# ceribell® **EEG Recorder** Operator Manual



Ceribell, Inc. 360 North Pastoria Avenue Sunnyvale, CA 94085 USA

www.ceribell.com



TÜV Rheinland LGA Products GmbH CE Tillystraße 2 90431 Nürnberg Germany +49 (0) 9116555225

> www.tuv.com Actor ID: 0197

24 Hour Technical Support: 1-800-763-0183

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#### Indications for Use

## Indications for Use

The Ceribell<sup>®</sup> 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 gualified 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.



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.



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 **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 12: 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 13: Home Screen



Brain Stethoscope button

Figure 14: Ceribell EEG Recorder

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



Figure 15: 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 the to go to the *Seizure Burden* page.



Figure 16: 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 17: 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 18: Record Page

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



Figure 19: 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<sup>®</sup> 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

- <u>Ceribell EEG Recorder assembly (Ceribell part number SA-00039)</u>: portable, battery-powered, 8-channel EEG monitoring system.
- <u>Ceribell EEG Portal (Ceribell part number SW-00001)</u>: 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.
- <u>Ceribell Mount Clip (Ceribell part number SA-00051)</u>: a mount clip for securing the Ceribell EEG Recorder to a hospital bed rail, IV pole, or equivalent.
- <u>Ceribell Charging Station (Ceribell part number SA-00040)</u>: a base station used to both charge and provide easy access to the Ceribell EEG Recorder.
- <u>Power adapter (Ceribell part number SA-00003)</u>: 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 20: 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 21: Device Charging: Charging Page

The Ceribell EEG Recorder will indicate "Ready to Record" when it has charged sufficiently to begin an EEG recording.



Figure 22: Device Charging: Ready to Record Page

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



Figure 23: 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 24: 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 25: 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 26: 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.



Tag Event button

Figure 27: 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



Continue to next 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			🤶 🔳 12:40PM
		Confirn		
	F	PATIENT ID	12345	
	F	IRST NAME	JOHN	
	L	AST NAME	DOE	
	[	D.O.B	07/09/1987	
	٩	No. PRIMARY Dx	1	
Ð	F	PHYSICIAN	SMITH	
	EDIT			CONFIRM

Figure 29: Confirm Patient Info Page

Figure 28: Sample Patient Info Entry 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 30: Check Electrode Connections Page

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



Figure 31: Electrode Headband Disconnected Page

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

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## **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 32: 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 33: 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 34: Fix Electrode Connections Page

#### **Electrode Impedance Audible Notifications**

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

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



Figure 35: 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 36: 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 37: 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 38: 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 39: 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 40: Tag Event Page

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



Figure 41: Medications Event Page

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



Figure 42: Patient Observation Tag Event Page

If **FREE TEXT** button 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 **50µV** or **100µV** button to select the display-unit scale.



Figure 43: 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 44: 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 45: 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* page.



Figure 46: 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 47: Seizure Burden Page

Note: A minimum of 5 minutes of recorded data must be transmitted 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 audible notification will sound, if turned on. Press the **OK** button to dismiss the notification and continue to the *Seizure Burden* page.



Figure 48: 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 49: 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 50: 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 51: 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 52: 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 53: Settings Page

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



Figure 54: 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 55: 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 56: 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 57: 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 **NOTICFICATIONS** button to go to the *Notifications* page.



Figure 58: 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 59: 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 60: 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 61: Electrode Impedance Default Notification Change Page

#### Setting Date/Time

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



Figure 62: 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 63: 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 64: 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 65: 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.

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 email 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:
  - "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<sup>1</sup>, if the prevalence of a pattern (e.g. seizure) is 10-49% of the record/epoch

- "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<sup>1</sup>, if the prevalence of a pattern (e.g. seizure) is 50-89% of the record/epoch, it is considered "Abundant".
- "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<sup>1</sup>, 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 nonseizure 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<sup>1</sup>. 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.

