cervella™

Cranial Electrotherapy Stimulator

User's Manual

www.cervella.us

Rev. 1.6

Thank you for purchasing the Cervella™ Cranial Electrotherapy Stimulator, a non-pharmacological alternative for treatment of anxiety and insomnia. Cervella™ features a number of innovative and patented features that increase ease-of-use and comfort during treatment and, consequently, improve patient's compliance.

Although we have designed Cervella™ with maximum use simplicity in-mind, please read this manual thoroughly prior to use. Also, be sure to follow the general instructions provided in this manual and any specific directions from your health care practitioner.

The parameter settings and treatment guidelines for this device are provided for reference only. Always consult your healthcare provider for individual treatment protocol.

Caution: US Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

NOTE: Always notify your healthcare practitioner immediately if your health conditions do not improve or if you experience any side effects.

You should follow the instructions contained in this manual in order to prevent abnormal operation that may damage the device and result in ineffective treatment or cause patient discomfort. Innovative Neurological Devices LLC will not be held responsible for injury, harm, or damage to person or property caused by misuse of this device.

SYMBOLS

There are no sterile parts of the Cervella device or parts that are meant to be sterilized.

Type BF Equipment. Internally powered only.

See instructions for use. Read this manual thoroughly prior to using the device.

Keep dry.

This product contains Li-Ion batteries and must be properly recycled. Do not throw in the trash with ordinary household waste. Dispose in accordance with local recycling instructions.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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Principle of Operation

Cervella works by sending micro pulses of electricity to your brain via electrodes integrated into the ear pads of the stereo headset. According to clinical and research studies, the micro current has several effects on the brain: it affects the Default Mode Network (DMN), alters endogenous brain oscillations, and has an effect on the change of neurotransmitter levels such as serotonin. The efficacy and mechanisms of action of cranial electrotherapy stimulation for treatment of anxiety and insomnia are demonstrated and documented through a number of clinical trials and research papers. We encourage you to visit our website (www.cervella.us) for a summary list of publicly available clinical and research information.

Most patients start feeling the positive effects of cranial electrotherapy stimulation within the first week. Note that results may vary and are dependent on individual conditions. Patient should always consult his or her healthcare provider before starting Cervella and follow the treatment plan as directed. Anxiety is often reduced after a single treatment but may reoccur so consistent treatment sessions are recommended. Many patients suffering from anxiety find it useful to use Cervella at the onset of anxiety or before a high stress situation. Insomnia is often reduced after a single treatment but, like in the case of anxiety consistent treatment sessions are recommended even when you are feeling better. When conditions improve, please use Cervella at reduced intervals or on an as-need basis as instructed by your healthcare provider.

Indications

Cervella cranial electrotherapy stimulator is indicated for treatment and management of anxiety and insomnia.

Contraindications

There are no known contraindications for use of the Cranial Electrotherapy Stimulator. However, there are conditions where the use of a CES device has not been tested. Consequently, Cervella should not be used by patients with implanted medical devices such as pacemakers, implanted defibrillators or metal implants in head or neck. Safety of stimulation has not been established during pregnancy. Epilepsy patients should not be using the device without clinical supervision. Always consult your healthcare provider before using Cervella.

Precautions

- For external use only. Do not use this device for other purposes other than indicated in this manual.
- **Children should not be allowed to use the Cervella device without adult supervision.**
- Do not use over skin lesions, fresh cuts, scars, and when skin irritation is present.
- Remove any earrings, piercings, hearing aids, or jewelry before starting treatment.
- Ensure that you are using conductive gel (best) or water to wet the contact patch area. Make sure that both ear cushions are in tight contact with your skin and the skin is clean of oil and make-up. Using Cervella at high current levels and without conductive gel or water at the contact patch interface may cause skin irritation.
- Device parts that are in physical contact with human body after usage should be kept clean.
- Do not operate dangerous equipment or drive motor vehicles during treatment.
- Treatment immediately prior to bedtime may cause difficulty falling asleep.
- Use only the power supply provided with the Cervella device to charge the device and the headset.
- Do not operate the device in areas of strong electromagnetic interference.
- To avoid explosion, do not use this device near flammable anesthetics or in a hyperbaric oxygen chamber.
- The device enclosure is not user-serviceable. Opening of the device will result in voiding of warranty.

Adverse Events

Adverse events are rare. Adverse events from patient data and clinical studies report a few instances of dizziness, skin irritation, headaches. Prolonged treatment at high current levels may cause headaches, dizziness, or nausea. These adverse effects are usually mitigated by reducing the current intensity level. In rare conditions, patient may experience skin irritation from the conductive gel. In this case, we recommend that patients use distilled water in-lieu-of the conductive gel. Worsening of conditions, although uncommon, may occur. Always notify your healthcare practitioner immediately if your health conditions do not improve or if you experience any side effects.

Intended Use

The intended use of the Cervella device is Home Use which includes use in both professional healthcare facilities and homes.

