden (percentage of time epochs classified as seizure) over a moving 5-minute window and generates the following notifications to the user:

    1. “Frequent seizure detected” notification is generated when the seizure burden calculated over the last 5 minutes is greater than or equal 10% (30 seconds or more of detected seizure activity). Per ACNS guidelines[1], if the prevalence of a pattern (e.g. seizure) is 10-49% of the record/epoch
    2. “Abundant seizure activity detected” is generated when the seizure burden calculated over the last 5 minutes is greater or equal to 50% (150 seconds or more of detected seizure activity). Per ACNS guidelines[1], if the prevalence of a pattern (e.g. seizure) is 50-89% of the record/epoch, it is considered “Abundant”.
    3. “Continuous seizure activity detected” is generated when the seizure burden calculated over the last

5 minutes is greater or equal to 90% (270 seconds or more of detected seizure activity). Per ACNS guidelines[1], if the prevalence of a pattern (e.g. seizure) is greater or equal to 90% of the record/ epoch, it is considered “Continuous”.

The seizure burden output provides the user with a quantified value that conveys the amount of detected seizure activity within the 5 minute moving window. Seizure burden is presented to the user as a graph, which allows the user to identify trends over the course of the recording. The individual classification of each segment/epoch of time as either seizure or non-seizure is represented as an increase, decrease, or no-change in the seizure burden value. If desired, the user can determine the start and end of each identified seizure episode by reviewing the seizure burden graph.

Seizure detection notifications are based on the seizure burden value reaching specific thresholds of seizure activity, as defined by the ACNS guidelines[1]. Because seizure burden is determined based on a 5 minute moving window, note that the three levels of notification are by definition additive. The “Frequent” seizure activity notification must always occur before the “Abundant” seizure activity notification; the “Abundant” seizure activity notification must always occur before the “Continuous” seizure activity notification.

For example, if the software has detected a seizure event that is 7 minutes long, the seizure burden value will progressively increase starting from 0%. After 30 seconds of detected seizure activity, the seizure burden value will reach 10% and the “Frequent” seizure activity notification will occur. After 150 seconds, the seizure burden value will reach 50% and the “Abundant” seizure activity notification will occur. After 270 seconds, the seizure burden value will reach 90% and the “Continuous” seizure activity notification will occur. After 300 seconds (5 minutes), the seizure burden will reach 100%, indicating that seizure has been detected for the entire portion of the moving window. The seizure burden value will remain at 100% for 2 additional minutes until 7 minutes. The seizure burden value will then progressively decrease from 100% back to 0%.

Warning: The Ceribell EEG Recorder provides notifications for Seizure Detection that can be used when processing a record during acquisition. These include an on screen display and the optional sending of an email message. Delays of up to several minutes can occur between the beginning of a seizure and when the Ceribell EEG Recorder notifications will be shown to a user.

Warning: The Ceribell EEG Recorder Seizure Detection output cannot be used as a substitute for review of the underlying EEG by a trained expert.

Warning: Do not rely solely on the Seizure Detection output for review of the study. The Seizure Detection output is a tool used to assist the qualified practitioner with the analysis and diagnosis of the patient.

[1] *Hirsch LJ, Fong MWK, Leitinger M, et al. American Clinical Neurophysiology Society's Standardized Critical Care EEG Terminology: 2021 Version. J Clin Neurophysiol. 2021;38(1):1-29. doi:10.1097/WNP.0000000000000806*

Electrographic Status Epilepticus Monitor

Once an EEG recording has been started with the Ceribell Pocket EEG Device for an adult patient, the Status Epilepticus Monitor analyzes the EEG waveforms for the presence of electrographic status epilepticus (ESE). The American Clinical Neurophysiology Society's (ACNS) Guideline 14 ("Standardized Critical Care EEG Terminology: 2021 Edition") defines ESE as follows:

> ESE is defined as an ESz [electrographic seizure] for ≥ 10 continuous minutes or for a total duration of ≥ 20% of any 60-minute period of recording.

There are no user actions required to initiate monitoring the EEG for ESE, the Status Epilepticus Monitor software is active at any time in which an EEG recording is ongoing for patients ages 18 years and older.

The Status Epilepticus Monitor software provides two possible outputs: "Electrographic Status Epilepticus not detected" or "Electrographic Status Epilepticus detected." The output is updated once every ten seconds. In EEG recordings where ESE is detected, the "Electrographic Status Epilepticus detected" message is displayed persistently, and the time of the detection is also displayed

If the Ceribell Pocket EEG Device is not connected to WiFi, the message "Electrographic Status Epilepticus data is not being received" is displayed. In cases where the EEG recorder is not connected to WiFi or if the WiFi connection becomes interrupted, transfer the EEG recording using the USB connection. Refer to the Ceribell Pocket EEG Device instructions for use for further details regarding USB data transfer. Once an EEG recording has been transferred via USB, the waveforms are processed by the ESE detection algorithm in the same manner as when the data is transmitted using WiFi.

The Ceribell Pocket EEG Device periodically checks the status of each EEG electrode connection and alerts the user if one of the electrodes appears to be disconnected. It is important to promptly correct any electrode issues that are observed. The Status Epilepticus Monitor is not able to analyze EEG waveforms on channels where one or more of the electrodes is disconnected.

Principles of Operation

The ESE detection algorithm used by the subject device identifies sections of EEG that may correspond to ESE by through the following steps:

1) Preprocessing: band-pass filtering and segmenting the incoming signals into non-overlapping 10 second epochs.

2) Feature extraction: multiple time and frequency domain features are calculated for each time epoch of each EEG channel.

3) Classification algorithms: the extracted features are the inputs for classifier algorithms on each EEG channel that use a machine-learning model to determine the time epochs on each EEG channel that may correspond to electrographic seizures.

4) Control policy: the classification results are combined time-wise and channel-wise to identify electrographic seizures within the EEG recording.

5) ESE determination: the criteria for ESE are applied. As defined in ACNS Guideline 14, ESE is present when electrographic seizure is detected for either: (a) ≥ 10 continuous minutes, or (b) a total duration of ≥20% of any 60-minute period.

The device output is binary: ESE is either detected or not detected. When ESE is detected, a notification is also provided to the user that states that ESE was detected and the time that it was detected. The machine-learning model used for classification is a random forest algorithm. Each of the 8 EEG channels has a separately generated random-forest algorithm and the results of each random forest decision tree is then fed into a control policy. The control policy combines the outputs of each channel's classification algorithm to identify electrographic seizures.

Development and training of the machine-learning model is performed with EEG recordings that have been annotated by expert neurologists. Datasets that are used for validation are segregated so that they are never used for development or training of the algorithm.

Validation of Seizure Detection Software

Clinical Performance Data

The following clinical performance data were submitted to support a determination of substantial equivalence:

The EEG recordings dataset used for performance validation was gathered from real-world clinical usage of the Ceribell Pocket EEG Device in acute care hospital settings. There were no patient inclusion or exclusion criteria applied, therefore the data are fully representative of the intended patient population. To form the reference standard for seizures, the EEG recordings were retrospectively reviewed by a panel of 3 expert neurologists who were fellowship trained in epilepsy or neurophysiology. A majority agreement of at least 2 of the neurologists was required to form a determination of seizures.

Importantly, none of the data in the validation dataset were used for training of the Seizure Detection algorithm; the validation dataset is completely independent.

Table 3: Performance validation dataset

	Number of Patients
Ages 1-11	450
Ages 12-17	392
Ages 18+	859
Total	1701

Table 4: Distribution of seizure episodes meeting the ACNS definitions of Frequent, Abundant, and Continuous per the established majority agreement between 3 expert reviewers.

	Ages 1-11	Ages 12-17	Ages 18+	Total
Seizure Episodes with Seizure Burden ≥10% (meeting ACNS definition of 'Frequent' activity)	129	77	140	346
Seizure Episodes with Seizure Burden ≥50% (meeting ACNS definition of 'Abundant' activity)	60	22	61	143
Seizure Episodes with Seizure Burden ≥90% (meeting ACNS definition of 'Continuous' activity)	27	10	31	68

Acceptance Criteria

Performance of the Seizure Detection algorithm is assessed by evaluating the positive percent agreement (PPA) and the false positive rate per hour (FP/hr) of the algorithm compared to the expert reviewer reference standard:

- Positive Percent Agreement (PPA):
  For each threshold of Seizure Burden activity (Frequent, Abundant, Continuous)
  Lower bound of the 95% confidence interval ≥ 70% PPA
- False Positive rate per hour (FP/hr):
  For each threshold of Seizure Burden activity (Frequent, Abundant, Continuous)
  Upper bound of the 95% confidence interval ≤ 0.446 FP/hr

Device Performance

Performance against the acceptance criteria was assessed for age ranges 1-11, 12-17, and 18+. In all cases, the acceptance criteria were met, and the Seizure Detection algorithm PASSES.

