

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 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.

Warnings



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.

Warnings



Warning: The Seizure Detection output has not been tested with patients under 18 years old.

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 2: Enter the Patient Information

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

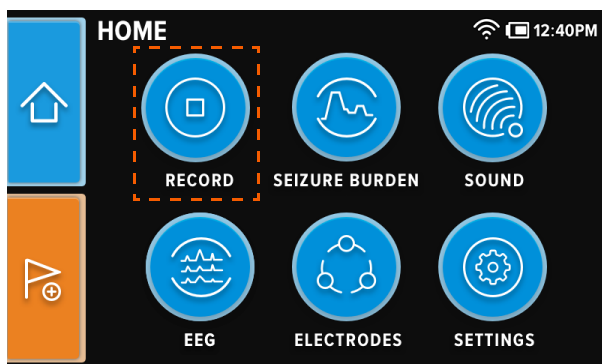


Figure 2: Home Screen

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

PATIENT INFO: ID 12:40PM

PATIENT ID

Q W E R T Y U I O P

A S D F G H J K L

123 Z X C V B N M

. , _ ? SPACE ENTER

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.

PATIENT INFO: First Name 12:40PM

Patient First Name

Q W E R T Y U I O P

A S D F G H J K L

123 Z X C V B N M

. , _ ? SPACE ENTER

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. Enter the Ordering Physician Name and press the **ENTER** button to continue to the Confirm Patient Info page. This field is optional.

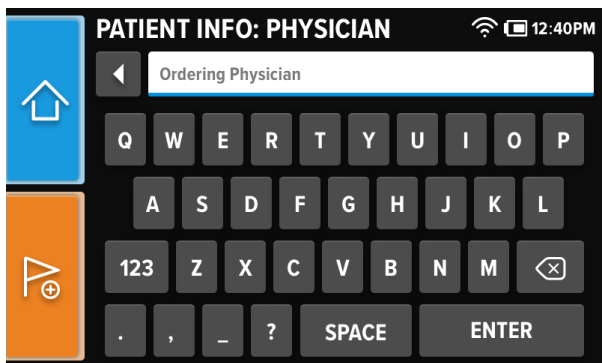


Figure 7: Patient Info: Ordering Physician Entry Page

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

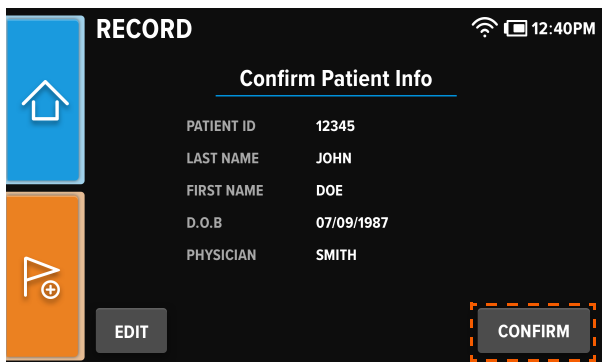


Figure 8: Confirm Patient Info Page

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

Step 3: Connect the Ceribell EEG Headband

- A. Plug the Ceribell EEG Headband or other EEG electrodes into the connector labeled “Headband” on the side of the Ceribell EEG Recorder.
- B. Set up the headband, 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.

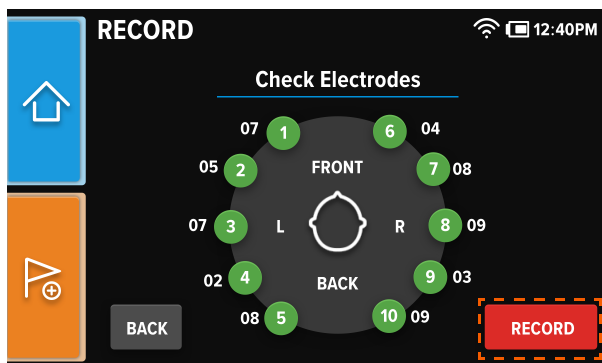


Figure 9: Check Electrode Connections Page

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.

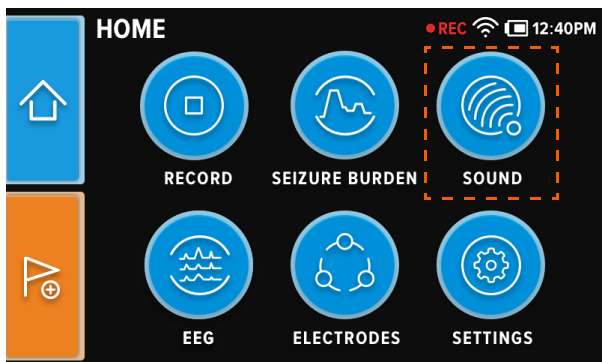


Figure 10: Home Screen



Figure 11: Ceribell EEG Recorder

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

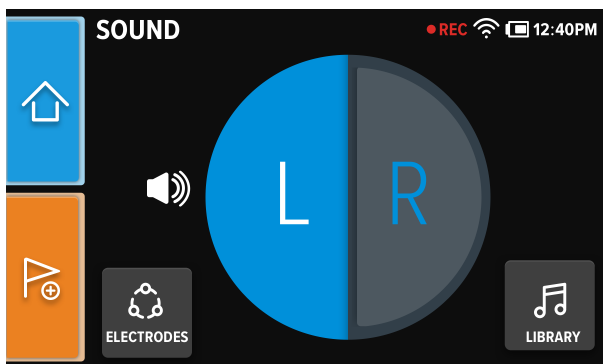


Figure 12: Sound Page

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.

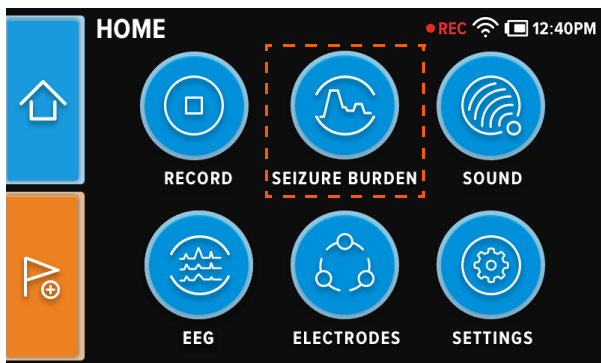


Figure 13: Home Screen

- B. The *Seizure Burden* page displays the Seizure Burden plot for the recording. Navigate backward and forward through the Seizure Burden plot by pressing the left and right arrow buttons beneath the plot.

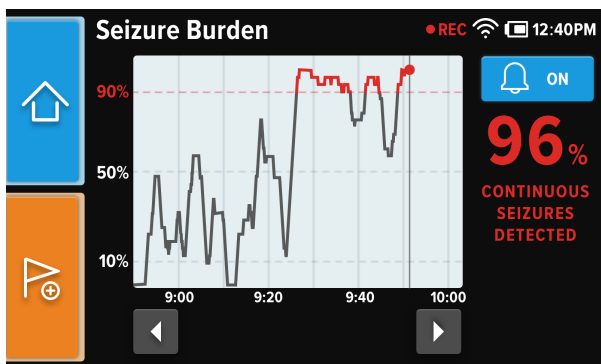


Figure 14: Seizure Burden Page

Note: The Seizure Burden plot displays the percentage of detected seizures over a five minute period. WiFi must be enabled and a minimum of 5 minutes of recorded data must be transmitted for the Seizure Burden plot to display.

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.

