

CEFALY®
ENHANCED

A medical device for the treatment of migraine.

USER MANUAL

CEFALY®
ENHANCED

- NON-INVASIVE
- PORTABLE
- COMFORTABLE
- WEARABLE
- DRUG-FREE

CEFALY Enhanced is indicated to be used for:

- Acute treatment of migraine with or without aura in patients 18 years of age or older.
- Preventative treatment of migraine in patients 18 years of age or older.

CEFALY Enhanced is for patients diagnosed by a physician with migraine per the indications for use.

IMPORTANT: Please read this manual prior to operation and use of the CEFALY Enhanced. The device operation, uses, storage, precautions and warnings are intended to keep you safe, prevent injury and avoid device malfunction or damage.

Need help getting started? Visit our website or call us at the number below to schedule a **free CEFALY Coach Session** for personal one-on-one assistance! To view this user manual in Español, please visit cefaly.com/start.

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Table Of Contents

1. Safety Information 12

1.1. Purpose 12
1.2. Indications for Use 12
1.3. Contraindications 13
1.4. Conventions Used in this Manual 14
1.5. General Warnings and Cautions 16
1.6. Side Effects 25
1.7. A Note for New Users 28

2. About CEFALY Enhanced 29

2.1. What's Included in the CEFALY Enhanced Package 29
2.2. Physical Description of CEFALY Enhanced and Electrode 32
2.3. Understanding CEFALY Enhanced Status 36

2.4. Best Practices and Recommendations 42
2.5. Electrode Care 44
3. Setting Up CEFALY Enhanced 46
3.1. Open the CEFALY Enhanced Package 46
3.2. Charge the Battery 47
4. Preparing for Migraine Treatment 50
4.1. Clean Your Skin 50
4.2. Open the Electrode 51
4.3. Position the Electrode on Your Skin 52
4.4. Attach CEFALY Enhanced to the Electrode 53
5. Delivering Acute Migraine Treatment (Program 1 – ACUTE) 54
5.1. Choose the ACUTE Treatment Program 54

5.2. Monitoring Your ACUTE Treatment 58
5.3. What to Expect During Your ACUTE Treatment 58
5.4. Ending Your ACUTE Treatment 61
6. Delivering Preventative Migraine Treatment (Program 2 – PREVENT) 62
6.1. Choose the PREVENT Treatment Program 62
6.2. Monitoring Your PREVENT Treatment 64
6.3. What to Expect During Your PREVENT Treatment 65
6.4. Ending Your PREVENT Treatment 67
7. Controlling Your Treatment (ACUTE or PREVENT) 69
7.1. Stabilizing Intensity During First 14 Minutes 69
7.2. Manually Increasing the Intensity During First 14 Minutes 70
7.3. Stopping Your Session Early 72

7.4. Accidental Interruptions 73

8. Care Information 74

8.1. Cleaning and Maintenance 74

8.2. Operating and Storage Conditions 75

8.3. Disposal 75

9. Troubleshooting 76

Problem #01 - The CEFALY Enhanced emits one long beep when the device button is pressed. 76

Problem #02 - The CEFALY Enhanced turned off during my session 77

Problem #03 - I cannot feel any stimulation. 78

Problem #04 - The treatment intensity feels too high and is painful. 81

Problem #05 - The intensity feels too low. 82
Problem #06 - My skin is reddened when I remove the electrode. 83
Problem #07 - I experience painful headaches, nausea, tooth pain, tinnitus (noise or ringing in the ears), or hyperlacrimation (overproduction of tears) that persist after a session is over. 84
Problem #08 - The CEFALY Enhanced does not power on 85
10. Self-Care for Migraines 88
10.1. How Do I Differentiate Headache from Migraine? 88
10.2. What Should I Do to Avoid Migraine Attacks? 91
11. Technical Information 94
11.1. About the CEFALY Enhanced Device 94
11.2. About the Battery 98
11.3. USB Power Adaptor 98

11.4. Electromagnetic Compatibility....99
11.5. Guidance and Manufacturer's Declaration - Electromagnetic Emission....99
11.6. Warranty....106
12. About CEFALY Technology 109
13. Glossary 110
13.1. Terms & Definitions....110
13.2. Symbols....112
14. Compliance Statement 116
14.1. FCC - Regulatory Compliance Statement....116
14.2. ISED Canada - Regulatory Compliance Statement....118
14.3. FCC & IC Radiation Exposure Statement....118

Critical CEFALY Enhanced Facts

Read this user manual thoroughly before using CEFALY Enhanced.

Uses

- Helps relieve acute migraine pain.
- Helps in reducing the number of monthly migraine days.

Who Should Use CEFALY Enhanced

- Acute treatment of migraine with or without aura in patients 18 years of age or older.
- Preventative treatment of migraine in patients 18 years of age or older.

See page 85 of this manual on how to differentiate migraine from other types of headaches.