Table 5: Device performance

Activity Category	Age Group	Positive Percent Agreement (PPA)	95% Confidence Interval	False Positive Rate (FP/hr)	95% Confidence Interval	Pass / Fail
Seizure Episodes with Seizure Burden ≥10% (meeting ACNS definition of 'Frequent' activity)	Ages 1-11	96.12%	[88.35, 99.28]	0.2700	[0.2445, 0.2986]	Pass
	Ages 12-17	87.01%	[73.16, 93.55]	0.2141	[0.1920, 0.2394]	Pass
	Ages 18+	95.71%	[91.30, 98.43]	0.1343	[0.1250, 0.1445]	Pass
	Overall	93.93%	[90.03, 96.52]	0.1763	[0.1670, 0.1859]	Pass
Seizure Episodes with Seizure Burden ≥50% (meeting ACNS definition of 'Abundant' activity)	Ages 1-11	96.67%	[87.50, 100.00]	0.1561	[0.1369, 0.1772]	Pass
	Ages 12-17	95.45%	[73.33, 100.00]	0.0921	[0.0776, 0.1082]	Pass
	Ages 18+	96.72%	[88.37, 100.0]	0.0547	[0.0480, 0.0615]	Pass
	Overall	96.50%	[92.12, 98.77]	0.08180	[0.0754, 0.0885]	Pass
Seizure Episodes with Seizure Burden ≥90% (meeting ACNS definition of 'Continuous' activity)	Ages 1-11	92.59%	[76.00, 100]	0.0843	[0.0697, 0.1006]	Pass
	Ages 12-17	100.0%	[100, 100]	0.0399	[0.0301, 0.0511]	Pass
	Ages 18+	93.55%	[78.26, 100.0]	0.0249	[0.0204, 0.0299]	Pass
	Overall	94.12%	[85.45, 98.48]	0.03951	[0.0351, 0.0443]	Pass

Acceptance Criteria:
PPA: Lower bound of the 95% confidence interval ≥ 70% PPA
FP/hr: Upper Bound of the 95% confidence interval ≤ 0.446 FP/hr

Validation of Electrographic Status Epilepticus Detection Performance

Performance Validation Methodology

The performance of the Status Epilepticus Monitor was established through the retrospective analysis of clinically collected EEG data. The following steps summarizes the test procedure:

1. A dataset of EEG recordings that were recorded with the Ceribell Pocket EEG Device and obtained from hospitalized patients greater than or equal to 18 years of age was selected for validation testing. This dataset was completely separate and independent from the data used to design and train the algorithm.
2. A team of EEG trained neurologists reviewed and categorized each of the EEG recordings to establish a ground-truth reference standard.
3. The Status Epilepticus Monitor software algorithm was run on the validation dataset and performance metrics were calculated for the results of each device as compared to the reference standard.
4. Statistical analysis was performed on the results to evaluate and compare the performance to the pre-determined acceptance criteria.

Validation Dataset

The validation dataset consisted of 353 EEG recordings obtained from patients in acute-care hospital environments using the Ceribell Pocket EEG Device. The 353 EEG recordings were taken from 6 different hospitals. The 6 hospitals varied in size and location, ensuring that the data were representative of the intended patient population. The subjects represented all Ceribell EEGs that were performed at each hospital over a fixed time period.

Three EEGs were excluded because they were from patients < 18 years of age. There were no exclusion criteria other than patient age. Therefore, the dataset is representative of the intended patient population. The resulting dataset included a total of 350 EEG recordings.

The gender and age distribution of the validation dataset is shown in the following tables:

Table 6: Distribution of patient ages in the validation dataset.

Subject Age (years)	Included Subjects	Excluded Subjects	Percent of Total Included Subjects
< 18	0	3	N/A
18-20	4	0	1%
21-30	14	0	4%
31-40	23	0	7%
41-50	40	0	11%
51-60	39	0	11%
61-70	79	0	23%
71-80	63	0	18%
81-90	73	0	21%
>90	15	0	4%
Total:	350	3	
Mean Age of Included Subjects:	65.3		

Table 7: Distribution of patient gender in the validation dataset.

Subject Gender	N	Percent of Total
Male	188	54%
Female	162	46%
Total:	350	

Data Labeling

The “ground-truth” reference standard for the validation dataset was established by having each EEG session independently reviewed by 3 separate neurologists, each with fellowship training in clinical neurophysiology or epilepsy. The neurologists reviewed the EEGs according to their standard clinical practices, and the ACNS Guideline 14 definition of ESE was applied. Each neurologist reviewed their assigned EEG recordings independently with no knowledge of each other’s reviews and no knowledge of the device output. Additionally, the neurologists were not given access to any automated seizure detection software tools for their reviews. This ensured complete independence between each of the expert reviews.

The ground-truth reference standard was defined by agreement between a minimum of 2 of the expert reviewers, forming a majority opinion. Based on the expert reviews,

each EEG recording was classified into one of two categories, ESE-positive and ESE-negative. The ESE-negative subjects were further sub-categorized into those that contain seizures and other epileptiform patterns versus those that do not contain any epileptiform activity. These sub-categories provide additional context when examining false-positive cases. The table below shows classification results for all 350 cases.

Categories:

1) ESE-positive
2) ESE-negative
   a. ESE-negative: contains seizures or other epileptiform activity
   b. ESE-negative: does not contain any epileptiform activity

Table 8: Expert neurologist reference standard categorization of the validation dataset.

Ground-Truth Classification	N
ESE-positive	10
ESE-negative: contains seizures and/or other epileptiform activity	94
ESE-negative: does not contain any epileptiform activity	246
Total:	350

Results

After the clinical validation dataset was compiled, the subject device algorithm was run on the dataset and the results compared to the reference-standard. The resulting sensitivity was 100% and the specificity was 94%. There were 10 true-positive detections and 0 false-negative detections (100% sensitivity). There were 319 true-negative detections and 21 false-positive detections (94% specificity). Of the 21 false-positive detections, 19 were determined by the expert reviewers to contain seizures or other epileptiform activity.

Because the algorithm performed with 100% sensitivity in a small sample size of 10 ESE true-positive detections, there are limitations to the utility of calculating 95% confidence interval using the BCa Bootstrap method (as was done with the predicate device). As a result, two additional confidence interval calculation methods were also applied: the Wilson interval and the Jeffreys interval.

Table 9: Sensitivity and specificity results of the clinical performance validation along with the 95% confidence interval computed with three different methodologies.

	Result	95% Confidence Interval BCa Bootstrap	95% Confidence Interval Wilson	95% Confidence Interval Jeffreys
Sensitivity	100%	[100%, 100%]	[72%, 100%]	[78%, 100%]
Specificity	94%	[91%, 96%]	[91%, 96%]	[91%, 96%]

Benefit Risk Analysis

Analysis of the benefits and risks of the subject device is performed according to the FDA guidance document "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics." (September 2018). Ceribell believes that the submitted performance validation data clearly demonstrates significant benefit of the subject device due to the magnitude and the probability of the benefit of faster diagnosis of ESE. At the same time, the identified risks of the subject device are of low probability and low severity, post-mitigation.

The greatest benefits of the subject device are specifically tied to the intended use of diagnosing electrographic status epilepticus. The maximum benefit of the subject device occurs when ESE is recognized and diagnosed during the time prior to the availability of a qualified neurologist to perform a full review of the underlying EEG. Initiation of treatment for Status Epilepticus is highly time sensitive, yet in the standard-of-care workflow it can take 12-24 hours just to get the EEG read by a qualified neurologist. The diagnosis of ESE provided by the subject device allows administration of first-line anti-seizure medications (ASMs) and initiation of other time-sensitive actions to be performed as quickly and as accurately as possible by the intensivist and other members of the bedside critical care team. At the same time, the subject device does not replace the full review of the underlying EEG by a qualified neurologist because pathologies other than ESE may be present in the EEG.