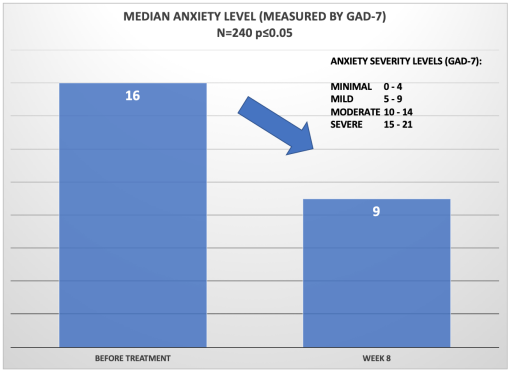
Clinical Testing

During clinical testing, 240 randomly-selected patients who were prescribed the Cervella device for treatment of Anxiety, Insomnia, or combination of these two disorders were evaluated. Patient population included ages 14-76 and was comprised of 57% females and 43% males. The device set-up was in accordance with the Cervella Operation section of the User's Manual (electrode gel applied at the mastoid area). Patients were instructed to use the device for 30 minutes daily at the default 100Hz frequency setting and to adjust the treatment intensity so that the "tingling" sensation was just barely perceptible.

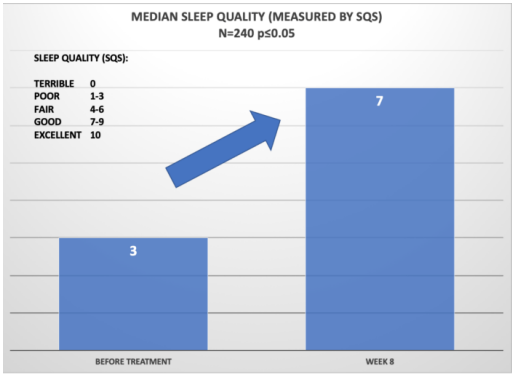
Subject patients reported anxiety levels and sleep quality before the study and after approximately 8 weeks or 60 days. Patients who have been diagnosed with anxiety, were evaluated using GAD-7 (General Anxiety Disorder-7) questionnaire. Patients who have been diagnosed with insomnia, were evaluated with SQS (Sleep Quality Scale). Patients who were diagnosed and prescribed the Cervella device for both anxiety and insomnia, were evaluated using GAD-7 for anxiety and they were also asked to complete the SQS for insomnia separately.

Overall, 92% of patients reported that the Cervella was beneficial with treatment of the underlying conditions.

The result of this clinical study is shown below:



The median anxiety level before treatment was 16 which is in the 16 – "Severe" anxiety category. Post treatment (approx. 8 weeks) the median anxiety level among patent population was reported as 9 – "Mild", a reduction of 7 points on the GAD-7 scale.



Before treatment, the median sleep quality, as measured by SQS, was reported as 3 – "Poor." After approximately 60 days or 8 weeks, the medial sleep quality improved to 7 – "Good" which is a 4-point improvement on the SQS scale.

There were no significant adverse events reported during this clinical study. The minor adverse events that were observed included headaches (<1% of patient population), and allergic reaction to conductive gel (<1% of population). Patients who experienced headaches were instructed to use the device at lower intensity setting and reported that the condition self-resolved within few hours and did not re-occur once the intensity was lowered to a more comfortable level. Patients who experienced allergic reaction to conductive gel were instructed to substitute water and reported no further irritation.

Cervella Description

Cervella consists of a main device and a stereo headset that is connected to the main device via a cable. The device is controlled with an app installed on user's smart device. Cervella communicates with the smart device via a Bluetooth® connection. In addition, the Cervella stereo headset is also Bluetooth-enabled for second Bluetooth connection allowing patient to use the audio portion of the headset during treatment.

The components of the Cervella device are shown below:

1.	External Cardboard Box	(P/N: IND-BOX)
2.	Cervella Cranial Electrotherapy Stimulator (CES)	(P/N: IND-CES)
3.	Cervella headset with integrated electrodes	(P/N: INC-HEADSET)
4.	Switching AC/DC Power Adapter	(P/N: GAT-0501000U)
5.	USB Charging Cable	(P/N: IND-USB)
6.	Connecting Cable	(P/N: INC-CC)
7.	Conductive Gel	(P/N: Spectra 360 12-02)
8.	Protective Case	(P/N: IND-CASE)
9.	Printed User's Manual (not pictured)	(P/N: IND-OIM)

Cervella App Set-Up

Charge both the Cervella device and the stereo headset fully before first use. First, insert the power cord into Micro-USB charging port on the Cervella device (1) and connect the other side to the power adapter provided. When Cervella charge is completed (indicated by the Cervella LED turning green, charge your stereo headset (2) so you can use the headset for audio and Active Noise Cancellation (ANC) functions during treatment.

Ensure that your smart device (e.g. phone or tablet) and audio source (can be same or different from device running the Cervella app) is Bluetooth capable and features Bluetooth® version 4.0 or above. Cervella is designed to work with smart devices such as cellphones or tablets running on Apple iOS or Google Android operating systems.

STEP 1: Download and install the Cervella App on your smart device by visiting the Apple App store (if you own an iOS device) or the Google Play store (if you own an Android device) and typing "cervella" in the search box.