Operating and Storage Conditions	
Use and charge CEFALY Enhanced At room temperature between 50° F and 95° F (10° C and 35° C) in a dry environment (relative humidity between 30% to 75%) and at normal atmospheric pressures (700 hPa to 1060 hPa).	**Store CEFALY Enhanced** At temperatures between 23° F and 95° F (-5° C to 35° C) in a dry environment (relative humidity 45% to 75%) and at normal atmospheric pressure (500 hPa to 1060 hPa).
If further assistance is required, contact Customer Service (see page 3).	

1. Safety Information

1.1. Purpose

This user manual describes the proper use of CEFALY Enhanced.

1.2. Indications for Use

CEFALY Enhanced is for patients diagnosed by a physician with migraine.

CEFALY Enhanced is indicated for:

- Acute treatment of migraine with or without aura in patients 18 years of age or older.
- Preventative treatment of migraine in patients 18 years of age or older.

Migraine may indicate that you have a serious medical condition and you should have them evaluated by a physician. The safety and effectiveness of the CEFALY Enhanced has not been demonstrated for patients with medication overuse headache or chronic tension-type headaches.

1.3. Contraindications

Contraindications

The following are the conditions under which CEFALY Enhanced should not be used. Usage under such conditions may create unfavorable results and/or lead to adverse events.

Do not use CEFALY Enhanced if you:

- Have implanted metallic or electronic devices in the head.
- Are suffering from pain of unknown origin.
- Have a cardiac pacemaker or implanted or wearable defibrillator.

1.4. Conventions Used in this Manual

Special conventions have been used throughout this User Manual to highlight important information. Here is a list of the special conventions used.

- Warnings are placed in a box with a light red color in the background.
- Cautions are placed in a box with a light yellow color in the background.
- Notes have been added to provide supplemental information to certain instructional text.



WARNING: Read all the cautions and warnings included in the manual before using CEFALY Enhanced because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the device.



WARNING: Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of CEFALY Enhanced. Standard warnings relate to significant harm to the user and not to CEFALY Enhanced.



CAUTION: Alerts the user to the possibility of a problem with CEFALY Enhanced associated with its use or misuse. Such problems include CEFALY Enhanced malfunction, failure, damage to CEFALY Enhanced or damage to other property.

1.5. General Warnings and Cautions

WARNINGS

- Do not use CEFALY Enhanced while sleeping.
- Do not use CEFALY Enhanced in a wet environment, such as in the bath or shower.
- Do not use CEFALY Enhanced while driving, operating machinery, or during any activity that requires you to be alert and focused. Wait for 1 hour after each treatment session before resuming any such activity.
- Do not use in the presence of electronic monitoring equipment (e.g., cardiac monitors, electrocardiogram (ECG) alarms).
- The CEFALY Enhanced and electrodes are designed for and should be used only in the forehead region.
    - Do not use CEFALY Enhanced in the neck region.

- Do not use CEFALY Enhanced close to the thorax (chest region) to avoid the risk of cardiac fibrillation.

- Avoid incorrect electrode positioning to prevent serious injury. See Section 4.3.
- Use CEFALY Enhanced only on normal, intact and clean skin.
  - Do not use over open wounds.
  - Do not use over skin eruptions.
  - Do not use over swollen, infected or inflamed areas.
  - Do not use over, or close to, cancerous lesions or skin abnormalities that could be cancerous.
- Use caution or avoid using CEFALY Enhanced if there has been any loss of feeling in the skin of your forehead or scalp until the normal feeling is resumed.
- Use CEFALY Enhanced only with the electrodes and accessories recommended by CEFALY Technology.

- Keep the CEFALY Enhanced out of the reach of children.
- Strangulation risk due to the length of the charging system cable.
- Suffocation risk in case of swallowing the electrode.

If you have known allergies to acrylates, contact CEFALY Technology for hypoallergenic electrode alternatives.

All clinical trials regarding the efficacy and safety of the CEFALY Enhanced have been performed on adults (ages 18-65 years old). There are currently no trial results or data specific to use in individuals under the age of 18 or over the age of 65.

Ask a doctor before use if you:

- You are under 18 years of age.
- You are over 65 years of age.
- You are pregnant or may become pregnant.

- You suspect or know that you have heart problems.
- You had a recent head injury.
- You have ever suffered a seizure.
- You have never been diagnosed with a migraine by a health professional.
- You have a headache that is different from your usual migraines.
- You have the worst headache of your life.
- You have fever or a stiff neck.
- You have a headache that began after a head injury, exertion, coughing, or bending.
- You experienced your first headache after the age of 50 years.
- You have a migraine so severe as to require bed rest.

Consult your healthcare provider before using the CEFALY Enhanced if you have Medication Overuse Headache, Chronic Tension-Type Headache, or Refractory Migraine, as the safety and effectiveness of the device have not been demonstrated for subjects with such conditions.

If the frequency of your headache is not reduced after 2 or 3 months of daily use of Program 2 (prevention), ask your doctor.

The long-term effects of chronic use of CEFALY Enhanced are unknown.

Migraines may indicate that you have a serious medical condition. You should have them checked by a doctor.