Risks of the subject device can be categorized into risks associated with false-positive detections, false-negative detections, device malfunctions, or device misuse. In general,

these risks are all low in part due to the fact that in all potential cases of failure of the subject device, the patient remains no worse off compared to the current standard-of-care, where the intensive care physician is forced to make a treatment decision without having EEG data available.

Table 5 and Table 6 on the following pages provide a detailed analysis of the benefits and risks of the subject device.

Conclusion:

The performance demonstrated in the clinical validation study clearly demonstrate that the benefits of the subject device outweigh the risks.

Table 10: Benefits analysis of the subject device.

Benefits	Magnitude of Benefit	Probability of Benefit	Overall Benefit Evaluation
Patient with ESE is treated with ASMs 12-24 hours faster compared to the current standard-of-care when the subject device correctly identifies that ESE is present.	High As discussed above, early identification and treatment of ESE is associated with significantly lower morbidity and mortality.	High The subject device was 100% sensitive to ESE in the performance validation study.	High
Patient without ESE avoids unnecessary treatment with ASMs when the subject device correctly determines that ESE is not present.	Low Ruling out ESE may avoid unnecessary patient treatment. However, this benefit is “low” because the use of ASMs in hospital environments is commonplace and carries relatively low risk because of the clinicians’ familiarity with management of these medications.	High The performance validation study showed that the subject device had 94% specificity.	Low

Table 11: Risks analysis of the subject device.

Risk	Severity	Mitigations	Risk Probability (post-mitigation)	Overall Risk Evaluation
False-positive: Subject device diagnoses ESE when ESE is not present. Patient is treated with ASMs even though they are not in status epilepticus	Moderate (Note: this has been updated from Low to Moderate following the SIR teleconference) The use of ASMs in controlled hospital environments (with or without confirmation of seizures through EEG) is commonplace and carries relatively low risk because of the clinicians' familiarity with management of these medications. As with any sedative medication, there is risk of over-sedation.	• The subject device is designed such that the majority of "false-positive" cases still contain seizures or other abnormal epileptiform patterns. In these cases, treatment with ASMs may still be beneficial to the patient. • Full review of the EEG by a qualified neurologist (potentially 12-24 hours later) may determine that ASM treatment can be discontinued.	Low The performance validation study results showed there were 21 "false positives" out of 350 cases (6%) and 19 of the 21 "false-positive" cases (90.5%) still contained seizures or other epileptiform patterns where treatment with ASMs may still have been beneficial.	Low
False-negative: Subject device fails to diagnose ESE when ESE is present Treatment with ASMs is delayed.	High Delayed treatment of status epilepticus results in worse outcomes. However, this scenario is equivalent to the current standard-of-care.	• The subject device is designed to be highly sensitive to minimize the risk of "false-negative" cases. • The intensivist may still elect to treat the patient with ASMs based on other clinical observations; the EEG will still be reviewed by a qualified neurologist – the patient is no worse off than they would have been in the current standard-of care without the subject device.	Low The performance validation study showed that the subject device was 100% sensitive to ESE.	Low

Risk	Severity	Mitigations	Risk Probability (post-mitigation)	Overall Risk Evaluation
Device malfunction: Subject device fails to provide output.	Low The user can revert to the current standard-of-care practice	• The subject device alerts the user if the ESE detected/not-detected output is not available. The user can revert to the current standard-of-care without the subject device output.	Low Verification and validation testing confirm that the subject device meets its design requirements.	Low
Device misuse: User incorrectly utilizes the output of the subject device (i.e., uses the device output to make clinical determinations outside of the diagnosis of ESE).	Moderate Depending on the patient's condition, this may involve over-treatment or delayed-treatment with ASMs.	• The subject device is only capable of providing a binary diagnostic output of ESE detected/ESE not-detected. A qualified neurologist must review the EEG for other possible abnormal epileptiform findings – this limits the potential for device misuse. • The use of ASMs in controlled hospital environments (with or without confirmation of seizures through EEG) is commonplace and carries relatively low risk because of the clinicians' familiarity with management of these medications. As with any sedative medication, there is risk of over-sedation.	Low	Low

Validation of Infant Seizure Detection Software

Clinical Performance Data

The following clinical performance data were submitted to support a determination of substantial equivalence:

The validation dataset consisted of EEG recordings obtained from patients less than 1 year of age who received continuous EEG monitoring within the hospital environment. There were no patient inclusion or exclusion criteria applied; therefore, the data are fully representative of the intended patient population. To form the reference standard for seizures, the EEG recordings were retrospectively reviewed by a panel of 3 expert pediatric neurologists who were fellowship trained in epilepsy or clinical neurophysiology. A majority agreement of at least 2 of the neurologists was required to form a determination of seizures.

Importantly, none of the data in the validation dataset were used for training of the Seizure Detection algorithm; the validation dataset is completely independent.

The patient's postmenstrual age (PMA) at the time of EEG recording, stated in weeks, is the terminology used for the validation dataset. Postmenstrual age is gestational age plus chronological age. Gestational age is the time elapsed between the first day of the last menstrual period and the day of delivery and chronological age is the time elapsed since birth.

Table 12: Performance validation dataset.

Patient Characteristics (N=713)	N (%)
Sex	
Male	383 (53.7)
Female	323 (45.3)
Unknown	7 (1.0)
Postmenstrual Age	
25-36 weeks	155 (21.7)
37-44 weeks	321 (45.0)
> 44 weeks	237 (33.2)

Table 13: Distribution of seizure episodes meeting the ACNS definitions of Frequent, Abundant, and Continuous per the established majority agreement between 3 expert reviewers.

	25-36 weeks	37-44 weeks	> 44 weeks	Total
Seizure Episodes with Seizure Burden ≥10% (meeting ACNS definition of 'Frequent' activity)	76	171	54	301
Seizure Episodes with Seizure Burden ≥50% (meeting ACNS definition of 'Abundant' activity)	25	66	23	114
Seizure Episodes with Seizure Burden ≥90% (meeting ACNS definition of 'Continuous' activity)	8	3	13	34

Acceptance Criteria

Performance of the Seizure Detection algorithm is assessed by evaluating the positive percent agreement (PPA) and the false positive rate per hour (FP/hr) of the algorithm compared to the expert reviewer reference standard:

- Positive Percent Agreement (PPA):
  For each threshold of Seizure Burden activity (Frequent, Abundant, Continuous)
  Lower bound of the 95% confidence interval ≥ 70% PPA
- False Positive rate per hour (FP/hr):
  For each threshold of Seizure Burden activity (Frequent, Abundant, Continuous)
  Upper bound of the 95% confidence interval ≤ 0.446 FP/hr

Device Performance

Performance against the acceptance criteria was assessed in the intended patient population. In the overall dataset, the acceptance criteria were met and the Seizure Detection algorithm PASSES.

Table 14: Device performance

Activity Category	Age (PMA)	Positive Percent Agreement (PPA)	95% Confidence Interval	False Positive Rate (FP/hr)	95% Confidence Interval
Seizure Episodes with Seizure Burden ≥10% (meeting ACNS definition of 'Frequent' activity)	25-36 weeks	88.16%	[74.24, 98.44]	0.357	[0.281, 0.458]
	37-44 weeks	90.64%	[83.86, 94.76]	0.153	[0.127, 0.183]
	> 44 weeks	98.15%	[91.18, 100.0]	0.219	[0.181, 0.264]
	Overall	91.36%	[85.71, 94.91]	0.204	[0.180, 0.230]
Seizure Episodes with Seizure Burden ≥50% (meeting ACNS definition of 'Abundant' activity)	25-36 weeks	92.00%	[69.23, 100.00]	0.115	[0.074 0.177]
	37-44 weeks	90.91%	[78.19, 97.93]	0.056	[0.042, 0.077
	> 44 weeks	91.30%	[68.42, 100.00]	0.111	[0.084, 0.146]
	Overall	91.23%	[82.67, 96.57]	0.083	[0.069, 0.100]
Seizure Episodes with Seizure Burden ≥90% (meeting ACNS definition of 'Continuous' activity)	25-36 weeks	75.00%	[60.00, 100.00]	0.090	[0.054, 0.151]
	37-44 weeks	100.0%	[75.29, 100]*	0.033	[0.022, 0.048
	> 44 weeks	92.31	[62.50, 100.00]	0.081	[0.056, 0.115]
	Overall	91.18%	[75.00, 100.00]	0.057	[0.045, 0.072]

* For metrics where the point estimate reached 100%, the 95% confidence interval was calculated using the Clopper-Pearson exact method. Please note that correlation effects are not accounted for in this exact calculation. All other confidence intervals are calculated using the bootstrap method with patient-level sampling to account for correlation effects.