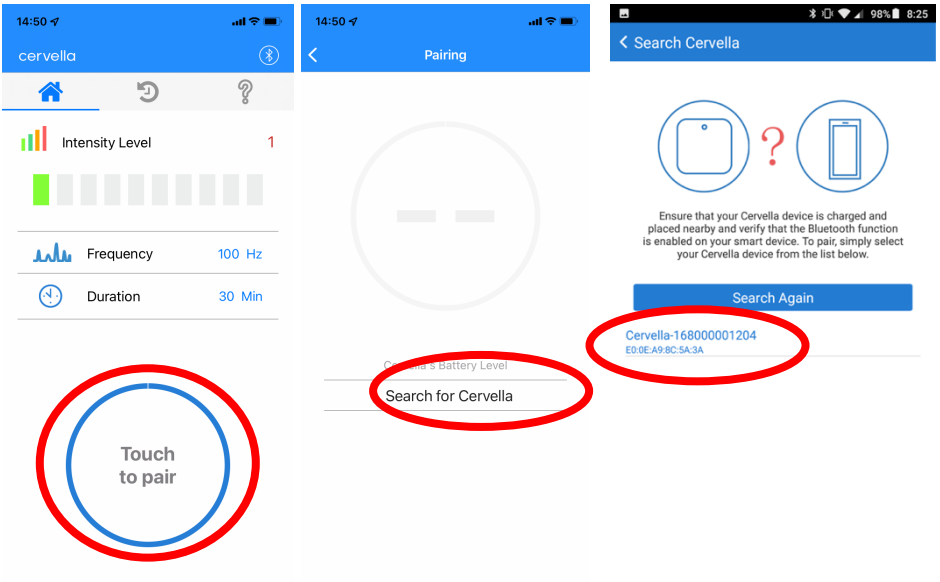
STEP 2: Verify that the Bluetooth functionality is enabled on your smart device and that your smart device features Bluetooth 4.0 or higher in order to use the Cervella device. Ensure that you can have Internet access from your smart device.

STEP 3: Launch the Cervella App and accept the permission settings.

Note: Cervella device is not intended to be used for patients under 18 without adult supervision.

STEP 4: Press Touch to pair and press “Search for Cervella” to enter the pairing menu. If your Cervella is nearby and charged, it should appear in the list as shown below. Select “Cervella-XXXX” which will complete the pairing process and the app will return to HOME menu.

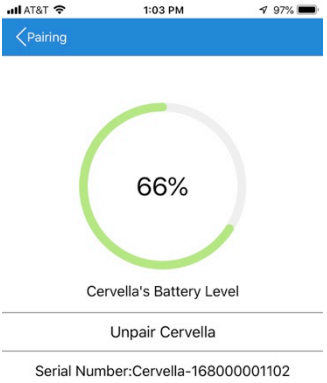
Next, press “Touch to Connect” and LED on the Cervella device should turn on GREEN. *Note: the app always searches for closest Cervella, so if there are multiple Cervella devices in the area, the closest to your smart device will appear on top of the list.*



STEP 5: If planning to use the headphones, pair the headphones with your smart device as described in the ***Headphones*** section of this manual. This will enable you to use the stereo headset for listening to audio from your smart device during treatment.

Your Cervella device is now ready to use!

Cervella Battery Level



You can check the level of the Cervella internal battery by going into the Pairing Menu as shown. There are no ON/OFF switches so Cervella goes to "sleep" when you turn off the Cervella app and the LED on top of Cervella turns off. Remember to charge the Cervella device prior to use, as you cannot use the Cervella stimulation while charging. Do not be concerned if, after full charge, the battery level shows 99%. The device charging system does not "top off" the battery on purpose in order to maximize the battery lifespan.

Bluetooth Information

In order to ensure uninterrupted communication between the Cervella and your controlling smart device, ensure that you keep the distance to the Cervella device within 15ft (5m). If this distance is exceeded, Cervella may turn off and the treatment will stop. In order to continue treatment, move back within range, reconnect the Cervella using "Touch to Connect" function inside the timer circle within the app, and re-start the treatment.

For optimal audio quality, ensure that the audio source is kept within 15ft (5m) from the Cervella headphones. If the distance is exceeded, you may hear the audio break-up or stop. If the audio degrades or stops completely, please turn off the Cervella audio headset, move within range, and turn on the headset back on.

Cervella Operation

STEP 1: Ensure that the Cervella device and your stereo headset are charged prior to use, as you cannot use the Cervella while being charged. Make sure that the skin around your ears is clean of oil and make-up. Remove any earrings, piercings, hearing aids, or jewelry before starting treatment. Apply a layer of conductive gel or (if not available) water at the point of skin contact behind each ear area (mastoid) as circled below and also to the gold-colored skin mastoid contact portion of the ear cushions. **Only apply the gel to the electrode area that will be in contact with the mastoid area behind each ear as shown below.**

Do NOT operate the device without gel (or water if not available) on the mastoid area and electrode as skin irritation and uncomfortable treatment may result.

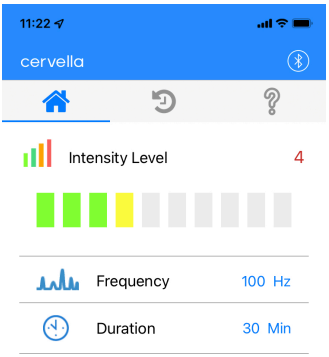
STEP 2: Connect the Cervella device and the headset using the connecting cable. One end of the cable connects to the Cervella port and the other end connects to the circular port under one of the ear cushions. Next, place the headset on patient's head and ensure that the electrodes are making good skin contact by gently pressing the ear cushions against the patient's head as shown below.