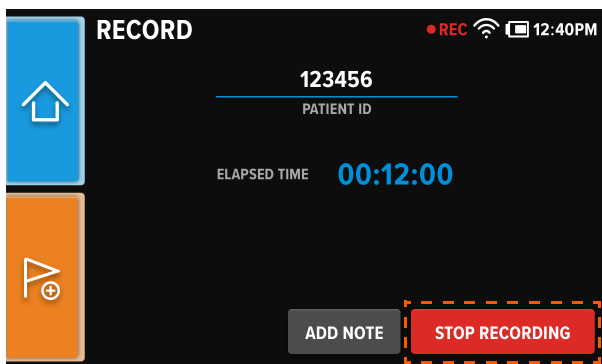


Figure 15: Record Page

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

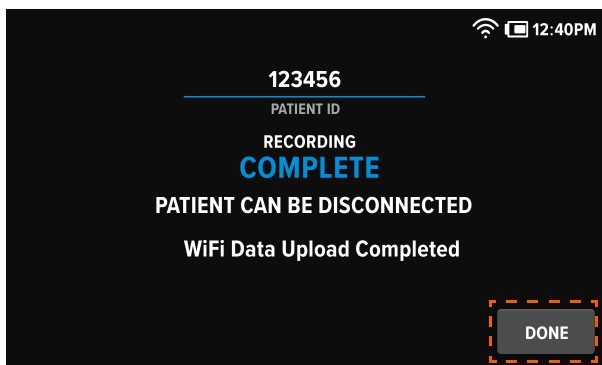


Figure 16: Recording Complete Page

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 8-channel EEG monitoring system. 10 patient electrodes (5 left, 5 right) are required to form the 8 channels. The Ceribell EEG Recorder can be used with any EEG electrodes. Channels 1-5 should be used for the patient's left hemisphere, with channel 1 at the front of the patient's head and channel 5 at the back of the patient's head. Channels 6-10 should be used for the patient's right hemisphere, with channel 6 at the front of the patient's head and channel 10 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. When viewing EEG signals, the operator can select between viewing all 8 channels simultaneously or viewing only one channel at a 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 files are transferred from the Ceribell EEG Recorder to the computer using either a micro-USB cable or wirelessly using a WiFi connection.

System Components

- Ceribell EEG Recorder assembly (Ceribell part number SA-00004): 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-00025): a mount clip for securing the Ceribell EEG Recorder to a hospital bed rail or equivalent.
- Ceribell Charging Station (Ceribell part number SA-00028): 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.

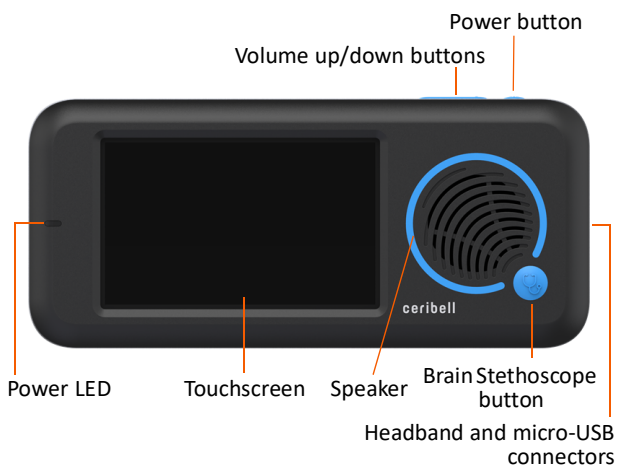


Figure 17: Ceribell EEG Recorder

On the left side of the touchscreen display, a blue LED on the illuminates whenever the device is powered on. On the right side of the device are headband and micro-USB connectors. The EEG electrode headband plugs into the headband 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 18: Device Charging 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.

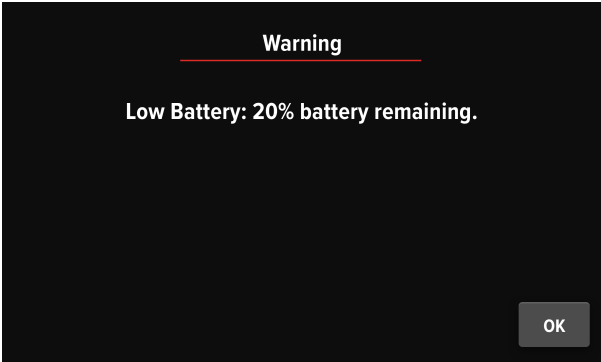



Figure 19: Low Battery Warning Page

 **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 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 touchscreen 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.

When the device is on, pressing the power button will toggle the touchscreen display on and off.

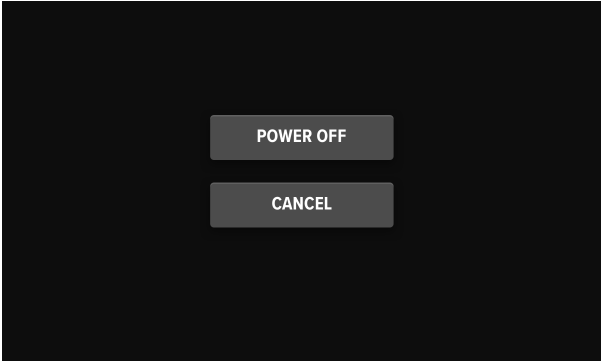


Figure 20: Power Off Confirmation Page

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.

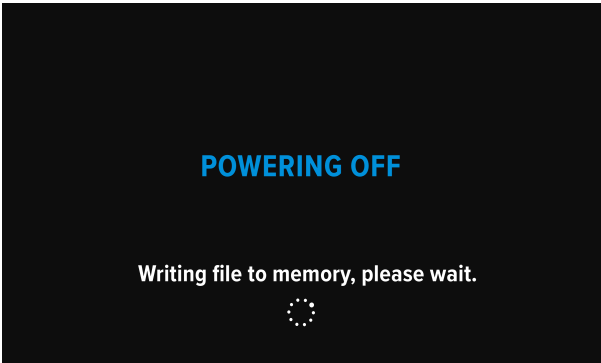


Figure 21: Powering Off Page

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 “Tag Event” button provides quick access to tag an event during recording from any system page.

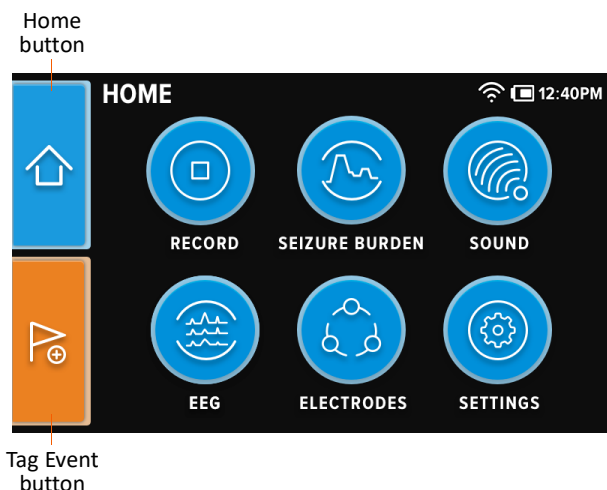


Figure 22: Home Screen

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.

Return to previous
Patient Info entry page

PATIENT INFO: First Name

Patient First Name

Q W E R T Y U I O P

A S D F G H J K L

123 Z X C V B N M

. , _ ? SPACE ENTER

Continue to next
Patient Info entry page

Figure 23: 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.

RECORD

Confirm Patient Info

PATIENT ID	12345
LAST NAME	JOHN
FIRST NAME	DOE
D.O.B	07/09/1987
PHYSICIAN	SMITH

EDIT CONFIRM

Figure 24: 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.

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.