Subgroup Performance

Subgroup analyses were performed to assess the impact of sex, clinical study site, EEG recording duration, and as shown above, age. All subgroup analyses demonstrated acceptable variation among subgroups, supporting performance across the intended use population.

Predetermined Change Control Plan (PCCP)

The Ceribell Seizure Detection Software and Ceribell Infant Seizure Detection Software have both been cleared by the FDA with an Authorized PCCP. The Authorized PCCPs outline specific modifications intended to improve algorithm clinical or computational performance through the expansion of training data and optimization of the algorithm. The PCCPs outline Ceribell's data management and algorithm development practices, including how and when performance is evaluated.

The PCCPs also define validation requirements for algorithm updates. Prior to release, the updated algorithm is validated through testing against previously established acceptance criteria using an independent validation data set. Updates will be implemented using a validated Software Update process. When an update is performed, Ceribell will update this operator manual and notify customers of the update.

There have been no PCP changes to the algorithm to date.

System Information

System Specifications

Table 15: System Specifications and Operating Conditions

Conditions EEG Data Acquisition	
Channels	8 (4 left, 4 right)
Sampling rate	250 Hz
Frequency response	0.5 Hz to 100 Hz
Accuracy of EEG measurement signal reproduction	±20% or ±10µV, whichever is greater
Physical and Electrical Characteristics	
Internal battery	3.7 V (nominal) 20 Ah Li-ion battery pack
External power adapter Ceribell part number: SA-00003	Input: 100-240 V ac Output: 5 V dc *Note: Only use included power adapter to charge the device.*
Charging cable Ceribell part number: EC-00095	1 m micro-USB cable *Note: The micro-USB cable can also be used to connect to a computer for file transfer. Only use the included micro-USB cable to connect the device to the power adapter or a computer.*
Dimensions	180 mm x 80 mm x 38 mm
Weight	550 g
Connectivity	
Wired data transfer	Micro-USB interface. USB 2.0.
Wireless data transfer	2.4 and 5 GHz IEEE 802.11 a/b/g/n WiFi interface WPA/WPA2/WPA3 security protocols
Wireless characteristics	Frequency range: 2412-2472 MHz, 5180-5825 MHz Effective radiated power: 0.04 W Modulation type: DSSS/OFDM (802.11 a/b/g/n)
Environmental Requirements (Operating)	
Temperature	15° C to 32° C
Humidity	Up to 80% relative humidity at 32° C (non-condensing)
Environmental Requirements (Storage and Shipping)	
Temperature	-20° C to 50° C
Humidity	Up to 75% relative humidity at 50° C (non-condensing)
EEG Electrodes	
EEG electrodes that are used with the Ceribell EEG Recorder should have cable length less than 2 m.	

Essential Performance

Essential Performance Requirements for the BSD8 vary depending on the operational mode. Some requirements are applicable to all operating modes of the BSD8, and others are applicable only to specific operating modes.

Table 16: Essential Performance for BSD8

Essential Performance Function	Applicable Device Modes
While acquiring EEG signals, the BSD8 must meet all of the additional essential performance requirements of IEC 60601-2-26 subclause 201.4.3.101. Note that single channel display mode must be used to display EEG signals with sufficient resolution to verify these requirements.	During EEG acquisition.
If operation of the BSD8 is interrupted at any time due to an external event (e.g. electrostatic discharge, electromagnetic interference, or user error), the BSD8 must resume normal operation within 30 seconds of the user resetting the device.	At all times.
The BSD8 must not allow EEG acquisition when a power source (including a computer) is plugged into the micro-USB port.	At all times.
While plugged into a power source (including a computer), all EEG acquisition functions are automatically disabled. The BSD8 must maintain basic safety, but there are no additional essential performance requirements.	While plugged into a power source.
The BSD8 must maintain isolation between the power supply (internal or external) and the patient leads.	At all times.

WiFi Connection

The Ceribell EEG Recorder can be connected to a wireless (WiFi) network to transfer EEG recordings. The network must be IEEE 802.11 b/g compatible, and the network must support WiFi Protected Access (WPA/WPA2) security.

The use of the WiFi functionality of the Ceribell EEG Recorder does not present any hazards to the system operator or patient. The WiFi connection only allows data to be transferred from the Ceribell EEG Recorder to a computer; data cannot be transferred from a computer to the Ceribell EEG Recorder. If a WiFi connection is not available, transfer EEG recordings using the micro-USB cable.

Connection of the Ceribell EEG Recorder to a wireless network could result in previously unidentified risks to the system operator or patient. Before connecting the Ceribell EEG Recorder to a wireless network, perform a systematic risk assessment to identify, analyze, evaluate, and control any risks. When changes are made to the wireless network, the risk assessment should be reviewed to determine if there have been any changes to the previously identified risks.

Cybersecurity

Ceribell designs and implements its systems using a risk-based cybersecurity framework consistent with industry best practices for medical devices. Data transmitted between the Ceribell EEG Recorder and the Ceribell application is encrypted using Transport Layer Security (TLS).

Ceribell follows a Secure Product Development Lifecycle (SDLC) and adheres to established cybersecurity best practices. This includes routine software vulnerability scanning as well as third-party assessments that help ensure ongoing protection and system integrity.

Customer Responsibilities

As part of the shared responsibility model, customer institutions are responsible for implementing and maintaining appropriate administrative, technical, and physical safeguards to ensure the secure use of the Ceribell system. At a minimum, customers must implement:

Endpoint Requirements

All endpoint devices used to transfer EEG recordings to the Ceribell application, or to access and view EEG recording within the Ceribell application must be assessed and maintained in accordance with your institutional cybersecurity and IT policies as well as, the following recommended cybersecurity controls:

- The endpoint must be kept regularly updated with critical security updates/patches as recommended by the manufacturer.
- The endpoint must have antivirus/anti-malware software installed and regularly updated.
- A hardware or software firewall must be used and kept regularly updated; including unnecessary network ports must be disabled.
- Must report any Incident that may impact Ceribell products.

Responsibilities for Secure Use

Customers are expected to enact the following controls:

- Ensure compliance with applicable federal, state, and local regulatory requirements governing the use and protection of patient data.
- Review and execute applicable service agreements with Ceribell.
- Promptly request removal or deactivation of user accounts for individuals who no longer require access to the system.
- Restrict the authority to request or approve new user accounts to designated personnel.
- Maintain appropriate internal access controls and security measures for IT systems and networks that interface with the Ceribell system.
- Promptly notify Ceribell of any suspected or confirmed cybersecurity incidents that may affect the Ceribell system.

All communications both incoming and outgoing for the EEG Recorder and EEG Recording Viewer are performed securely on port 443. Details are provided in the table below.

Table 17: Incoming and Outgoing Communications for the EEG Recorder and EEG Recording Viewer

Port	Function	Direction (Incoming/Outgoing/ Both)
443	Transmit EEG data and algorithm results to and from the EEG Recorder. Transmit EEG data and algorithm results to the Viewer Software.	Both

Network Diagram

The below diagram provides a global system view of the Ceribell System.

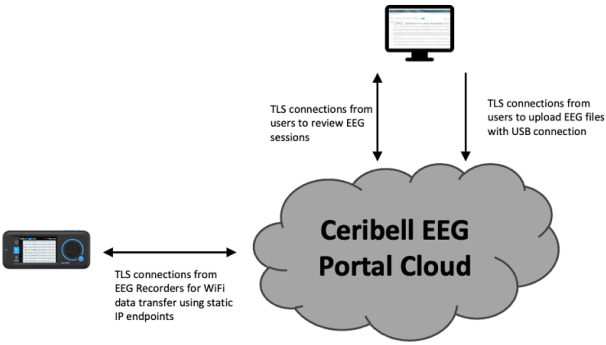


Figure 115: Network Diagram of the Ceribell System

Detection and Response to Anomalies

Ceribell has implemented continuous security monitoring, logging, and alerting capabilities across its production environment. Security events are reviewed in accordance with Ceribell's Incident Response Plan.