Home Menu

STEP 3: Launch the Cervella App. The app will start in the Home menu as shown below. The default and most widely used and studied frequency for cranial electrotherapy stimulation is 100Hz. Cervella clinical studies have been conducted at this frequency (See Clinical Testing section). If the default frequency is not effective, try 0.5Hz or 1.5Hz. Next, select the Duration of the treatment. The optimal and default treatment duration is 30 minutes. Treatments in excess of 1 hour are typically not necessary and treatments shorter than 20 minutes may not be effective.

STEP 4: Press the circular button on the App to connect to Cervella. The LED indicator on the Cervella should turn on **BLUE** and be blinking and the countdown timer should start. **If the light remains solid BLUE and timer does not start, the electrodes are not making good electrical contact with your skin at the mastoid.**

Tap the intensity bar up to adjust the current intensity until you start feeling a tingling sensation. Then, tap the intensity bar down to reduce the intensity so the tingling sensation is barely perceptible. If the tingling sensation is uncomfortable even at the lowest setting, it usually means that there is not enough conductive gel between the skin and the ear cushion at the mastoid area contact patch. **Note: you should never adjust the treatment level so that the tingling sensation is uncomfortable or painful. It has been clinically demonstrated that higher current levels do not result in better or faster clinical outcomes so only use the current level that is comfortable.**



If you need to pause the treatment, simply remove the headset. Cervella will automatically resume the treatment when it detects good contact between the electrodes and patient's skin. If you need to stop the treatment, tap the circle area on the app and the treatment will stop and the timer will reset.

You may use the audio feature of your stereo headset during treatment (turn on and pair your headphones first).

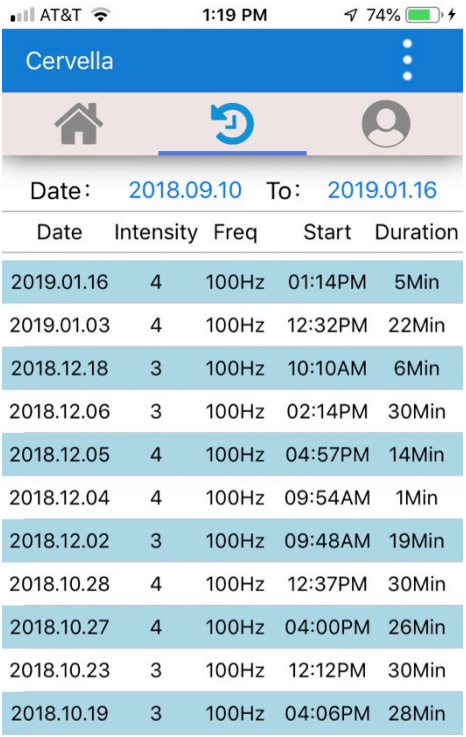
Cervella features a multi-color LED status indicator, which informs the user about the status of the device as described below:

When Cervella is Charging	When Cervella needs to be recharged	When Cervella is connected to the smart device and app	When Cervella is operating
Indicator changes to blinking RED	When the battery level drops below 20%, the indicator changes to RED, and blinks 3 times every 10 seconds	Indicator changes to GREEN when the device is connected/paired with the App and smart device	Indicator changes to blinking BLUE once the treatment is undergoing and the current is flowing
Indicator color is GREEN when Cervella is completely charged	When the battery level drops below 5%, the LED color is alternating RED and GREEN and blinks	Indicator is OFF when the App is exited and the battery level is above 20%	Indicator color is solid BLUE when the device is disconnected from the headset or the headset is removed from patient's head and there is no current flow

TABLE 1: Cervella LED Status Indicator

Treatment History

The treatment history screen automatically logs patient's treatment parameters including treatment date, time, treatment intensity level, frequency, and duration. Treatment history screen is useful as a reference for the patient during discussion with his or her health provider.