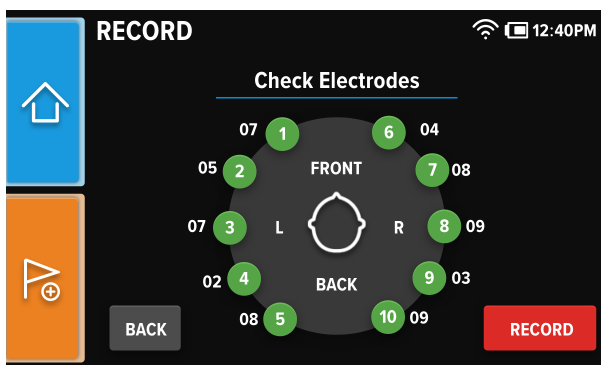


Figure 25: Check Electrode Connections Page

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

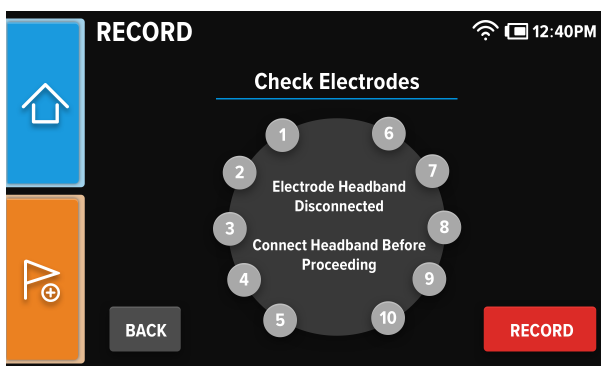


Figure 26: Electrode Headband Disconnected Page

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.

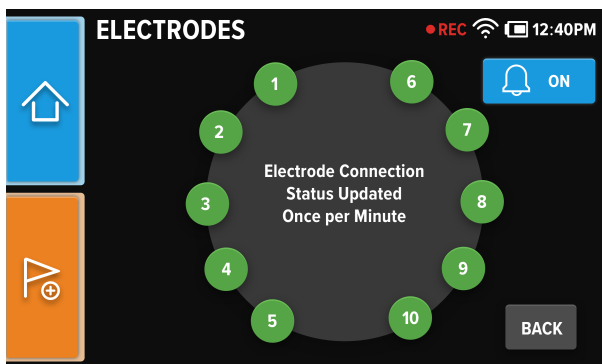


Figure 27: Electrodes Page

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.

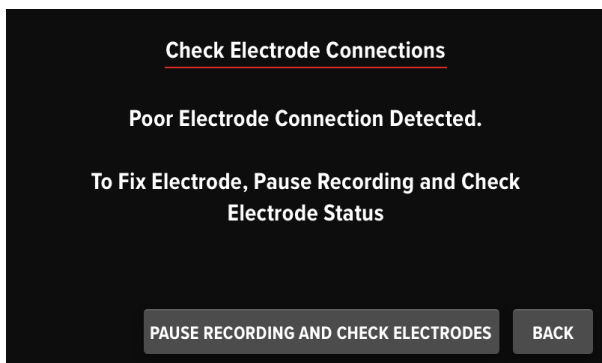


Figure 28: Check Electrode Connections Warning Page

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.

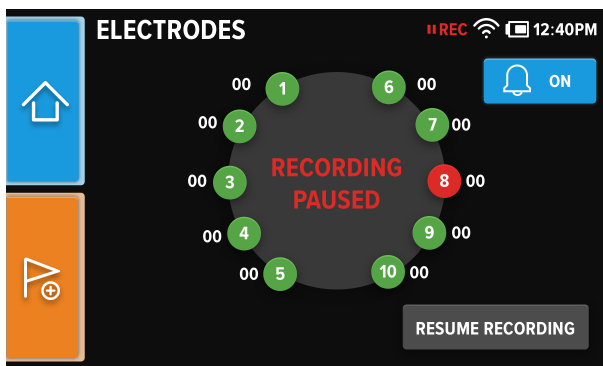


Figure 29: Fix Electrode Connections Page

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.

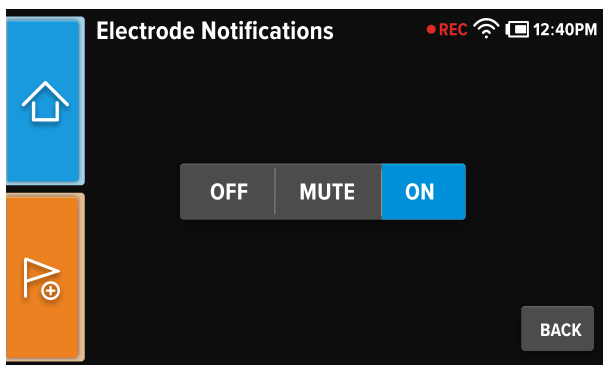


Figure 30: Electrode Impedance Notifications Page

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.

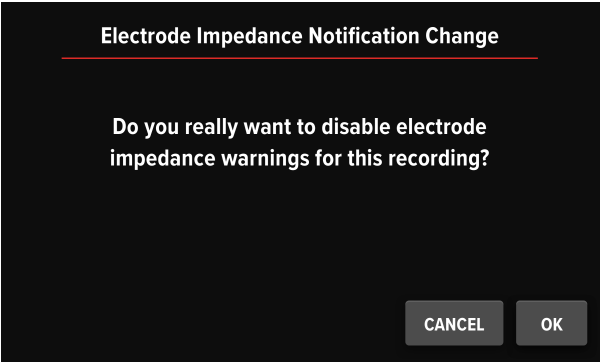


Figure 31: Electrode Impedance Notification Change Page

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.

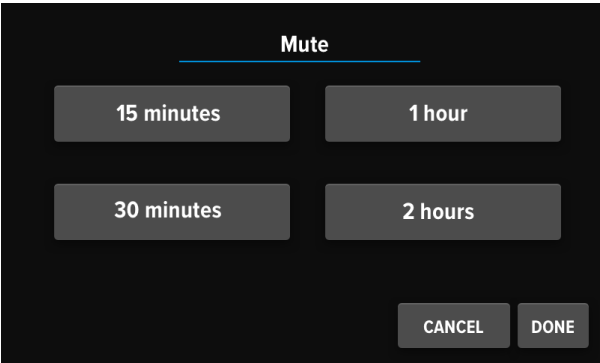


Figure 32: Electrode Impedance Mute Page

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.

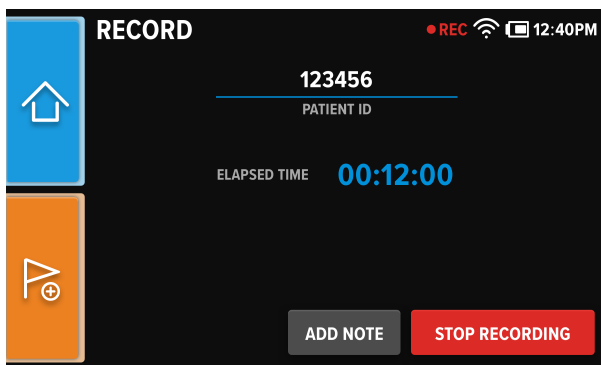


Figure 33: Recording Complete Page

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.

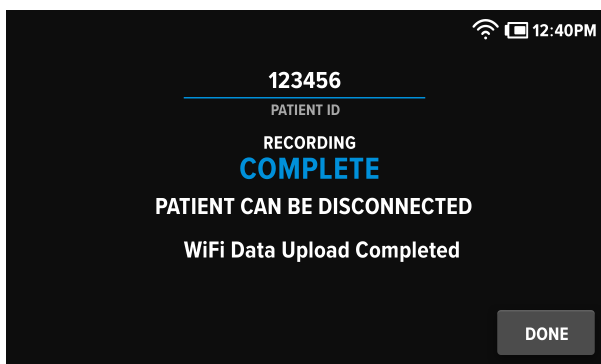


Figure 34: Recording Complete Page

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.