In the event of a confirmed security incident affecting customer systems or data, Ceribell will notify affected institutions in accordance with contractual and regulatory requirements. If you believe that a cybersecurity problem or vulnerability has occurred relating to any Ceribell devices, contact Ceribell customer support immediately.

To support security investigations and incident forensics, the system generates detailed, immutable (append-only) audit logs of all access to Protected Health Information (PHI).

Protection of Critical Functionality

The Ceribell system incorporates controls to protect the confidentiality, integrity, and availability of system data:

- Data Encryption: All patient data is encrypted using industry-standard cryptographic protocols including AES-256 for data at rest and TLS 1.2 or higher for data in transit.
- Secure Administrative Access: Access to backend infrastructure is restricted to authorized personnel. Administrative access requires multi-factor authentication (MFA).
- Data Redundancy: System data is continuously replicated to geographically separate regions to support high availability and reduce risk of data loss due to localized infrastructure disruptions.

Backup and Restoration

The Ceribell system includes automated backups to protect against data loss due and service disruptions:

- Automated Backups: Data is routinely backed up to geographically separate regions from the primary production environment.
- Restoration Process: Ceribell maintains formal Business Continuity and Incident Response Plans that define procedures for secure restoration of system data in the event of a significant service disruption. Backup and restoration procedures are tested periodically as part of Ceribell's Business Continuity Program.

Decommissioning

Devices should be returned to Ceribell for secure data sanitization in accordance with industry-recognized data destruction standards and must not be decommissioned by customers.

Electromagnetic Compatibility (EMC)

The Ceribell EEG Recorder needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in this section. WARNING: The use of accessories, transducers, and cables other than those specified by Ceribell may result in increased EMISSIONS or decreased IMMUNITY of the Ceribell EEG Recorder.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Ceribell EEG Recorder, including its cables. Otherwise, degradation of the performance of this equipment could result. See Table 21 for recommended separation between portable and mobile RF communications equipment and the Ceribell EEG Recorder. WARNING: The Ceribell EEG Recorder should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Ceribell EEG Recorder should be observed to verify normal operation in the configuration in which it will be used.

After a transient electromagnetic phenomena, the system shall return to a normal operational state within 30 seconds without loss of any operator settings or stored data.

Table 18: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Ceribell EEG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Ceribell EEG Recorder should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment · guidance
RF emissions CISPR 11	Group 1 Class B	The Ceribell EEG Recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11	Group 1 Class B	The Ceribell EEG Recorder is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Ceribell EEG Device or shielding the location.
Harmonic emisslons IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Note: All EEG acquisition functions are automatically disabled when the Ceribell EEG Recorder is plugged into an external power supply. EEG measurements or recordings cannot be taken while the Ceribell EEG Recorder is charging or connected to a computer.

Table 19: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Ceribell EEG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Ceribell EEG Recorder should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - guidance
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 air	± 8 kV contact ± 2, 4, 8, 15 air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EC 61000-4-5	±1 kV line to line	±1 kV differential mode	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 cycles 0% U_T; 250 cycle	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 cycles 0% U_T; 250 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/M	30 A/M	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment

Notes:

U_T is the a.c. mains voltage prior to application of the test level.

All EEG acquisition functions are automatically disabled when the Ceribell EEG Recorder is plugged into an external power supply. EEG measurements or recordings cannot be taken while the Ceribell EEG Recorder is charging or connected to a computer.

Table 20: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Ceribell EEG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Ceribell EEG Recorder should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and Amateur Bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and Amateur Bands	Portable and mobile RF communications equipment should be used no closer to any part of the Ceribell EEG Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7 GHz	10 V/m 80MHz to 2.7 GHz	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EQUIPMENT.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 21: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Ceribell EEG Recorder

The Ceribell EEG Recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ceribell EEG Recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ceribell EEG Recorder as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 22: Immunity to Proximity Fields from RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5 500				
5 785				

System and Package Labels

Table 23: System Labels

	System label located on back side of device The 2D barcode, GTIN number, and serial number together comprise the Unique Device Identifier for the device. Symbols: Device emits non-ionizing radio frequency signals Type BF applied part Follow instruction manual Manufacturer cTUVus Mark Device is categorized as electronic equipment. Contact manufacturer for disposal. FCC Mark MR Unsafe. Remove the Ceribell EEG Recorder and all accessories from the patient prior to entering an MRI (magnetic resonance imaging) scanning room. Part Number CE Mark European Authorized Representative Rx only: Federal (US) law restricts this device to sale by or on the order of a physician.
	Connector label located on side of device Symbols: Micro-USB connector port

	1-800 Customer Support label located on back side of device The 1-800-763 -0183 number is for 24 hour technical support. The QR barcode provides a link to the operator manual and training.
	Package label located on outside of device packaging The 2D barcode, GTIN number, and serial number together comprise the Unique Device Identifier for the device. Symbols: Manufacturer Part Number Storage Conditions Follow instruction manual Non-sterile Device CE Mark Rx only: Federal (US) law restricts this device to sale by or on the order of a physician.

Maintenance and Troubleshooting

Cleaning and Maintenance

The Ceribell EEG Recorder does not require any routine maintenance. Before using the device, verify that it does not appear physically damaged and that the controls and indicators appear to be functioning correctly.

The Ceribell EEG Recorder may be cleaned by wiping with a damp soft cloth. Standard hospital disinfectants and cleaning products, including Sani-Cloths, may be used. Allow the device to dry before using. Do not immerse the Ceribell EEG Recorder in water.

The Ceribell EEG Recorder is not designed to be sterilized. Do not attempt to sterilize the Ceribell EEG Recorder, as this may damage the device.

Servicing

⚠ **Warning**: The Ceribell EEG Recorder does not contain any user-serviceable parts. Contact Ceribell if your device requires service. Do not attempt to open or disassemble the Ceribell EEG Recorder.

If the Ceribell EEG Recorder does not appear to be functioning correctly, contact Ceribell to have the device serviced. The Ceribell EEG Recorder does not require routine servicing.

Troubleshooting

The Ceribell EEG Recorder uses a capacitive touchscreen. The touchscreen can be used while wearing thin latex or nitrile gloves. Multiple layers of gloves or very thick gloves may cause the touchscreen to be less sensitive. If reduced touchscreen sensitivity causes difficulty in using the device, reduce the number of gloves being worn or use thinner gloves.

If needed, the Ceribell EEG Recorder can be restarted by pressing and holding the power button for 10 seconds until the blue power LED turns off and then releasing the button. The Ceribell EEG Recorder will then restart and resume normal operation.

If restarting the device does not resolve the issue, contact Ceribell.

The following error and warning messages may be encountered when using the Ceribell EEG Recorder.

Table 24: Troubleshooting Guide

Error or Warning Message	Suggested Action
Low Battery	The device should be plugged in and charged as soon as possible.
Low Memory	Two hours or less of EEG recording time remain. Delete files from the device before starting the EEG recording.
Check Electrode Connections	One or more of the EEG electrodes has a poor connection. Navigate to the *Check Electrodes Connections* page to view electrode connection status.
System Error	The device has detected an internal fault. EEG acquisition is disabled. Contact Ceribell for service.

Delirium Appendix

Note: This Delirium Appendix to the Operator Manual applies exclusively to the Delirium Monitor. This functionality is currently available only to sites enrolled in the Ceribell Delirium Pilot Program. Access to these features is controlled by Ceribell.

Indications for use (Delirium Monitor System)

The Ceribell Delirium Monitor System is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor System is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients in critical care settings within hospitals.

The Ceribell Delirium Monitor System analyzes discrete segments of EEG to notify clinicians when EEG patterns associated with delirium are detected while monitoring the patient. Changes in patient condition that are detected by the device should be verified before commencing any interventions.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Warnings and Precautions

Warning: The Delirium Monitor is not intended to be used as a stand-alone diagnostic.

