

We Salute our Veterans. Thank you for your Service!

rvella

Cervella CES (Cranial Electrical Stimulation)

Drug-Free Treatment for Anxiety, Insomnia, and Depression

Clover Medical Solutions has been providing superior products and services to VA Hospitals and Clinics Nationally for over 10 years and are proud to be servicing the Veterans of the United States!

Our Clinical Educators work directly with patients to provide product education and clinical follow-ups.

Our clinicians also provide clinical updates to the referring Provider.

What are the Benefits of this Simple Treatment?

- 1. It can be done discretely via Headphones, almost anywhere
- 2. The treatment is only 30 minutes
- **3.** Treatment is so Simple and uses a smart phone app

What is Cervella™?

Cervella[™] is an FDA-cleared medical device for non-drug treatment of anxiety, depression, and insomnia. Cervella[™] works by delivering micro pulses of electric current through patient's brain via conductive electrodes that are integrated into the ear cushions of an audio headset. Cervella[™] can be used during rest, work, study, or play.

How does Cervella[™] work?

Cervella[™] is a type of Cranial Electrotherapy Stimulator (CES) medical device. Cervella™ transmits small pulses of electric current across patient's brain via a pair of conductive electrodes placed on patient's head. CES devices are approved by the FDA for treatment of insomnia, depression, and anxiety. They exhibit very good efficacy, do not present significant side effects, and they are not habit-forming. According to research, the micro current that is delivered by Cervella[™] has several effects on the brain: it affects the Default Mode Network (DMN), alters the endogenous brain oscillations, and causes change in neurotransmitter levels such as serotonin and endorphin.



Cervella[™] is a great alternative to drug therapies, especially for patients that respond poorly to anti-depressant drugs or experience significant side-effects with drug-based therapies. Cervella[™] can also be used in conjunction with drug or cognitive therapies.

Please Contact us by Phone or E-mail to find out how to place a consult through your VA hospital Prosthetics Department to order the Cervella[™] for your patients.

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E-mail: Heather@CloverMedicalSolutions.com

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Cervella™ FAQs FREQUENTLY ASKED QUESTIONS

CLINICAL FAQS

Q: How Soon will I start feeling better?

Results vary and may take up to several weeks dependent on your condition. Anxiety and Insomnia are often reduced after a single treatment, however consistent treatment sessions are recommended because symptoms can reoccur. Many patients suffering from anxiety find it useful to use Cervella at the onset of anxiety or before a high stress situation. Patients with depression will often see improvements in a few weeks.

When conditions improve you will still need to continue treatment as instructed by your healthcare provider.

Who Should Not Use Cervella?

There are no known contraindications. However, there are conditions where the use of a CES device has not been tested.

- Cervella should not be used by patients with implanted medical devices such as pacemakers, implanted defibrillators, or medical devices implanted in the head or neck (i.e. hardware – plates, screws, etc.)
- Safety of stimulation has not been established during pregnancy.
- The device should not be used for people with irritated or broken skin around the ears (especially mastoid) which is the area of the electrode contact with the skin.
- Patients wearing hearing aids will have to remove the hearing aids prior to use of the headphones.
- Epilepsy patients should not be using the device without clinical supervision.
- Do not operate vehicles or dangerous equipment during treatment and within several hours post-treatment.

Q: What are the Potential Side Effects of Cervella?

Although rare, below are potential side effects that need to be discussed with your Provider. Although rare, Side Effects may occur 24-48 hours after treatment

- A: Skin Irritation at electrode site (avoid by proper skin cleansing and use of gel)
- Dizziness and/or light-headedness. (For safety reasons, remain seated for 10-15 minutes after initial treatments to determine if any dizziness occurs)
- Mild Headache
- Sleepiness
- Paradoxical effects such as increased anxiety or Insomnia

Q: What Should I do if I Experience any Side Effects?

Speak to your Provider because you may need to reduce the intensity level, frequency, or adjust time of day treatment administered.

Q: What is the Best Time to Use Cervella?