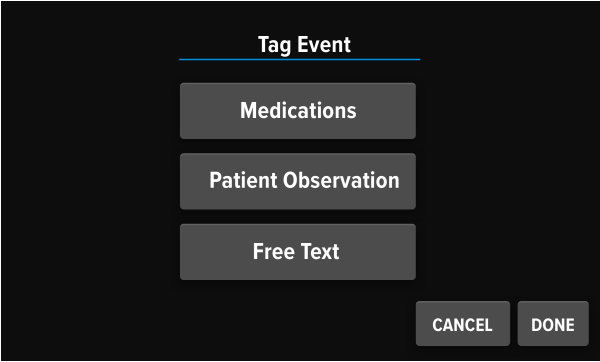


Figure 35: Tag Event Page

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

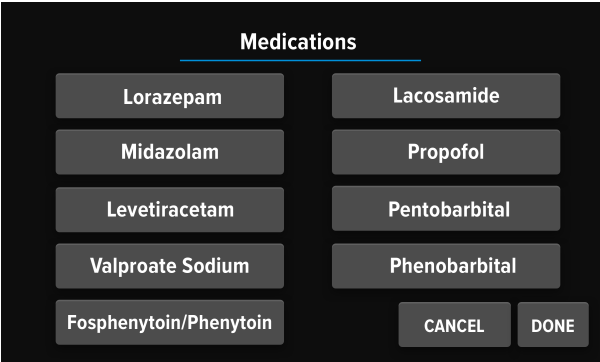


Figure 36: Medications Event Page

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

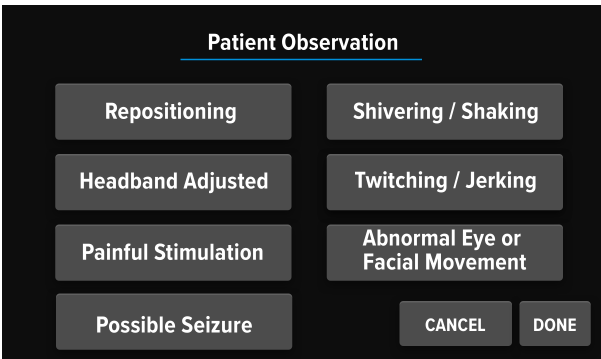


Figure 37: Patient Observation Tag Event Page

If **Free Text** was selected, enter the desired note, and press the **ENTER** button.

Viewing EEG Waveforms

EEG waveforms can be viewed at any time, both when a recording is in progress and when a recording is not in progress. To view the EEG waveforms, press the **DISPLAY** button on the Home Screen to go to the *EEG Display* page. Press the **50 μ V** or **100 μ V** button to select the display-unit scale.



Figure 38: 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.

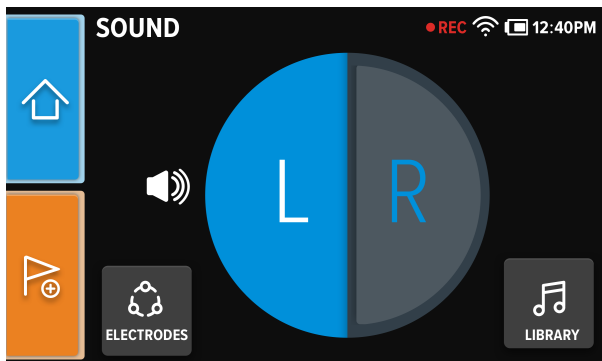


Figure 39: Sound Page

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.

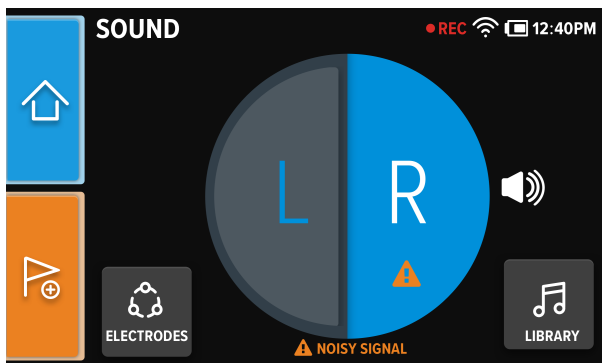


Figure 40: Noisy Signal Alert

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 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*

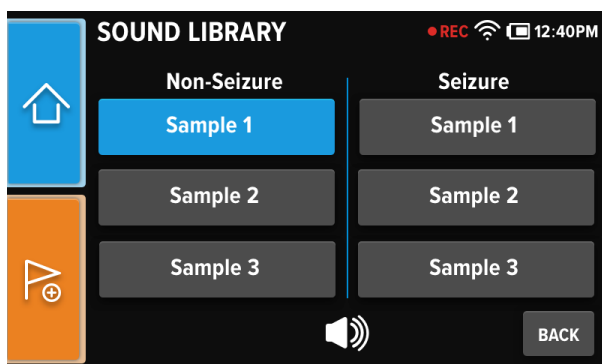


Figure 41: Sound Library Page

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. Navigate backward and forward through the Seizure Burden plot by pressing the left and right arrow buttons beneath the plot.

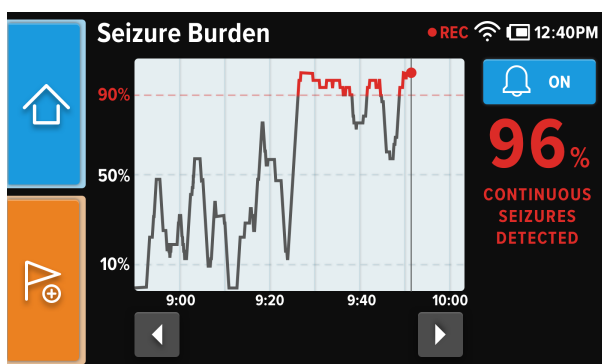


Figure 42: Seizure Burden Page

*Note: A minimum of 5 minutes of recorded data must be trans-
mitted for the Seizure Burden plot to display.*

Continuous Seizure Notifications

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



Figure 43: Continuous Seizure Notifications Page

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.

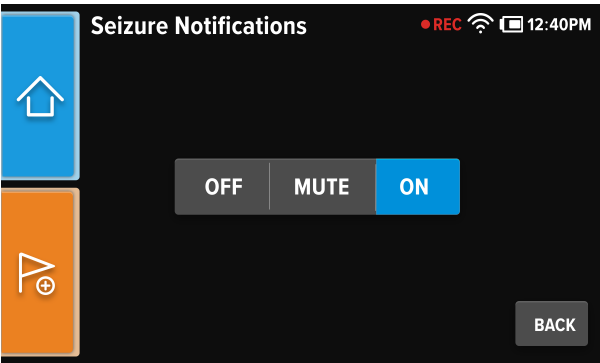


Figure 44: Seizure Burden Notifications Page

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.

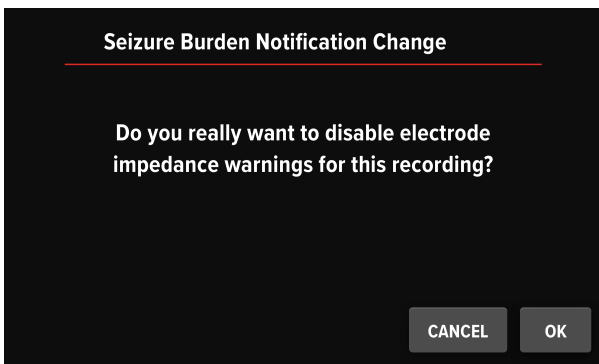


Figure 45: Seizure Burden Notification Change Page

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.