Caution: The Ceribell Delirium Monitor System analyzes discrete 30-minute segments of EEG to notify clinicians when EEG patterns associated with delirium are detected. The performance of Ceribell Delirium Monitor has been validated by comparing its output to a bedside clinical assessment of delirium conducted during the same time period. This validation measured the accuracy of the device output for each point at which a bedside clinical assessment was performed. Bedside clinical assessments of delirium are made using the delirium diagnostic criteria of the DSM-5. These diagnostic criteria result in a determination that the patient is either delirium-positive or delirium-negative and a bedside clinical assessment is only able to determine the condition of the patient at the time the assessment is performed. Therefore, the output of the device can only be compared to a

clinical ground truth during time periods that are classified by a bedside clinical assessment. Changes in patient condition that are detected by the device should be verified before commencing any interventions, and the output of the device should not be used as the sole determinant of the time that the patient's condition changed.

Caution: The Delirium Monitor is only compatible with the Ceribell EEG Recorder and the Ceribell EEG Headband. Users of the Delirium Monitor must have familiarized themselves with all the manuals and labeling of the Ceribell EEG Recorder and the Ceribell EEG Headband. Consult the instructions for use for the Ceribell EEG Recorder and the Ceribell EEG Headband for further information.

Caution: The Delirium Monitor is only intended for use with adult patients (18 years and older). The Delirium Monitor output has not been tested on pediatric patients.

System Overview

The Ceribell Delirium Monitor is intended to analyze EEG recordings captured with the Ceribell EEG Recorder and the Ceribell EEG Headband to assess delirium in adult patients in critical care environments. The Delirium Monitor is not intended to be used as a stand-alone diagnostic device.

Intended users of the Delirium Monitor are medical professionals that are part of the clinical care team in hospital environments who are well-trained in the standard of care for delirium. Users of the Delirium Monitor must be familiar with the operation of the Ceribell EEG Recorder. All functions relating to EEG signal acquisition, EEG waveform display, data transmission over WiFi or USB, and EEG data storage are performed by the Ceribell EEG Recorder and are unchanged with the installation of the Delirium Monitor software. For further information, consult the instructions for use of the Ceribell EEG Recorder.

Ceribell EEG Recorder and EEG Headband Setup and Operation

The Delirium Monitor requires the use of the Ceribell EEG Recorder and EEG Headband. Before proceeding, review the main content of this Operator Manual and the Instructions for Use provided with the EEG Headband.

Ceribell EEG Recorder Software

The process of connecting a patient to a Ceribell EEG Headband and the Ceribell EEG Recorder is not changed in any way when the Delirium Monitor software is installed. EEG recordings are started following the instructions for use of the Ceribell EEG Recorder which are summarized above, and there are no workflow differences with the Delirium Monitor software.

There are no user actions required to initiate monitoring the EEG for Delirium; the Delirium Monitor software is active at any time in which an EEG recording is ongoing.

Updates to the screen when the Delirium Monitor software is installed are shown below.

Home Screen

The Home screen functionality has no differences when the Delirium Monitor software is installed, and can be referred to in the Operator Manual described above for the Home Screen. With the Delirium Monitor software installed, the Home Screen shows a **DELIRIUM** button to access the Delirium Monitor page.

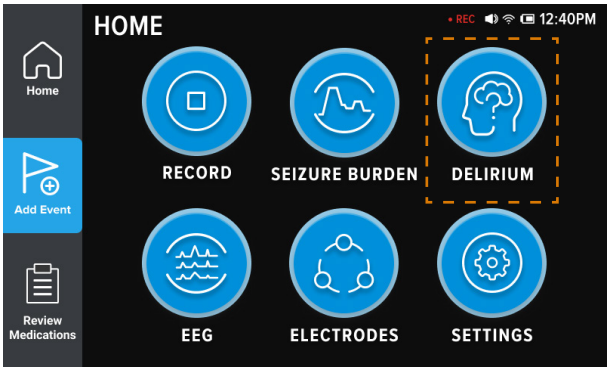


Figure 116: Home Screen Page

Viewing Delirium Monitor

During a recording, the Delirium trendline will be continuously updated while the Ceribell EEG Recorder is connected to WiFi.

The Delirium Monitor displays the binary output of Delirium positive or Delirium negative over a 30 minute period.

Navigate backward and forward through the Delirium trendline by pressing the left and right arrow buttons beneath the plot.

The live seizure burden percent is available on the screen as well. Navigate to the Seizure Burden page by selecting the **SWITCH TO SEIZURE BURDEN** button.

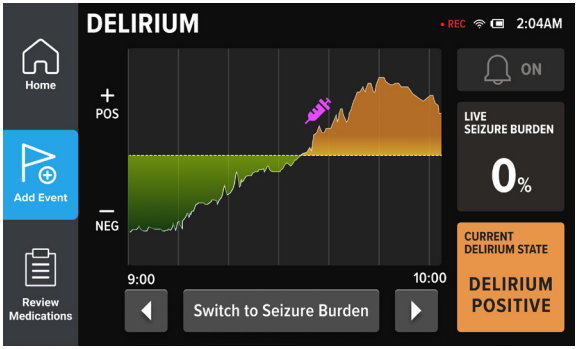


Figure 117: Delirium Monitor Page

Viewing Seizure Burden

The Seizure Burden functionality has no differences when the Delirium Monitor software is installed, and can be referred to in the instructions for use described above in the Viewing Seizure Burden section.

With the Delirium Monitor software installed, the Seizure Burden page also shows the Delirium current binary status as either Delirium Positive (Delirium detected) or Delirium Negative (Delirium not detected).

Navigate to the Delirium page by selecting the **SWITCH TO DELIRIUM** button.

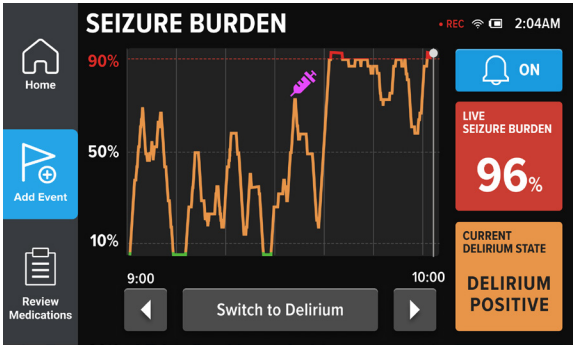


Figure 118: Seizure Burden Page

Ceribell EEG Portal

Delirium Monitor

Follow the same log in procedure explained above in Logging into the Ceribell EEG Portal and to View EEG Recordings.

Click on the desired EEG recording row to go to the Seizure Burden and Delirium Trendline Page. The page shows both the Seizure Burden graph and Delirium Monitor trendline for the recording.

For a live recording the following page can be seen:

Figure 119: Delirium Monitoring: Live Recording Page

For a completed recording the following page can be seen:

Figure 120: Delirium Monitoring: Completed Recording Page

To view a list of tags and notes added during the recording, click the Annotation List button. Click on the filter chips to sort tags and notes. Click the **ANNOTATION LIST** button again to close the list.

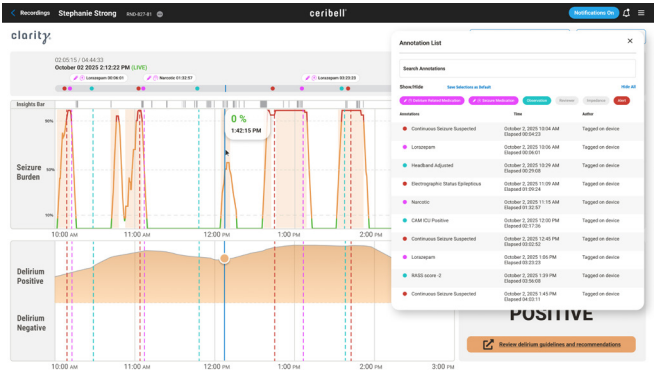


Figure 121: Delirium Monitoring: Annotation list Open

If the patient experiences “Delirium positive”, a link to Review delirium guidelines and recommendations will appear. Click Review delirium guidelines and recommendations to see the following:

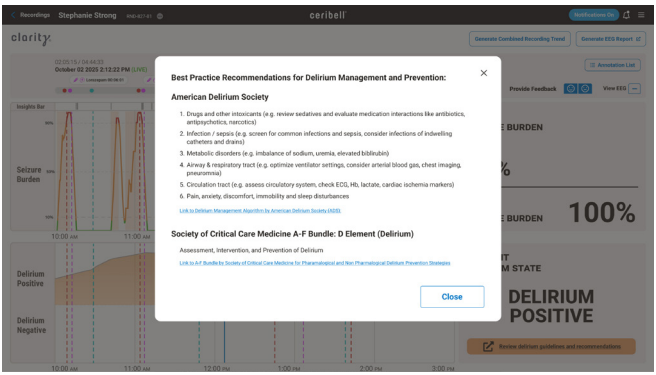


Figure 122: Delirium Guidelines and Recommendations POP-UP

Selecting the 

button will open a pop-up listing all recordings associated with the selected patient.