For treatment of insomnia, the best time to use Cervella is about 3 hours prior to bedtime.

For anxiety and depression treatment, Cervella can be used anytime or immediately prior to a potentially stressful or anxietyinducing event. Note, some patients respond feeling very alert and energized after the treatment so for those patients it is not recommended that the device is used immediately before sleep as it may cause difficulty in falling asleep.

EQUIPMENT OPERATION FAQS

Q: Can I Listen to Music and use Noise Cancelling Feature during Treatment?

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 and/or with a different device (e.g. your computer). You are able to pair to both the Cervella app and music at the same time or even make a phone call during your treatment as there are 2 Bluetooth connections.

Q: Which is the best frequency to use?

The default and most widely used and studied frequency for cranial electrotherapy stimulation is 100Hz. If the default frequency is not effective, please try 0.5Hz or 1.5Hz. In clinical research, the 100Hz seems to be a very good (effective) frequency (it is also one of the most widely studied) so that is why we use it as default.

Q: Which is the best Intensity Level to use?

The optimal treatment intensity level is when you feel a slight tingling sensation due to current flow, 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.

It is much more important that you use the device for full 30 minutes during each session vs. using Cervella for a shorter duration at a higher setting.

Q: How do I check the charge on my device?

When you look at your main screen you will see three dots in the right hand corner. Click on the 3 dots and you will see Pairing and Help. Click on pairing and that will display the battery level of the device and also allow you to unpair the device if needed.

Q: How do I know that my Cervella is charging properly and holding a charge?

When you charge your Cervella device, the Cervella LED should blink RED and turn solid GREEN when charge is completed. If you were to plug the Cervella into charger again after full charge, you will see the LED blinking RED again making you think the device is not holding charge. However, this is done on purpose in order to extend the lifespan of the battery inside the Cervella device.

The Li-Ion batteries do not like to be charged to 100% so we purposely do not "top off" the battery charge so that we can extend the battery number of charge cycles. That is also why when you go to the Pairing menu in the Cervella app after full charge you can often see the Cervella charge level to be 99% instead 100%. Your device is charging and operating exactly as intended.

Q: How do I know that the current is flowing and the Cervella device is working properly during treatment?

There are two indicators. First, the LED on the Cervella box will be blinking BLUE. Second, the counter on the Cervella app will count down treatment time. If the LED is solid blue or the counter is stopped, you do not have a good contact between the gold electrodes of the headset and your mastoid area or you do not have the device connected properly.

HINT: you can test the operation of the Cervella system by starting the treatment and just touching the two ear cushions together. You should see the LED blinking blue and timer counting down and stop as soon as you separate the ear cushions indicating a break in the connection.

Innovative Corporate Solutions, Inc. Dba Clover Medical Solutions

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PRODUCT ORDERING & INFORMATION SHEET CERVELLA Cranial Electrotherapy Stimulator

PRODUCT NAME / ITEM #	PRODUCT DESCRIPTION
Cervella CES System Item # CMS-CES	Cervella Cranial Electrotherapy Stimulator System Includes the Following: Image: Cervella Cranial Electrotherapy Stimulator System Image: Cervella Stimulator with internal Li-lon Battery Cervella Stimulator with internal Li-lon Battery Cervella Headset with Integrated Treatment Electrodes Cervella to Headset connecting cable (1.2m) Cervella Charging cable from USB type A to USB Micro B. (1.2m) Cervella USB Charger: Input: 110-240VAC 0.4A 50/60Hz. Output: 5VDC 1A 360 Electroconductive Gel Cervella protective case in black (8.5inx7inx3.5in)
CMS-MCC	Cervella Main Unit to Headset Connecting Cable (1.2m)
CMS-UCC	Cervella USB Charging Cable
CMS-UCR	Cervella USB Charger
CMS-CG	Tube: 360 Electroconductive Gel
CMS-Case	Cervella Protective Case
CMS-CEC	Cervella Conductive Ear Cushions (pair)