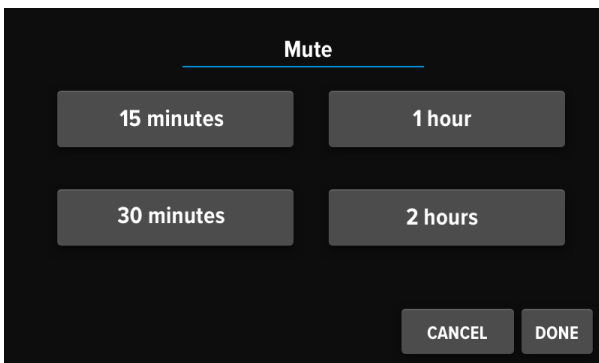


Figure 46: Seizure Burden Mute Page

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 2 hours of recording time memory is remaining.

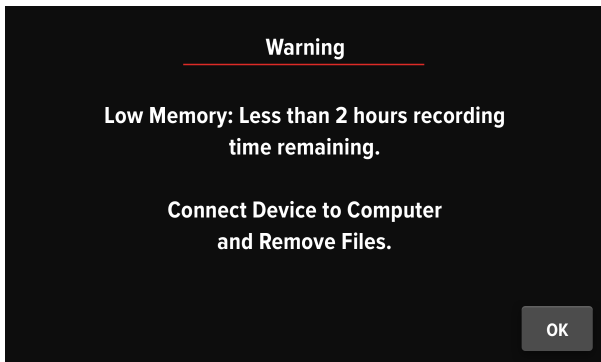


Figure 47: Low Memory Warning Page

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.

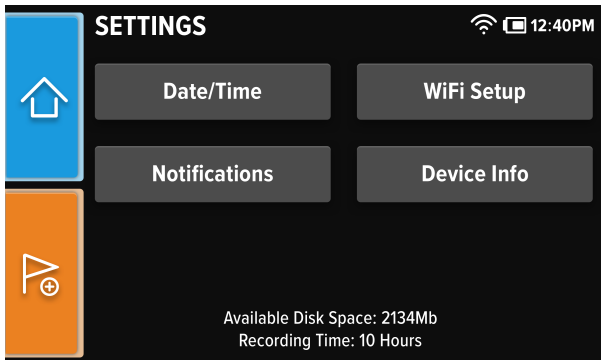


Figure 48: Settings Page

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

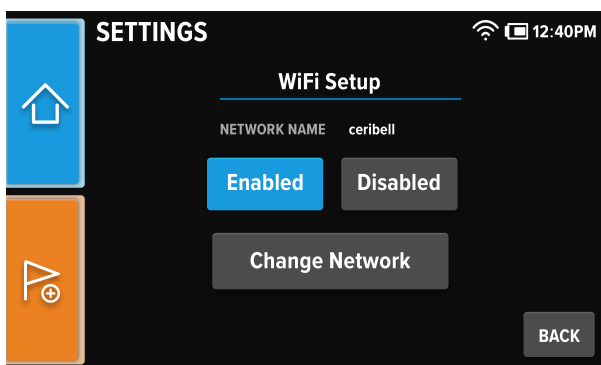


Figure 49: WiFi Setup Entry Page

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.

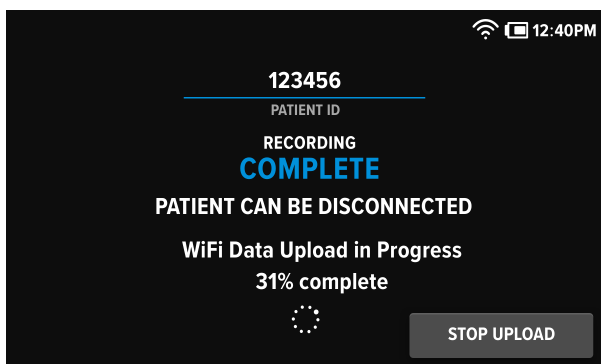


Figure 50: Wifi Upload Status Page

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 51: 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 52: 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.

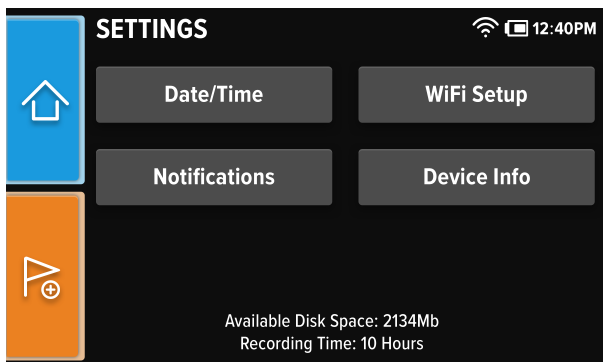


Figure 53: Settings Page

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.

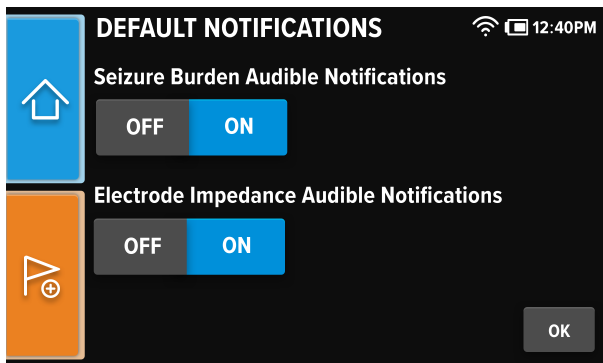


Figure 54: Default Audible Notifications Page

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.

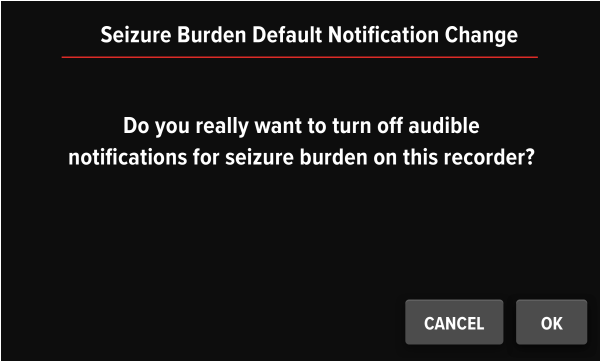


Figure 55: Seizure Burden Default Notification Change Page

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.

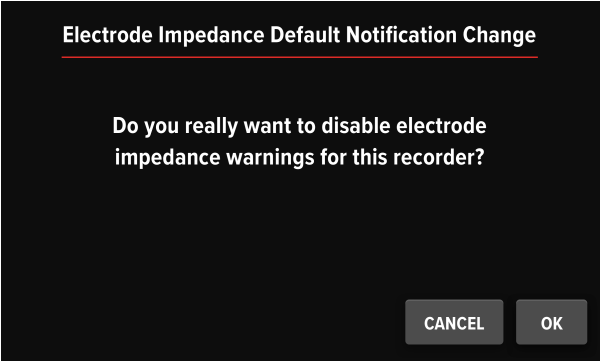


Figure 56: Electrode Impedance Default Notification Change Page

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.

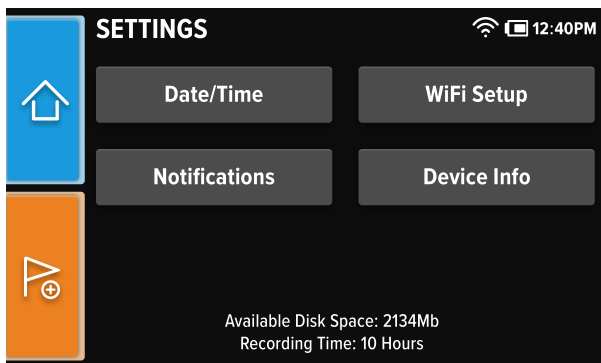


Figure 57: Settings Page

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 58: Device Info 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.

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

- Operating System: Windows 7 or greater; Mac OS X 10.10 or greater
- Web browser: Mozilla Firefox, Microsoft Internet Explorer, Microsoft Edge, Safari, or Google Chrome

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, multiple time and frequency domain features are calculated for each time epoch. These features are used by a classifier algorithm which determines 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 guidelines¹, 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 guidelines¹, 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 guidelines¹, 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 guidelines¹. 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.