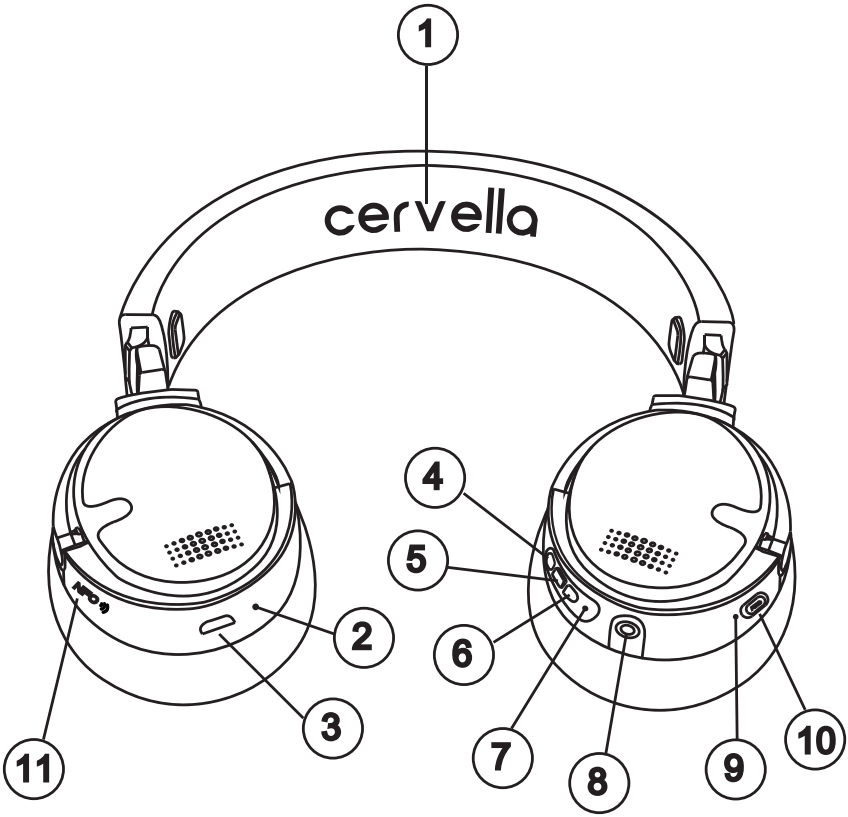


Date	Intensity	Freq	Start	Duration
2019.01.16	4	100Hz	01:14PM	5Min
2019.01.03	4	100Hz	12:32PM	22Min
2018.12.18	3	100Hz	10:10AM	6Min
2018.12.06	3	100Hz	02:14PM	30Min
2018.12.05	4	100Hz	04:57PM	14Min
2018.12.04	4	100Hz	09:54AM	1Min
2018.12.02	3	100Hz	09:48AM	19Min
2018.10.28	4	100Hz	12:37PM	30Min
2018.10.27	4	100Hz	04:00PM	26Min
2018.10.23	3	100Hz	12:12PM	30Min
2018.10.19	3	100Hz	04:06PM	28Min

User Menu

The User Menu shows the user's information entered during registration process. User can log in and out of the account in case more than one user uses the Cervella device. Each user account stores user's treatment history in an encrypted and de-identified (anonymous) format on the cloud server.

Cervella Headphones



#	Name	Description
1	**Headband**	Adjustable headband
2	**Battery Indicator LED**	Glows **RED** while charging and glows **BLUE** when the headset is fully charged.
3	**Micro USB Charging Port**	Headphone powers off while charging. **Note: Do not use headphones while charging.**
4	**Volume+ / Skip Forward**	Press it to increase the volume. Press and hold it to skip to next audio track.
5	**MFB (Multi-function Button)**	**Power On/Off:** Press and hold 2 seconds to power on, press and hold 3 seconds to power off. (Once powered on, the headset enters pairing mode automatically after 5 seconds)
		Phone Call Control: Press to answer/hang up. Press and hold to reject call.
		Voice Control: Press twice to activate Siri (if paired to an Apple device).
		Music Play Control: Press to play/pause.
6	**Volume-/Skip Backward**	Press to turn volume down. Press and hold to play previous audio track.
7	**Status Indicator LED**	**Pairing:** The LED blinks alternating **RED** and **BLUE**
		Connected: The LED blinks **BLUE** quickly every 5 seconds
		Calling: The LED blinks **BLUE** slowly every 5 seconds
		ANC (Active Noise Cancellation) Mode: LED glows **GREEN** when turned on.
8	**3.5mm Cervella connection**	This port is used to connect the headset to the Cervella device. **Note: Do not use to connect to audio source as damage to your audio device may occur!**
9	**Microphone**	Microphone for calling when paired to your smartphone.
10	**Active Noise Cancellation**	Press to turn on/off ANC function.

Headphone Pairing

STEP 1: To put your headphone in pairing mode, press and hold the MFB button (5) for 2 seconds until the headset powers on and enters pairing mode automatically after 5 seconds. LED indicator (7) will flash BLUE and RED alternately. Note: the headphones will power off after 5 minutes if no Bluetooth device is connected.

STEP 2: Activate Bluetooth on your smartphone (or other Bluetooth-enabled audio source) and set it to search for new devices.

iPhone Settings > Bluetooth > On
Android Settings > Bluetooth: On > Scan for devices NOTE: Menus may vary by device

STEP 3: Select "**Cervella-headset**" from the list of available Bluetooth devices. If necessary, enter four zeros (0000) for pass code or accept connection. Once successfully paired, the headphone LED indicator flashes BLUE.

Note: Avoid connecting additional Bluetooth devices (other than Cervella device and headphone connection) to your smart device in order to ensure uninterrupted audio streaming during treatment.

Active Noise Cancellation (ANC)

ANC Button: Press the ANC button on the right of the headphone to activate the noise cancellation and the LED indicator turns green. Press ANC button again to turn off the noise cancellation and indicator turns off.

Charging the Headphones

Please plug Micro USB into headphone charging port and connect the other side to the USB charger provided. The Battery Indicator LED (2) indicator turns RED while charging and turns blue when fully charged. Note: The headphone reminds you that the battery is low every 15 minutes when the battery power is below 10%.

Clinical

Q: How soon will I start feeling better?

A: Most patients start feeling the positive effects of cranial electrotherapy stimulation within the first week. Note that results vary and are dependent on your condition. Always consult your healthcare provider before starting Cervella and follow the treatment plan as directed. Anxiety is often reduced after a single treatment but may reoccur so consistent treatment sessions are recommended. Many patients suffering from anxiety find it useful to use Cervella at the onset of anxiety or before a high stress situation. Insomnia is often reduced after a single treatment but consistent treatment sessions are recommended even when you are feeling better. When conditions improve, please use Cervella at reduced intervals or on an as-need basis as instructed by your healthcare provider.