<sup>1</sup> 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 EEG-trained neurologists)			sets by
		No seizure or Seizure Duration < 150 seconds	150 seconds ≤ Seizure Duration < 270 seconds	Seizure Duration ≥ 270 sec- onds	Total
Ceribell	Below 50% Threshold (no "Abundant" notification provided)	NA	2	1	3
Device Output	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 b EEG-trained neurologists)		
		No seizure or Seizure Duration < 270 seconds	Seizure Duration > 270 seconds	Total
Ceribell	Below 90% Threshold (no "Continuous" notification provided)	NA	2	2
Device Output	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 bur- den), PPA and FP/hr	Ceribell non-inferior to Persyst 13 with 10% non-inferiority margin
"Frequent" seizure activity notifications (≥10% seizure bur- den), PPA and FP/hr	PPA: 95% CI lower bound ≥ 70% FP/hr: 95% CI upper bound ≤ 0.446
"Abundant" seizure activity notifications (≥50% seizure bur- den), PPA and FP/hr	PPA: 95% Cl lower bound ≥ 70% FP/hr: 95% Cl upper bound ≤ 0.446
"Continuous" seizure activity notifications (≥90% seizure bur- den), 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-dis- tance 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 Sei- zure Activity Notification Level	PPA	PPA 95% CI	Conformance to PPA Accep- tance Criteria	FP/hr	FP/hr 95% Cl	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.

LOG IN		
Username Username		
Password Password		
Forgot password?	Log In	

Figure 66: 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.

ceribell		Carlos Carlos		and the second second		Send Feedback Centrel DA +
Patient List						Cupicad EEG File
Pubert Name	Medical/ID		Organization -      Review State	us - Pecording Oute		Search Show All
Patient Name	Medical ID	Organization	Ordering Physician	Recording Date	Duration	Review Status
Chaya Krajcik	56061236	Ceribel Review	Dr. Taryn Klein	Sep 11, 2018 7:59 PM - Sep 12, 2018 9:52 AM	13:53:46	<ul> <li>Reviewed by Ceribell QA on Nov 16, 2018 (UTC-8)</li> </ul>
Enid Johnston	74773716	Ceribel Review	Dr. Vaughn Heathcote	Sep 6, 2018 12:35 PM - Sep 6, 2018 2:04 PM	01/29/10	Needs Review
Delores Becker	12223753	Ceribel Review	Columbus Schulist H	Aug 23, 2018 3:41 AM - Aug 23, 2018 3:56 AM	00:14:15	Transfit Review
Mariam Manguardt	36220560	Ceribel Review	Dr. Cedrick Zierre	Aug 9, 2018 3:04 PM - Aug 9, 2018 3:29 PM	00:24:27	<ul> <li>Reviewed by Ceribel QA on Nov 16, 2018 (UTC-8)</li> </ul>
Lauretta Pritsch	83096187	Ceribel Review	Murphy Pacocha	Aug 8, 2018 400 PM - Aug 8, 2018 501 PM	01:01:02	<ul> <li>Reviewed by Ceribel QA on Nov 16, 2018 (UTC-8)</li> </ul>
Isabel Feest	24717068	Centrel Review	Dr. Van Osinski	Aug 8, 2018 4:16 AM - Aug 8, 2018 6:17 AM	02:01:18	P Needs Review
Yesenia Kohler	77741533	Ceribel Review	Dr. Hansen	Aug 6, 2018 612 PM - Aug 6, 2018 814 PM	02:01:07	P Needs Review
Rocky Boetrm	54093099	Ceribel Review	Brandy Winthelser	Aug 4, 2018 1:25 AM - Aug 4, 2018 3:27 AM	02:02:02	P Needs Review
Rose Bick	43971358	Ceribel Review	Dr. Reynolds	Aug 3, 2018 5:31 PM - Aug 3, 2018 8:01 PM	02:29:55	Needs Review
Oswaldo Rosenbaum	42407154	Ceribel Review	Dr. Abelardo Maggio	Aug 3, 2018 12:09 AM - Aug 3, 2018 1:25 AM	01:16(22	P Needs Revew
			· · · · 2 3			

Figure 67: Ceribell EEG Portal - Patient List Page

#### **Ceribell EEG Portal**

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.

÷	Fa	nny Lowe 565-199-8934	J Smith QA 👻
Dis 1	play Dis v	Scale         High Pass         Low Pass         Notch           +V-SDuv         0.1Hz         >         70Hz         50Hz         © Annotations         © Report	✓ Reviewed
8:5	2, Sep 12	100/W 1100: 1100: 1000 12 H4 H III H HH 11X SPEED	16:52, Sep 12
	1-2 FP1-F7	Muniph Manuna Manuna Manuna	Seizure Burden
	<b>2 -3</b> F7 - T3	mander of the war and many warden and the second of the se	90% 930 Sep 12
	<b>3 - 4</b> T3 - T5	Marken Marken Marken Marken Marken	90% 930 Seg 12
	<b>4-5</b> T5-01	Man man mark man was marked and the second	90% 11:15 Sep 12 90% 11:15 Sep 12
	6.7	"Annah hala hala hala hala hala hala hala	90% 11:15 Sep 12
	7-8	man white a second of the seco	90% 11:15 Sep 12
R	8-9 T4-T6	"how work work where we wanted the second se	50% 11:15 Sep 12
	9-10	Mar Man Mar	10% 14/21 Sep 12
	Seizure Bu	den v Sebare Burden Details	10% 15:32 Sep 12
90% 50%	~		$\sim$
10%	1.		