Warning: The Seizure Detection output has not been tested with patients under 18 years old.

¹ L.J. Hirsch et al, "American Clinical Neurophysiology Society's Standardized Critical Care EEG Terminology: 2012 version." *J Clin Neurophysiol* 2013;30: pp. 1–27.

Validation of the Seizure Detection Module

Clinical Performance Data

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

Demographics

The demographics of Ceribell's seizure detection validation dataset are as follows:

Table 1: Seizure Detection Validation Dataset Demographics

Total Subjects	60
Gender	Male: 29 (48.3%) Female: 31 (51.7%)
Age	Average: 56.5 Minimum: 22 Maximum: 88

Patient Baseline Characteristics

The validation dataset had no inclusion/exclusion criteria related to patient baseline characteristics. In general, ICU patients who receive EEG monitoring present with one or more neurological diagnoses that are potentially indicate an increased risk of seizures. EMU patients typically have a prior history of seizures that warrants EEG monitoring.

Enrollment

The validation dataset was obtained from previous studies that retrospectively reviewed all adult EEGs from patients who underwent inpatient EEG monitoring over a period of time. Data from one hospital was used for ICU EEG data, and data from a second hospital was used for EMU EEG data. From the ICU and EMU source datasets, a total of 60 subjects aged 18 or older were randomly selected for inclusion in the Ceribell seizure detection validation study; 30 from the ICU dataset and 30 from the EMU dataset.

Masking

All of the EEG data used for Ceribell's seizure detection validation was retrospectively obtained from pre-existing EEG databases. The EEG trained neurologists who reviewed the data to provide the clinical reference were masked. The EEGs used for the validation protocol were selected with no knowledge of how the Ceribell or Persyst 13 seizure detection would perform. No patients from the validation dataset were used for algorithm training or development.

General summary

The following is a summary of the validation procedure performed:

- A validation dataset of full montage EEG recordings obtained from adult (18 years and older) patients were chosen for validation testing. This dataset was completely separate and independent from the data used to design and train the algorithm.
- A reference standard was established for the validation dataset by EEG trained neurologists who reviewed and annotated the EEG recordings for seizure episodes.
- Both Ceribell EEG Recorder and predicate Persyst 13 (K151929) Seizure Detection modules were run on the validation dataset and performance metrics were calculated for each as compared to the reference standard established per above.

- Statistical analysis was performed on the results to evaluate and compare the performance to the predetermined acceptance criteria.

Selection of Validation Sets

For the validation data set, 50% of the data was from the ICU and 50% was from the EMU. The reference standard for the validation data set was obtained by having trained experts review and annotate the EEG files for onset and conclusion of seizure episodes.

The expert EEG reviewers used to generate the reference standard were affiliated with multiple different institutions. All were fellowship trained in epilepsy or clinical neurophysiology. To validate seizure detection notifications, positive percent agreement (PPA) and false positives/ hour (FP/hr) were calculated for the Ceribell Seizure Detection module and Persyst 13 with respect to the reference standard.

The three levels of seizure detection notification for Ceribell (“Frequent,” “Abundant,” and “Continuous”) are additive – the “Frequent” notification must always occur first before the “Abundant” or “Continuous” notification. Therefore, it is most relevant to compare the Ceribell “Frequent” notification output to the Persyst 13 seizure notification output. The Ceribell “Frequent” notification output represents the detection of 30 seconds or more of seizure activity within a 5-minute moving window. The Persyst 13 seizure notification output represents the detection of 11 seconds or more of continuous seizure activity. There is no clinically relevant distinction between these two types of notifications. The validation protocol requires that the PPA and FP/hr for the Ceribell “Frequent” notification output must be statistically non-inferior to the Persyst 13 seizure detection notification output. Additionally, to assess device effectiveness and clinical utility, performance of all Ceribell’s notification levels, “Frequent”, “Abundant” and “Continuous, with respect to the reference standard are calculated and presented with the results along with their 95% confidence intervals. The criteria for minimally acceptable device performance was to have a positive percent agreement with a 95% CI lower bound above 70% and a false positive rate with a 95% CI upper bound below 0.446 per hour.

Note: Validation was based upon demonstrating that Ceribell was non-inferior to Persyst 13 with a 10% non-inferiority Margin.

Results of Clinical Performance Testing

Table 2: Contingency Table of Ceribell Device Output for “Abundant” Notification with respect to Clinical Reference for the Validation Dataset

		Clinical Reference (Review and Annotation of validation datasets by EEG-trained neurologists)			
		No seizure or Seizure Duration < 150 seconds	150 seconds ≤ Seizure Duration < 270 seconds	Seizure Duration ≥ 270 seconds	Total
Ceribell Device Output	Below 50% Threshold (no “Abundant” notification provided)	NA	2	1	3
	Above 50% Threshold (“Abundant” notification provided)	FP/hr = 0.1996	18	22	40
	Total	NA	20	23	43
	Sensitivity	NA	90.0%	95.6%	93.02%

Table 3: Contingency Table of Ceribell Device Output for “Continuous” Notification with respect to Clinical Reference for the Validation Dataset

		Clinical Reference (Review and Annotation of validation datasets by EEG-trained neurologists)		
		No seizure or Seizure Duration < 270 seconds	Seizure Duration > 270 seconds	Total
Ceribell Device Output	Below 90% Threshold (no “Continuous” notification provided)	NA	2	2
	Above 90% Threshold (“Continuous” notification provided)	FP/hr = 0.1247	21	21
	Total	NA	23	23
	Sensitivity	NA	91.3%	91.3%

Reference Standards

For both the ICU and EMU datasets:

The neurologist reviews are completed prior to the start of any validation testing, and the same reference standard is used to test the performance of both the Ceribell seizure detection feature and the Persyst 13 seizure detection. Therefore, it is not possible for a neurologist to bias his or her review in a way

that affects the outcome of the validation testing. EEG trained neurologists (physicians who have obtained fellowship training in epilepsy or neurophysiology) reviewed and annotated the EEG recordings for seizure episodes. Each seizure episode was manually annotated by an expert panel, with agreement between at least two neurologists required to determine the reference standard.

Pass/Fail Criteria

The seizure detection notification validation tests performed and their acceptance criteria are summarized below in Table 4. The seizure burden output validation tests performed and their acceptance criteria are summarized below in Table 5.

Table 4: Summary of Validation Testing for Seizure Notifications

Test Description	Acceptance Criteria
“Frequent” seizure activity notifications (≥10% seizure burden), PPA and FP/hr	Ceribell non-inferior to Persyst 13 with 10% non-inferiority margin
“Frequent” seizure activity notifications (≥10% seizure burden), PPA and FP/hr	PPA: 95% CI lower bound ≥ 70% FP/hr: 95% CI upper bound ≤ 0.446
“Abundant” seizure activity notifications (≥50% seizure burden), PPA and FP/hr	PPA: 95% CI lower bound ≥ 70% FP/hr: 95% CI upper bound ≤ 0.446
“Continuous” seizure activity notifications (≥90% seizure burden), PPA and FP/hr	PPA: 95% CI lower bound ≥ 70% FP/hr: 95% CI upper bound ≤ 0.446

Table 5: Summary of Validation Testing for Seizure Burden Output

Test Description	Acceptance Criteria
Seizure Burden output, L1-distance vs. reference standard	Ceribell non-inferior to Persyst 13 with 10% non-inferiority margin

Results

Table 6 below summarizes the results for performance metrics, PPA and FP/hr for all three Ceribell's seizure notification levels of "Frequent", "Abundant" and "Continuous" along with their 95% confidence intervals. The percentage agreement for the three notification levels ranged from 91.30% to 94.67%. The false positive rate ranged from 0.1247 to 0.2145.