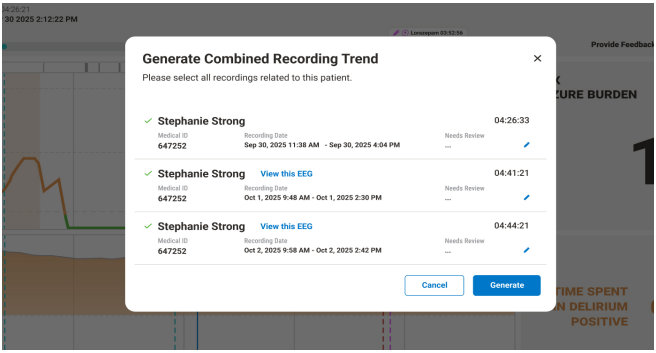


Figure 123: Generate Combined Recording Trend Page

After selecting the desired recordings, select **GENERATE** to generate a one-page summary of the selected reports.

Figure 124: Generate Combined Recording Trend Page

Select **EXPORT AS** to save the combined trend as a PDF. EMR Integration is not compatible with Delirium at this time, and a message will appear to contact a Ceribell representative if selected.

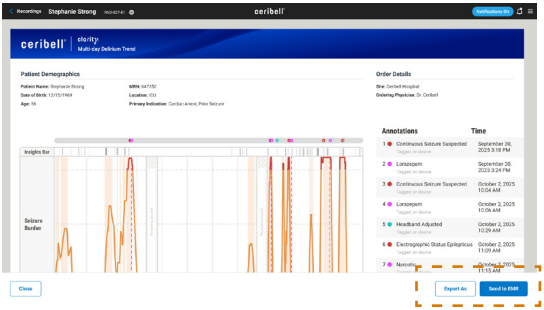
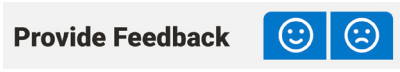


Figure 125: Generate Combined Recording Trend Page

Click  to provide feedback on the Seizure and Delirium output.

Selecting the **HAPPY FACE**  button will open the feedback survey pop-up.

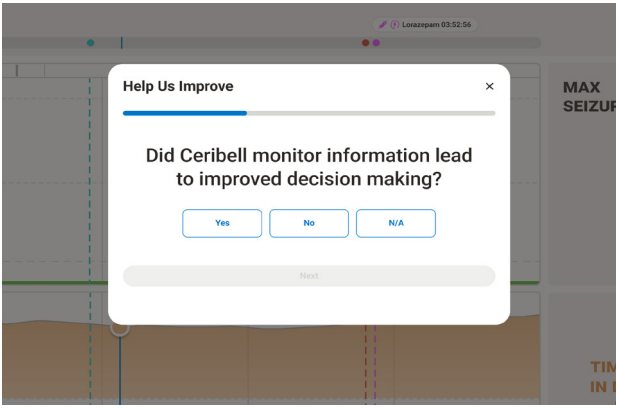


Figure 126: Provide Feedback: Happy Face

Selecting **YES**, **NO,** or **N/A** will activate the **NEXT** button.

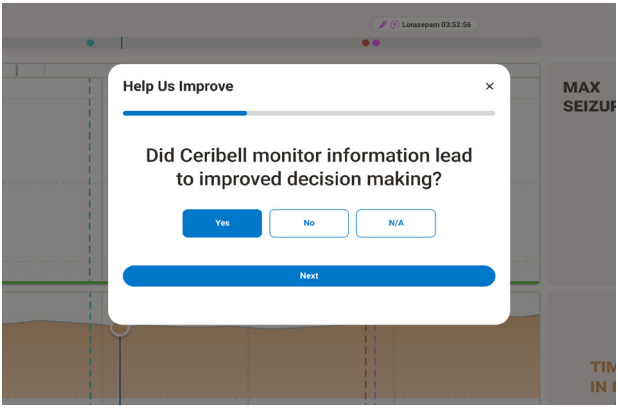


Figure 127: Provide Feedback: Happy Face, Answer Selected

For the final survey question, the **NEXT** button will be replaced with a **SUBMIT** button.

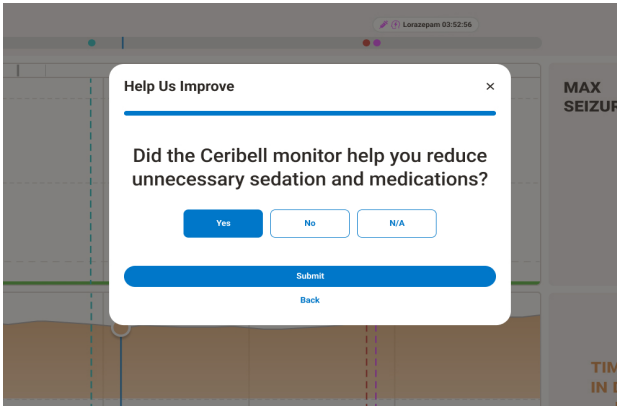


Figure 128: Provide Feedback: Happy Face, Final Question

If the **SAD FACE**  is selected, a free text prompt will be provided to submit an answer, followed by the above questions.

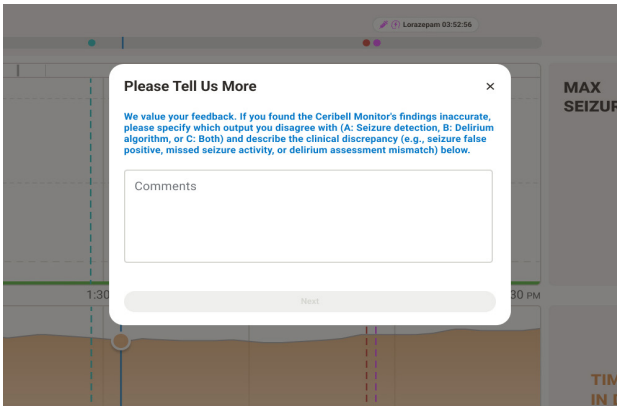


Figure 129: Provide Feedback: Sad Face

To view the raw EEG, click the **VIEW EEG** button. Instructions for Use regarding the EEG page can be seen above and are not changed.

Figure 130: View EEG Button

Click **GENERATE EEG REPORT** to generate an EEG report. Instructions for use regarding the EEG Report can be seen above and are not changed.

Figure 131: Generate EEG Report Button

System Workflow and Software

Once an EEG recording has been started with the Ceribell EEG Recorder, the Delirium Monitor analyzes the EEG waveforms over a 30-minute window and provides the Delirium Monitor output which is updated once every 10-seconds. The output of the delirium detection algorithm is presented to the user in both graphical and text formats, with the graph displaying a history of past output data points.

There are no user actions required to initiate monitoring the EEG for delirium; the Delirium Monitor software is active at any time in which an EEG recording is ongoing.

The Ceribell EEG Recorder periodically checks the status of each EEG electrode connection and alerts the user if one of the electrodes appears to be disconnected. It is important to promptly correct any electrode issues that are observed. The Delirium Monitor is not able to analyze EEG waveforms on channels where one or more of the electrodes is disconnected. For further information on checking the status of electrode connections, see the Ceribell EEG Recorder instructions for use above.

If a Ceribell Instant EEG Headcap is connected to the Ceribell EEG Recorder and the Delirium Monitor software is installed, the following message will appear if the user clicks on the DELIRIUM button on the home screen: “Delirium is not available for the headcap.”