Figure 68: Ceribell 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 second and 60 seconds per page can be selected.

D	Display	
ſ	10 s	Ŧ
Ì	1 s	
	5 s	
2	10 s	
1	15 s	
Ł	30 s	
	60 s	

Figure 69: EEG Scan Page - Horizontal Scale Options

Select the vertical scale using the "Scale" dropdown menu. Various scale options between 10  $\mu V$  and 500  $\mu V$  can be selected.



Figure 70: EEG Scan Page - Vertical Scale Options

If desired, select a high pass filter using the "High Pass" dropdown menu. Various high pass filter options between 0.1 Hz and 1 Hz are available.

High Pass	
1 Hz	٣
Off	
0.1 Hz	
0.5 Hz	
1 Hz	

Figure 71: EEG Scan Page - High Pass Filter Options

If desired, select a low pass filter using the "Low Pass" dropdown menu. Various low pass filter options between 15 Hz and 100 Hz are available.

30 Hz	
Off	
15 Hz	
30 Hz	
70 Hz	
100 Hz	

Figure 72: EEG Scan Page - Low Pass Filter Options

If desired, enable or disable the 60 Hz notch filter using the **NOTCH** button.



Figure 73: EEG Scan Page - 60Hz Notch Filter button

#### Navigation

To navigate the EEG recording, use the recording navigation buttons.



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 74: 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.



Figure 75: EEG Scan Page - Seizure Burden Details button



Figure 76: EEG Scan Page - Seizure Burden page

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





Figure 78: 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 79: 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.

	C Annotations	Report	<b>*</b> No
Search Annotations			_
Show All Sonification	Impedance 🗸 Bedside	✓ Reviewer	
Annotation	Time	Author	
Sonify left hemisphere	Sep 6, 2018 12:35:2 00:00:13	1 PM Tagged on d	evice
Sonify right hemisphere	Sep 6, 2018 12:35:3 00:00:31	9 PM Tagged on d	evice
Sonify stopped	Sep 6, 2018 12:35:4 00:00:40	8 PM Tagged on d	evice
Sonify left hemisphere	Sep 6, 2018 12:37:0 00:01:56	4 PM Tagged on d	evice
Sonify stopped	Sep 6, 2018 12:42:0 00:06:56	4 PM Tagged on d	evice
Sonify left hemisphere	Sep 6, 2018 12:44:3 00:09:30	8 PM Tagged on d	evice
Sonify stopped	Sep 6, 2018 12:44:5 00:09:49	7 PM Tagged on d	evice
test Jane	Sep 6, 2018 1:18:12 00:43:04	PM Ceribell QA	
test annotation	Sep 6, 2018 1:18:17 00:43:09	PM Ceribell QA	

Figure 80: 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 81: EEG Scan Page - NOT REVIEWED Button

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



Figure 82: 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.

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 - 9	Sep 6, 2018 2:04 PM	01:29:10	Dr. Vaughn Heathcote
Impressions:			
Abnormal EEG following	ischemic stroke. Epileptiform act	tivity seen in final 15 minutes of recordin	g.
Edit Impressions			
Comments:			
No comments			
Edit Comments			

Figure 83: 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.

Send Feed	oack Ceribell QA 🗸
t Reviewed	Profile Download Log Out

Figure 84: 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 **SUB-MIT** button.

Send Feedback	
Name (optional):	
Dr. James	
Email (optional):	
james@hospital.com	
Topic (required):	
General	•
Comments (required):	
1	
	1
	Submit Cancel

Figure 85: 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 86: 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 measure-	±20% or ±10μV, whichever is greater		
ment signal reproduction			
Physical and Electrical Ch	aracteristics		
Internal battery	3.7 V (nominal) 20 Ah Li-ion battery pack		
External power adapter	Input: 100-240 V ac		
	Output: 5 V dc		
Ceribell part	Note: Only use included power adapter		
number: SA-00003	to charge the device.		
Charging cable	1 m micro-USB cable		
	Note: The micro-USB cable can also be		
Ceribell part	used to connect to a computer for file		
number: EC-00095	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	2.4 and 5 GHz IEEE 802.11 a/b/g/n WiFi		
transfer	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 Requirem	ents (Operating)		
Temperature	15° C to 32° C		
Humidity	Up to 80% relative humidity at 32° C		
	(non-condensing)		
<b>Environmental Requirem</b>	ents (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	d with the Ceribell EEG Recorder should		
have cable length less than 2	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/anti-malware 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.