Q: What should be the optimal treatment intensity level?

A: The optimal treatment intensity level is when you feel a slight tingling around your ears, but the sensation is never uncomfortable or painful. It has been clinically demonstrated that higher current levels do not result in better or faster clinical outcomes so only use the current level that is comfortable.

Q: What should I do if I experience headache, dizziness, nausea, or other adverse effects?

A: First, reduce the intensity level during treatment. Treatment sessions at current intensity levels higher than necessary may cause dizziness and nausea that can last several hours to a few days. If you continue experiencing adverse effects or if you experience paradoxical reactions such as increased anxiety or continued insomnia, consult your healthcare provider immediately.

Q: Which is the best frequency to use?

A: The default and most widely used and studied frequency for cranial electrotherapy stimulation is 100Hz. If the default frequency is not effective, try 0.5Hz or 1.5Hz.

Q: What is the optimal treatment duration and how often should I use the device?

A: The optimal and default treatment duration is 30 minutes. Treatments in excess of 1 hour are typically not necessary and treatments shorter than 20 minutes may not be effective.

Q: What is the best time to use Cervella?

A: For treatment of insomnia, the best time to use Cervella is about 3 hours prior to bedtime. For anxiety treatment, Cervella can be used anytime or immediately prior to a potentially stressful or anxiety-inducing event. It is not recommended, however, that Cervella is used immediately prior to bedtime as it may cause difficulty in falling asleep.

Q: When should I not use Cervella?

A: Do not operate vehicles or dangerous equipment during treatment and within several hours post-treatment.

Q: Can I use Cervella together with medication?

A: Generally, yes, but always consult your healthcare professional for specific instructions based on your individual health condition.

Operation

Q: How does Cervella work?

A: Cervella works by sending micro pulses of electricity to your brain via electrodes integrated into the ear cushions of the headset. According to clinical and research studies, the micro current has several effects on the brain: it affects the Default Mode Network (DMN), endogenous brain oscillations, and change in neurotransmitter levels such as Serotonin. While the mechanisms of actions are complex and subject to continued research, the efficacy of cranial electrotherapy stimulation for treatment of anxiety and insomnia are well demonstrated and documented.

Q: Why should I wet the ear cushions with conductive gel or water?

A: The ear cushions contain electrodes that are seamlessly integrated into to the ear cushions. The electrodes are conducting the electric current to your brain via the skin interface. In order for the electricity to flow efficiently, the skin and electrode interface must be of as low resistance as possible. The conductive gel and water lowers the resistance for electricity that allows for better current flow resulting in more comfortable and more effective treatment.

Q: What should I do if I experience stinging in the area of contact between the headset ear cushions and my skin?

A: Ensure that you are using conductive gel (best) or water to wet the contact patch area. Also, make sure that both ear cushions are in tight contact with your skin and the skin is clean of oil and make-up. Remove any earrings, piercings, hearing aids, or jewelry before starting treatment. Lastly, reduce treatment intensity until the stinging sensation is slightly noticeable but never uncomfortable. Using Cervella at high current levels and without conductive gel or water at the contact patch interface may cause skin irritation.

Q: Why is it that when I press, "START" in the timer circle, the timer does not start?

A: This is usually caused by the fact that the ear cushions are not making tight contact with your skin, you did not apply the conductive gel, the device is not paired with your app, or the Cervella and headset are not connected via the black cable.

Q: What do the various colors mean for the LED indicator on top of the Cervella?

A: The tri-color indicator LED shows you the status of the Cervella device. The LED will blink blue during treatment and solid blue when the treatment is paused. Red means that the Cervella needs to be recharged. Green means that Cervella is charged and is successfully paired with the app. For other colors, please refer to the TABLE 1 above.

Q: Can I listen to music and use the ANC feature during treatment?

A: Absolutely. You can pair the headset to your smart device and use it as a wireless Bluetooth stereo headset with or without the ANC (Active Noise Cancellation) feature. Your headset can be paired with the same device that runs the Cervella app or with a different device (e.g. your computer).

Q: How should I clean the ear cushions (electrodes) for Cervella?

A: You can wipe the ear cushions using a soft lightly damp cloth and let air dry. You should avoid leaving excess gel on the ear cushion surface as it will dry up and accumulate over time. Wiping ear cushions after each use will also make them last longer. You can also use isopropyl alcohol to disinfect the ear cushions and headband after use. Never use chlorine or aggressive chemicals cleaners to clean the Cervella.

Wireless Functionality (Bluetooth)

Q: What are the requirements for the Bluetooth communication?

A: In order to ensure uninterrupted communication between the Cervella App and the Cervella device, keep the maximum distance between the controlling device and Cervella within 15ft (5m) and keep the device away from sources of strong electromagnetic fields such as cell phones, WiFi routers, microwaves, and radio transmitters. If you are planning to use the audio feature of the Cervella headphones, also ensure that the audio source and the Cervella headphones are not separated by more than 15ft (5m). When this range is exceeded, you may see an error, “The connection has timed out unexpectedly” and the Cervella and App will stop. To restart treatment, reconnect Cervella by touching the timer circle on the app that will state, “Touch to Connect” and restart the treatment.

Q: Can I use my smart device for both Cervella treatment and to stream audio to the headset?