Compatibility with Other Ceribell Software

The Delirium Monitor Software may be utilized in parallel with Ceribell’s other analysis software, the seizure detection software, and this is the default configured operation of the platform. As such, users may receive a notification from the Seizure Detection Software when the condition is detected.

If a notification is generated for detection of the Seizure Detection Software condition, the user will be shown the notification. If the user presses **OK** on the notification, the user will be taken directly to the Seizure Burden page. The figure below shows the device user interface in a situation where the seizure detection software has generated an alert while the user is on the Delirium page, prior to user interaction. As is shown, all information is retained, and only the Seizure Detection Software notification is provided.

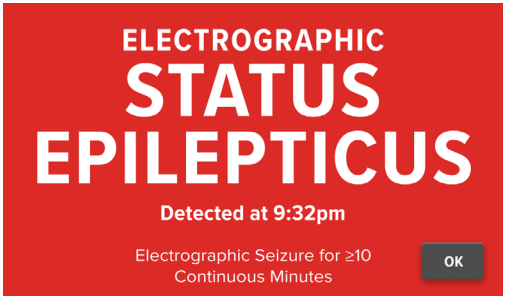


Figure 132: Electrographic Status Epilepticus Alert Page

If the Ceribell EEG Recorder is not connected to WiFi, the message “Last Update X Minutes Ago” is displayed. In cases where the EEG recorder is not connected to WiFi or if the WiFi connection becomes interrupted, transfer the EEG recording using the USB connection.

Refer to the Transferring EEG Recording Files via USB section of the Operator Manual for further details regarding USB data transfer. Once an EEG recording has been transferred via USB, the waveforms are processed by the Delirium detection algorithm in the same manner as when the data is transmitted using WiFi.

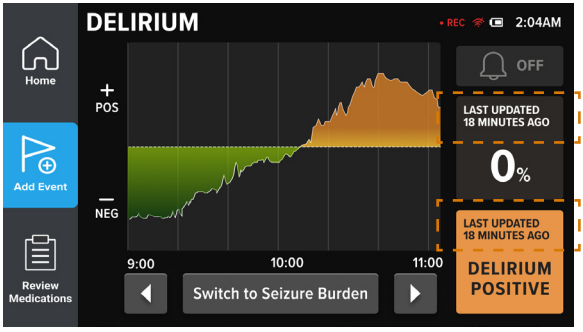


Figure 133: Delirium Monitor Page: No WiFi

Principles of Operation

The Delirium detection algorithm used by the subject device identifies sections of EEG that may correspond to delirium through the following steps:

1. Segment the EEG Signal: Divide the filtered signal from all eight EEG channels into 15-second segments, using a 5-second overlap between adjacent segments.

2. Classify each segment: Process the features from every individual channel segment through the classification algorithm to determine if delirium features are predominant in each segment.
3. Aggregate Data in a Moving Window: Apply a control policy to combine the classifications from all segments within a rolling 30-minute window.
4. Providing the assessment output to the intended users after the first 15 seconds of recording on the Ceribell EEG Recorder.
5. Thereafter, providing the classification assessment output to the intended users once every 10 seconds, generating a trendline of negative or positive outputs.

The classification output is binary: Delirium is either detected or not detected. The machine-learning model used for classification is a random forest algorithm. A set of time-domain and frequency-domain features are extracted for each of the 8 EEG channels, and these features are fed into the random forest decision tree that is used to make the Delirium determination.

Development and training of the machine-learning model is performed with EEG recordings that correspond to expert clinical assessments of Delirium. Datasets that are used for validation are segregated so that they are never used for development or training of the algorithm.

Validation of Delirium Algorithm Performance

Performance Validation Methodology

The performance of the Delirium Monitor was established through the analysis of clinically collected EEG data with corresponding expert clinical delirium assessments. The following steps summarizes the algorithm validation performance procedure:

1. A dataset was collected from five study centers in different geographical areas. This dataset was separate and independent from the data used to design and train the algorithm. None of the study centers, clinicians, and patients used in the validation dataset were used for algorithm design, development, or training.

2. Each enrolled subject received an expert clinical assessment for delirium up to 3 times daily for up to 3 days. During each expert assessment, the subject's EEG was concurrently recorded with the Ceribell EEG system. A total of 857 assessments from 225 subjects were included in the validation dataset.
3. The Delirium Monitor software algorithm was run on the validation dataset and performance metrics were calculated for the results of each device as compared to the reference standard.
4. Statistical analysis was performed on the results to evaluate and compare the performance to the pre-determined acceptance criteria.

Validation Dataset

The validation dataset consisted of 857 data points from 225 subjects from the intended patient population. The study was designed to have broad inclusion criteria representative of the intended patient population. The only exclusion criteria were: subjects under the age of 22, subjects who could not be clinically assessed for delirium, and subjects for whom the Ceribell EEG data could not be captured. Therefore, the dataset is representative of the intended patient population.

There were 135 males (60.0%) and 90 females (40.0%) in the sample. The average age was 62.4 years (standard deviation = 14.8). The minimum age was 24 and the maximum age was 92. There were 115 (51.1%) subjects below age 65 and 110 (48.9%) subjects who were 65 or older.

Safety

No adverse events were anticipated because the Ceribell EEG recorder and headband are 510(k) cleared and have been commercially available for approximately 5 years. During this time there have never been any events or injuries that required reporting to FDA per 21 CFR 803.50. One of the clinical study sites reported three protocol deviations from three different subjects where the subjects elected not to wear the Ceribell EEG headband continuously. This had no impact on the study data because EEG was still recorded concurrently with all clinical delirium assessments for each of these subjects.

Results

The results of the validation study are summarized in the table below. For both metrics of sensitivity and specificity, the performance of the Delirium Monitor surpassed the pre-defined acceptance criteria.

Table 25: Validation study results for the Delirium Monitor

	Results	95% Confidence Interval	Acceptance Criteria	Conformance to Acceptance Criteria
Sensitivity	81%	[76%, 87%]	Lower bound of the 95% confidence interval ≥ 70%	PASS
Specificity	81%	[73%, 89%]	Lower bound of the 95% confidence interval ≥ 70%	PASS

The full results of the Delirium Monitor classifications compared to the ground-truth reference standard are shown in the following confusion matrix table.

Table 26: Confusion matrix showing full results of the Delirium Monitor classifications compared to the ground-truth reference standard

		Delirium Monitor Algorithm Output	
		Negative	Positive
Expert Clinician Delirium Assessment	Negative	526	126
	Positive	38	167

Subgroup Performance

Subgroup analyses demonstrated acceptable variation among subgroups, supporting performance across the intended use population.

Repeatability

Repeatability was demonstrated on 614 paired test/re-test EEG segments. For the repeatability measurement, the two EEG segments were selected as those closest in time to each expert clinician delirium assessment. The EEG segment pairs were selected to be non-overlapping. While delirium is understood to wax and wane, this approach assumes that

within the period of the two adjoining EEG segments from the same subject, the underlying state of delirium positive or delirium negative would typically not fluctuate and therefore the two EEG segments would be expected to produce the same output. Therefore, a high correlation between pairs of assessments is a good indication of repeatability of the measurement. The analysis resulted in a Cohen's kappa value of 0.7565 (95% CI: 0.7122-0.8008) indicating "substantial agreement." The percent agreement above random chance was 34.94%.

Clinical Risk

The risks of the device are based on the data collected in the clinical validation study. Given that the Delirium Monitor runs on an FDA-cleared hardware platform, the major risks associated with it are a false positive or a false negative result. The Delirium Monitor is intended to aid in the screening and monitoring of delirium and does not replace the evaluation of the patient by a qualified clinician. Bedside delirium assessments should still be performed per the hospital's usual workflow.

Pre-determined Change Control Plan (PCCP)

The Delirium Monitor has been cleared by the FDA with an Authorized PCCP. The Authorized PCCP outlines specific modifications intended to improve algorithm performance through the expansion of training data and optimization of the algorithm. The PCCP outlines Ceribell's data management and algorithm development practices, including how and when performance is evaluated.
The PCCP also defines validation requirements for algorithm updates. Prior to release, the updated algorithm is validated through testing against previously established acceptance criteria using an independent validation data set. Updates will be implemented using a validated Software Update process. When an update is performed, Ceribell will update this operator manual and notify customers of the update.

There have been no PCCP changes to the algorithm to date.