In managing the secure use of the device, users are expected to enact the following controls:

- Users are responsible for adhering to all regulatory compliance regulations and for reviewing and approving the terms and conditions of service agreements with Ceribell.
- Users are responsible for making timely requests for removal of user accounts for any users who have been terminated or should otherwise no longer have access to the EEG Recording Viewer.

- Users are responsible for restricting authority of requesting new user accounts.
- Users are responsible for implementation of sound and consistent internal controls regarding protection of confidential information and general IT systems that interface with the device.
- Users are responsible for communicating any potential security breaches to Ceribell.

The following ports are utilized by the Ceribell EEG Recording Viewer:

- 443
- 40455
- 51768

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 9 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, EN 55032	Class A	The Ceribell EEG Recorder is suitable for use in all establishments, including	
Harmonic emissions IEC 61000-3-2	Class A	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 profes sionals 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.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		
Note: All EEG acquisition functions are automatically disabled when the Ceri- bell EEG Recorder is plugged into an external power supply. EEG measure- ments 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 dis- charge 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 rela- tive 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		
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 interrup- tions, and volt- age variations on power supply input lines IEC 61000-4-11	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>T</sub>	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>T</sub>	Mains power qual- ity should be that of a typical commer- cial or hospital envi- ronment.	
	(>95% dip in U <sub>T</sub> ) for 5 s	(>95% dip in U <sub>T</sub> ) for 5 s		
Power frequency (50/60 Hz) mag- netic 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 environ- ment	

Notes:

U<sub>T</sub> 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 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.

lan ann aite		Compliance	Floatromognatio
Test	Test Level	Level	Electromagnetic Environment - guidance
Test	lest Level	Levei	Destable and mabile DE commu
			pications againment should be
			used no closer to any part of the
			Coriball EEG Pacardar including
			cables than the recommended
			separation distance calculated
			from the equation applicable to
			the frequency of the transmitter.
			Recommended separation distance
Conducted RF	3 Vrms	3 Vrms	d = 1.2 √P
IEC 61000-4-6	150 kHz to		
	80 MHz		
Radiated RF	3 V/m	3 V/m	d = 1.2 √P 80 MHz to
IEC 61000-4-3	80 MHz to	,	800 MHz
	2.5 GHz		d = 2.3 √P 800 MHz to
			2.5 GHz
			where <i>P</i> 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 <sup>a</sup> , should be less than the compli- ance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked
			with the following symbol:
			((\cold ))

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.

<sup>a</sup> 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 EQUIP-MENT.

 $^{\rm b}$  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

#### 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	Separation distance according to frequency of transmitter m			
of transmitter W	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.

## Benefit/Risk Profile

The benefits of the Pocket EEG Device include the ability to acquire and record EEG waveforms for the diagnosis and monitoring of patients with seizures and other neurological disorders. The identified safety risks have been evaluated and addressed via conformance to the relevant harmonized consensus standards and are continually confirmed via review of clinical use and safety data.

The identified risks constitute acceptable risks when weighed against the benefits to the patient, and are compatible with a high level of protection of health and safety.

## **Adverse Event Reporting**

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## System and Package Labels

Table 13: System Labels



#### Table 13: System Labels

	Connector label located on side of device
	Symbols: Micro-USB connector port
	1-800 Customer Support label located on back side of device
Customer Support 1-800-763-0183 Scan for Training	The 1-800-763-0183 number is for 24 hour technical support.
	The QR barcode provides a link to product labeling and instructions for use.
	Package label located on outside of device packaging
Ceribelle Center Les recorder with to ler ity? Crete te break CA 9899 Crete te co Crete te Crete	The 2D barcode, GTIN number, and serial number together comprise the Unique Device Identifier for the device.
Up to "st endow burnenty critical consideration grant of the state of the stat	Symbols:
	Manufacturer
	REF 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 14	: Trouble:	shooting	Guide
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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</i> <i>Connections</i> page to view electrode connec- tion status.
System Error	The device has detected an internal fault. EEG acquisition is disabled. Contact Ceribell for ser- vice.

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