A: Absolutely. Please remember, however, that you will establish two (2) independent Bluetooth connections: the first connection will be between the Cervella device and the Cervella App on your smart device, and the second connection will be used to stream audio from your smart device to the Cervella headphones. Note: avoid connecting additional Bluetooth devices to your smart device in order to ensure uninterrupted audio streaming experience.

Troubleshooting

Cervella Troubleshooting

Problem	Possible Causes	Solution
The Cervella LED indicator does not turn on	The Cervella device is discharged.	Charge Cervella fully prior to use using the provided power adapter.
	Bluetooth function on user's smart device is not activated.	Activate the Bluetooth function on your smart device and perform pairing function inside the Cervella App.
No current output during treatment (LED STAYS SOLID BLUE)	Current intensity is set too low.	Increase current intensity via the Cervella App.
	Headset electrodes are not making a good contact with patient's head.	Check the position and tightness of ear cushions against the skin and apply conductive gel to electrodes and skin contact areas behind the ears.
	Patient's skin is not cleaned before using the device.	Clean the skin electrode contact areas with clean water or alcohol.
	Lack of conductive gel at the contact area between the electrodes and patient's skin.	Apply conductive gel (or water) at the point of contact between the electrode and skin behind each ear.

	Electrode cable connection is poor.	Check connection between the Cervella device and headset and check the position and firmness of the connectors.
	Device connection error.	Press “Stop” and exit the App, then restart the App, re-connect to Cervella device and restart the treatment. If problem persists, turn the Bluetooth off and on again in your smart device.
The Cervella LED indicator glows GREEN when “Start” is pressed	Device connection error.	Press “Stop” and exit the Cervella App completely, then restart the App and restart the treatment. If problem persists, turn the Bluetooth off and on again in your smart device.
The Cervella LED indicator is blinks RED	Cervella battery is low.	Recharge Cervella fully using provided power adapter.
The Cervella treatment stops and device turns off	Bluetooth communication between the app and Cervella is interrupted.	Ensure that your smart device with Cervella app and the Cervella device are within 15ft and there are no sources of strong electromagnetic interference near the device. Reconnect to device by pressing, “Touch to Connect” in the middle of the timer circle, and restart the treatment.

Stereo Headset Troubleshooting

Problem	Solution
The Cervella headset battery Indicator LED indicator blinks RED or is lit continuously?	The Cervella headset battery is low. Please charge the headphones as soon as possible.
The headphones do not turn on.	Cervella headset battery is discharged. Please recharge fully prior to use.
The headset battery Indicator LED does not illuminate during charging.	There may be no charge indication for the first few minutes if the battery is completely exhausted or charged for the first time after not being used for a long time, but the indicator LED should glow RED to indicate the charging state after a while.
There is no sound from the headphones.	• Check that Bluetooth headphone is charged and switched on. • Ensure the music sound output is routed to the Bluetooth device (Cervella-headphones). • Ensure the Cervella Bluetooth headphones and the phone are paired and connected successfully. • Ensure the distance between Bluetooth headphone and cellphone is no more than 15 feet. • Ensure your phone is within the range of signal and without external interference.
There is no sound in the headphone when in wired connection.	The Cervella headphones are designed to work with Bluetooth wireless audio only. **Never connect an audio cable to the headset port, which is designed for the connection to the Cervella main unit.**

Bluetooth connection is not successful.	• Make sure both the headphone and cell phone Bluetooth devices are turned on. • Make sure the headphone enters Bluetooth pairing mode (the indicator blinks red and blue) • Try to delete the previous connected Bluetooth Cervella headphone devices and empty the Bluetooth list. Search the device again.

Cervella Care

- **There are no sterile parts of the Cervella device or parts that are meant to be sterilized.**
- The Cervella device and all included accessories are intended to be reusable.
- The Cervella device consists of precision electronic components. Keep liquids from entering the device to prevent damage to the internal circuits.
- Do not expose the Cervella device and the stereo headset to temperature extremes. When not in use, store the device and headset in the storage case.
- Please use the device only with accessories provided by the manufacturer.
- In order to ensure good service life of the rechargeable battery inside the Cervella unit and the stereo headset, fully charge both the device and headset at least once every six months.
- Do not drop the device or headset.
- Keep device away from intense magnetic field and electronic devices that generate intense magnetic fields.
- Avoid exposing the device and accessories to extreme temperatures, humidity levels and dusty environments.

Cleaning Instructions

- Wipe excess gel off the surface of the ear cushions after each use. The ear cushions and the headband can be disinfected by wiping them with a 70% isopropyl alcohol solution.
- Please clean the device surface with a soft and dry cloth. Do not clean any parts of the device with bleach, acetone, or any aggressive cleaners.
- Do not attempt to sterilize any of the parts.

Batteries and Power Supplies

Please use only the power supply provided with the device. Please make sure power supply voltage matches information on the power label.

For safe and reliable battery operation, please refer to operation rules below:

- Actual lifespan of battery depends on frequency of use, charge-discharge cycle, and usage environment.
- Injury caused by leak or explosion of battery may happen if the battery is broken apart or burned.
- Battery should be replaced in the following cases:
    - Battery is not working properly, such as the case where the battery can only work for less than an hour after charging for hours.
    - Battery temperature is unusually high after it is charged or used in a single treatment.
- Note that Cervella battery is not user-replaceable.