Table 6: Performance Metrics for Seizure Notifications for all Three of Ceribell's Level of Seizure Activity Notification, as Compared to Reference Standard

Ceribell Seizure Activity Notification Level	PPA	PPA 95% CI	Conformance to PPA Acceptance Criteria	FP/hr	FP/hr 95% CI	Conformance to FP/hr Acceptance Criteria
"Frequent"	94.67%	[90.00%, 97.33%]	90.00% > 70%, therefore, PASS	0.2145	[0.119, 0.351]	0.351 < 0.446, therefore, PASS
"Abundant"	93.02%	[81.39%, 100%]	81.39% > 70%, therefore, PASS	0.1996	[0.093, 0.381]	0.381 < 0.446, therefore, PASS
"Continuous"	91.30%	[78.26%, 100%]	78.26% > 70%, therefore, PASS	0.1247	[0.054, 0.272]	0.272 < 0.446, therefore, PASS

Conclusion

The Ceribell EEG Recorder has the same intended use as the predicate devices. In addition, it has similar technological characteristics. Evaluation of the results and the test methods to account for different technological characteristics of the submitted performance data demonstrated that differences in technological characteristics between the subject device and predicates do not raise different questions of safety or effectiveness. Therefore, the Ceribell EEG Recorder is substantially equivalent to the predicates.

Logging Into the Ceribell EEG Portal

The Ceribell EEG Portal 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.

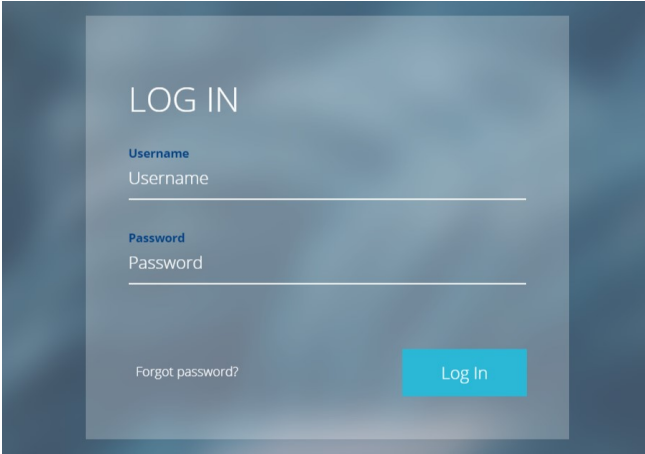


Figure 59: Ceribell EEG Portal - Login

Viewing EEG Recordings

After logging into the Ceribell EEG Portal, the *Patient List* 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.

Patient Name	Medical ID	Organization	Ordering Physician	Recording Date	Duration	Review Status
Chaya Hirsch	56061236	Ceribell Review	Dr. Taryn Klein	Sep 11, 2018 7:59 PM - Sep 12, 2018 9:52 AM	13:53:46	Ⓜ Reviewed by Ceribell QA on Nov 16, 2018 (UTC-8)
Erin Johnson	74773716	Ceribell Review	Dr. Vaughn Heathcote	Sep 6, 2018 1:25 PM - Sep 6, 2018 2:04 PM	01:29:10	🔍 Needs Review
Debra Becker	12223753	Ceribell Review	Columbus Schuller II	Aug 23, 2018 3:41 AM - Aug 23, 2018 3:58 AM	00:14:15	🔍 Needs Review
Warren Marquardt	36220560	Ceribell Review	Dr. Cedrick Ziemer	Aug 9, 2018 3:04 PM - Aug 9, 2018 3:29 PM	00:24:27	Ⓜ Reviewed by Ceribell QA on Nov 16, 2018 (UTC-8)
Lauretta Pison	83096187	Ceribell Review	Murphy Racolta	Aug 8, 2018 4:00 PM - Aug 8, 2018 5:01 PM	01:01:02	Ⓜ Reviewed by Ceribell QA on Nov 16, 2018 (UTC-8)
Isabel Reed	24717068	Ceribell Review	Dr. Van Oersing	Aug 8, 2018 4:10 AM - Aug 8, 2018 5:17 AM	02:01:16	🔍 Needs Review
Yvonne Kofler	77741533	Ceribell Review	Dr. Hansen	Aug 6, 2018 6:12 PM - Aug 6, 2018 8:14 PM	02:01:07	🔍 Needs Review
Roddy Boehm	54090399	Ceribell Review	Brandy Winkler	Aug 4, 2018 1:25 AM - Aug 4, 2018 3:27 AM	02:02:02	🔍 Needs Review
Rose Bick	43971358	Ceribell Review	Dr. Reynolds	Aug 3, 2018 5:31 PM - Aug 3, 2018 8:01 PM	02:29:55	🔍 Needs Review
Cristovao Rosenbaum	42487154	Ceribell Review	Dr. Abelardo Maglio	Aug 3, 2018 12:09 AM - Aug 3, 2018 1:25 AM	01:16:22	🔍 Needs Review


Figure 60: Ceribell EEG Portal - Patient List 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 wave-

form data recorded from the Cerebellum EEG Recorder.



Figure 61: Cerebellum EEG Portal - EEG Scan Page

Note: Click the  button in the upper left corner of the screen to return to the Patient List page.

Scaling and Filter Options

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

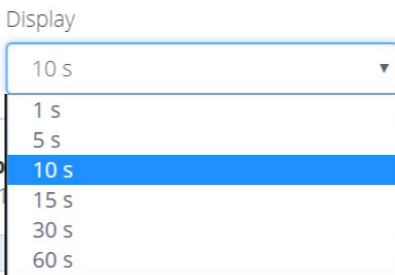


Figure 62: EEG Scan Page - Horizontal Scale Options

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

selected.

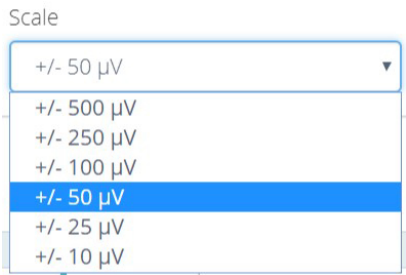


Figure 63: EEG Scan Page - Vertical Scale Options

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 64: 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 65: EEG Scan Page - Low Pass Filter Options

If desired, enable or disable the 60 Hz notch filter using the “Notch” button.

Notch

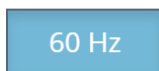


Figure 66: EEG Scan Page - “Notch” Button

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

1X Speed

Changes the EEG recording playback speed

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

Table 7: 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 67: EEG Scan Page - Seizure Burden

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

Seizure Burden Details

Figure 68: EEG Scan Page - Seizure Burden Details button



Figure 69: EEG Scan Page - Seizure Burden page

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

View EEG At Selected Position

Figure 70: Seizure Burden - Return from Full-Screen button

To hide the Seizure Burden plot, click the **SEIZURE BURDEN** button.

Seizure Burden ^

Figure 71: EEG Scan Page - Hide Seizure Burden Plot button

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.