Technical Specifications

Cervella Stimulator Device

Device Name:	Cervella Cranial Electrotherapy Stimulator
Model:	Cervella
Power Supply:	5V DC, 500mA
Waveform:	Bipolar quasi-square-wave
Output Mode:	10min – 60min (30 min default)
Stimulation Frequency:	0.5Hz, 1.5Hz, 100Hz (pulses per second – 100Hz default)
Stimulation Current Intensity:	50 μ A to 500 μ A user adjustable in 50 μ A increments
Stimulation Pulse Width:	5ms – 1s. The pulse width is variable and depends on frequency selection
Maximum Charge:	Variable form 2.5µC - 500µC (depending on frequency selection
Maximum Energy:	Variable from 12.5µJ – 2.5mJ (depending on frequency selection)
Bluetooth® Version:	4.0 BLE
Bluetooth® Frequency:	2.400 GHz – 2.4835 GHz (ISM Band), Class 2, ≤2.5mW
Bluetooth® Distance Range:	5m (15ft) maximum range recommended
Environmental temperature range:	-10°C - +55°C
Relative humidity range:	15% - 90%
Atmospheric pressure range:	960hPa - 1060hPa
Enclosure fluid protection:	IPX0
Electric shock protection:	BF
Operating method:	Continuous

Device and accessories are not sterile and not meant to be sterilized

Headphones

Bluetooth® Version:	4.2 BLE
Bluetooth® Frequency:	2.400 GHz – 2.4835 GHz (ISM Band), Class 2, ≤2.5mW
Bluetooth® Distance Range:	5m (15ft) maximum range recommended
Noise Cancellation:	ANC - Active Noise Cancellation
Headphone drivers:	32Ω 40mm 100 ± 3dB 20Hz - 20kHz
Stand-by Time:	800h
Talking Time:	65h
Music Playing Time	
Max volume, with ANC off	60h
Max volume, with ANC on	25h
Microphone:	Sensitivity: -38 ±3dB Frequency: 30Hz - 16kHz
Power Supply	5V, 650 mA
Charging Time:	1-2h
Battery:	1050 mAh

Electromagnetic Emissions and Immunity

Cervella has been designed and tested in accordance to IEC60601-1-2:2014 electromagnetic compatibility (EMC) safety regulations. Cervella is suitable for use in Home Healthcare and Professional Healthcare establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Cervella can be used in medical facilities except for near active high-frequency surgical equipment and RF shielded rooms for magnetic resonance imaging equipment, or anywhere where the intensity of electromagnetics disturbances is high.

The essential performance of the Cervella system is that the device will provide stimulation according to parameters listed in the Technical Specifications section of the User's Manual. The specifications can be lost or degraded due to electromagnetic disturbances including loss of device-to-app connection, unresponsive device, or inoperative device that may result in ineffective or incomplete treatment.

Cervella must only be used with the headset with integrated electrodes, headset-to-device connecting cable, AC/DC charger, and charger-to-device cable provided with the Cervella system as shown on Page 6 of this document.

WARNING

1. Use of the Cervella device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

2. Use of accessories (e.g. headset), electrodes, chargers and cables other than those specified or provided by the manufacturer of Cervella could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. For replacement accessories, please contact us at support@cervella.us.

3. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Cervella, including cables included with the device. Otherwise, degradation of the performance of this equipment could result in ineffective or incomplete treatment or device malfunction.

Guidance and manufacturer´s declaration – electromagnetic emission		
Cervella is intended for use in the electromagnetic environment specified below. The customer or the user of **Cervella** should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	**Cervella** 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	**Cervella** 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	Not Complies	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer´s declaration – electromagnetic immunity			
Cervella is intended for use in the electromagnetic environment specified below. The customer or the user of the **Cervella** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Cervella** requires continued operation during power mains interruptions, it is recommended that the **Cervella** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity			
Cervella is intended for use in the electromagnetic environment specified below. The customer or the user of the **Cervella** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the **Cervella**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site

			survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] 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 **Cervella** is used exceeds the applicable RF compliance level above, **Cervella** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating C**ervella**.

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

Warranty and Service Information

Innovative Neurological Devices LLC warrants the Cervella device to be free from defects in materials and workmanship for a period of one (1) year from the sale to the original customer. Accessories (cables, electrodes, power adapters, cases) and consumables (e.g. gel) are not covered by the warranty.

Note: With time, after repeated and prolonged use, the integrated treatment electrodes ear cushions may become worn or contaminated. The ear cushions with treatment electrodes are designed to be easily user-replaceable. You can remove each treatment electrode by gently twisting the ear cushion off counter-clockwise. For electrode ear cushion replacement, please visit www.cervella.us.

To obtain service for your Cervella device, visit www.cervella.us or call us at: **+1-855-413-3300.**

Company Contact Information

Cervella™ is manufactured by Innovative Neurological Devices LLC. Our contact information:

INNOVATIVE NEUROLOGICAL DEVICES LLC 13295 Illinois St. Suite 312 Carmel, IN 46032 USA	www.cervella.us support@cervella.us Toll Free: (855) 413-3300

Device Labeling

The following is the device label placed on the back of the Cervella stimulator. The items in RED are unique identifiers to each device (serial number, date of manufacture, and GUDID information in 2D and human-readable formats).