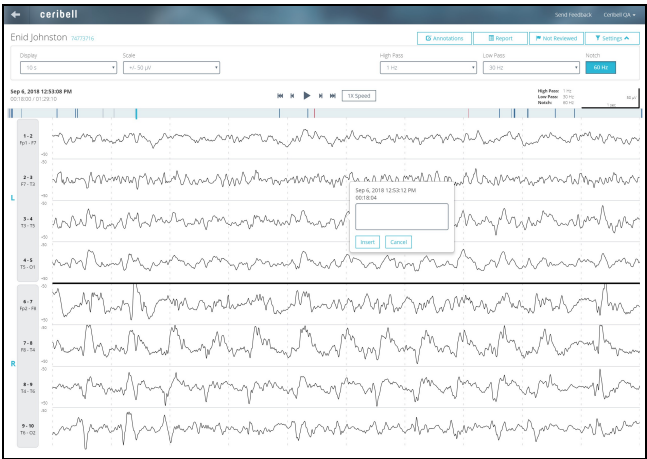


Figure 72: EEG Scan Page - Annotating an EEG Scan

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

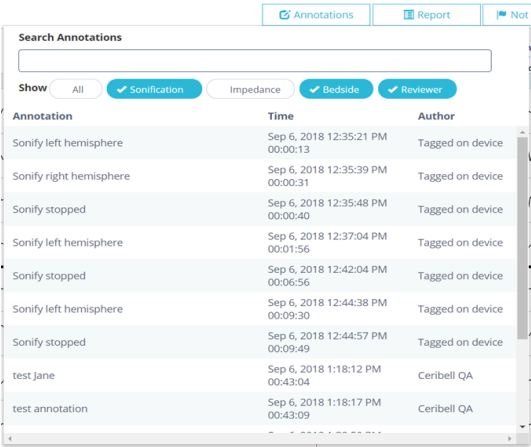


Figure 73: EEG Scan Page - ANNOTATIONS Button

Additional Options

To indicate that the recording has been reviewed, click the **NOT REVIEWED** button. After confirmation, the button changes to **REVIEWED**, and the status on the *Patient List* page changes from “Needs Review” to “Reviewed”. To unmark a recording as reviewed, click on the **REVIEWED** button.

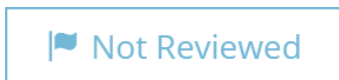


Figure 74: EEG Scan Page - NOT REVIEWED Button

To view a report for the EEG recording, click the **REPORT** button.



Figure 75: EEG Scan Page - REPORT Button

To add notes to the report, click the “Add Impressions” or “Add Comments” buttons in the “Impressions” or “Comments” fields, type in the notes, and then click the **SAVE AND CLOSE** button. To download the report, click the **DOWNLOAD** button. To copy the report, click the **COPY** button. To close the report, click the **SAVE AND CLOSE** button.

EEG Session Report

Patient Name:	Medical ID:	Date of Birth:	Age:
Enid Johnston	74773716	Jan 1, 1950	68
Recording Duration:	Recording Total Time:	Ordering Physician:	
Sep 6, 2018 12:35 PM - Sep 6, 2018 2:04 PM	01:29:10	Dr. Vaughn Heathcote	

Impressions:
 Abnormal EEG following ischemic stroke. Epileptiform activity seen in final 15 minutes of recording.
[Edit Impressions](#)

Comments:
 No comments
[Edit Comments](#)

Report prepared by: Ceribell QA

[Download](#)
[Copy](#)
[Save And Close](#)

Figure 76: EEG Scan Page - Sample Report

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

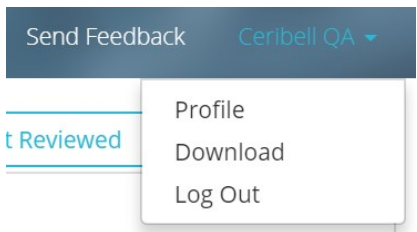


Figure 77: EEG Recording - Download

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

A screenshot of the "Send Feedback" form in the Ceribell EEG Portal. The form has a white background with a dark blue border. At the top, the title "Send Feedback" is in a light blue font. Below the title, there are four sections: "Name (optional):" with a text input field containing "Dr. James"; "Email (optional):" with a text input field containing "james@hospital.com"; "Topic (required):" with a dropdown menu showing "General"; and "Comments (required):" with a large text area. At the bottom right of the form, there are two buttons: "Submit" and "Cancel", both in light blue boxes with black text.

Figure 78: Ceribell EEG Portal - Send Feedback

Logging Out of the Ceribell EEG Portal

To log out of the Ceribell EEG Portal, click the name in the upper right corner of the screen, and then click the **Log Out** button.

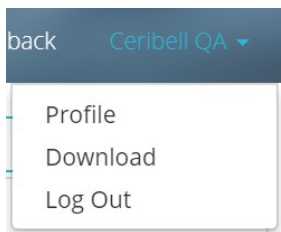


Figure 79: EEG Recording Viewer Logout

System Information

System Specifications

Table 8: System Specifications and Operating 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	3.6 V (nominal) 8250 mAh Li-ion battery pack
External power adapter	Input: 100-240 V ac Output: 5 V dc
Ceribell part number: SA-00003	<i>Note: Only use included power adapter to charge the device.</i>
Charging cable	1 m micro-USB cable
Ceribell part number: EC-00095	<i>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.</i>
Dimensions	180 mm x 80 mm x 28 mm
Weight	400 g
Connectivity	
Wired data transfer	Micro-USB interface. USB 2.0.
Wireless data transfer	2.4 GHz IEEE 802.11 b/g/n WiFi interface WPA/WPA2 security protocols
Wireless characteristics	Frequency range: 2412.0-2462.0 MHz Effective radiated power: 0.065 W Modulation type: DSSS/OFDM (802.11 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.	

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 Precautions and Controls

Any computer that will be connected to the Ceribell EEG Recorder to transfer EEG recordings or any computer that will be used to view EEG recordings taken with the Ceribell EEG Recorder should be evaluated for cybersecurity. The following cybersecurity controls are recommended:

- The computer should be kept regularly updated with critical security updates/patches as recommended by the manufacturer.
- Antivirus/antimalware software should be installed and regularly updated.
- A hardware or software firewall should be used and kept regularly updated; unnecessary network ports should be disabled.

If you believe that a cybersecurity problem or vulnerability has occurred relating to the Ceribell EEG Recorder, contact Ceribell immediately.

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. 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.

Portable and mobile RF communications equipment can affect the Ceribell EEG Recorder. See Table 7 for recommended separation between portable and mobile RF communications equipment and the Ceribell EEG Recorder. 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.

Table 9: 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	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.
RF emissions CISPR 11	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.
Harmonic emissions 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 10: 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV 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 ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV differential mode ± 2 kV common mode	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 s	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/M	3 A/M	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment
<p>Notes:</p> <p>U_T is the a.c. mains voltage prior to application of the test level.</p> <p>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.</p>			

Table 11: 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	3 Vrms	<p>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.</p> <p>Recommended separation distance</p> <p>$d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div></div>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 12: 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√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√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.			

System and Package Labels

Table 13: System Labels












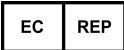








	<p>System label located on back side of device</p> <p>The 2D barcode, GTIN number, and serial number together comprise the Unique Device Identifier for the device.</p> <p>Symbols:</p> <ul style="list-style-type: none"> Device emits non-ionizing radio frequency signals Type BF applied part Follow instruction 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 EC European Authorized Representative <p>Rx only: Federal (US) law restricts this device to sale by or on the order of a physician.</p>
	<p>Connector label located on side of device</p> <p>Symbols:</p> <ul style="list-style-type: none"> Micro-USB connector port

Table 13: System Labels

	<p>1-800 Customer Support label located on back side of device</p> <p>The 1-800-763-0183 number is for 24 hour technical support.</p>
	<p>Package label located on outside of device packaging</p> <p>The 2D barcode, GTIN number, and serial number together comprise the Unique Device Identifier for the device.</p> <p>Symbols:</p> <ul style="list-style-type: none">  Manufacturer  Part Number  Storage Conditions  Follow instruction manual  Non-sterile Device  CE Mark <p>Rx only: Federal (US) law restricts this device to sale by or on the order of a physician.</p>

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 14: 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 <i>Check Electrodes Connections</i> page to view electrode connection status.
System Error	The device has detected an internal fault. EEG acquisition is disabled. Contact Ceribell for service.