You should check with your doctor if you do not understand or if you are not sure whether any of the above “Contraindications” or “Warnings” apply to you or your condition.

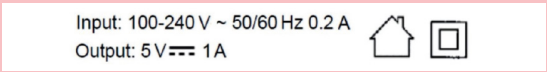
WARNINGS

Charging Information

Only use an adaptor that meets the requirements specified in the user manual and a CEFALY-provided USB cable and charging dock for charging the CEFALY device.

Please refer to the Adaptor requirement below. If you do not have a suitable adaptor, please contact Customer Service for assistance (Email: info@cefaly.us Phone: 1.844.475.7100)

The USB adaptor shall be a class II power supply that is IEC 60601-1 Ed 3.1 2012 certified, with two means of operator protection, input 110V~240 V, 50/60 Hz, max 0.2A and the output is 5 V direct current, 1 A. The USB adaptor shall have the below marking:



- Do not use third-party charging accessories, including accessories made by a different manufacturer or meant for a different device, such as your phone or tablet.
- Inspect your CEFALY device and charging accessories for signs of damage, including melting and warping where the charger plugs into the device. If you see signs of damage, stop charging the device and contact CEFALY.
- Charge your CEFALY device where you can clearly see it, away from anything that can easily catch fire. Do not charge your CEFALY device on or near a soft surface like a couch, pillow, curtains, or other materials, where it can overheat more easily.
- Charge your CEFALY device during the day when you are awake. Do not charge your CEFALY device overnight when you might miss early signs of the device overheating.
- Unplug the adaptor when your CEFALY device shows a solid green LED, that indicates the device is fully charged. Do not leave your CEFALY device plugged into the charger after it is fully charged.

- Protect your CEFALY device from extreme temperatures. Do not leave your CEFALY device in direct sunlight, or in your car on an especially hot or cold day. Only charge your CEFALY device indoors with temperature between 50° F and 95° F (10° C and 35° C).
- Adaptors that meet the specifications in the user manual and accessories provided by CEFALY limit the power provided to safely charge the battery, but other accessories may allow much higher power, increasing the risk of overheating, spark, or fire, which may lead to minor injuries or serious burns.
- If the device remains unused for an extended period, please check the battery level regularly, approximately every month. If the battery level is low, indicated by a solid yellow glow on the LED indicator, please fully recharge the device until the solid green LED is shown. Keeping the battery at an appropriate charge level helps maintain its health and longevity.

CAUTION

- If you have experienced a seizure or are diagnosed with epilepsy, we recommend that you discuss CEFALY Enhanced with your healthcare provider prior to use.
- If you have a history of herpetic infections/Shingles, please discuss with your healthcare provider prior to use.
- CEFALY Enhanced treatments are not a cure for migraine headaches.
- This unit will only work with CEFALY approved electrodes and accessories.
- Do not use CEFALY Enhanced in close proximity (less than 3.5 feet) to shortwave or microwave therapy equipment, as it may produce instability in the CEFALY Enhanced output.
- Use is incompatible with the simultaneous use of high-frequency surgical equipment.
- It may be dangerous to connect the CEFALY Enhanced with devices not identified in this user manual.
- Do not modify this equipment without written authorization from the manufacturer.

- Only individuals authorized by the manufacturer can repair this equipment.
- The CEFALY Enhanced contains a rechargeable lithium battery. Do not try to tamper with/misuse the battery as it could result in a fire/explosion/dangerous gas leak.
- The CEFALY Enhanced should only be charged with the charging dock included in the kit.
- Avoid continuing to use the device if it feels too hot at the forehead. To discontinue, remove the device from Electrode. Refer to Section 7.3 for stopping your session early.
- To minimize the risk of unexpected electric shock, avoid using CEFALY Enhanced at the same time as other active electronic medical devices.
- Do not touch the metal pin on the top of charging dock.

1.6. Side Effects

CEFALY Enhanced has few side effects, which have been demonstrated to be minor and fully reversible with cessation of device use, through clinical trials.

If you experience any serious side effects, or if any side effects persist for more than a few weeks, stop use of CEFALY Enhanced and consult your healthcare provider or seek immediate medical attention.

Common

• *Sleepiness*

The main side effect is a tendency towards sleepiness. This means that CEFALY Enhanced cannot be used when driving, or when operating machinery, or during any activity that can put you at risk of injury. Approximately 0.5% of subjects reported sleepiness during the CEFALY Enhanced session.

• *Headache After a Session*

Approximately 0.5% of subjects reported a headache after a session of preventative treatment (Program 2 - PREVENT Treatment).

Uncommon

• *Forehead Skin Redness*

At the end of the session, the skin on the forehead under the electrode may occasionally

appear blotchy. This effect is caused by activation of the skin blood circulation. This redness may persist for several minutes. Usually it disappears within 15 minutes. Approximately 0.2% of subjects reported reversible forehead skin redness.

• *Nausea*

Rare occurrence of nausea during a session of acute treatment (Program 1 - ACUTE Treatment) has been reported in the clinical trials.

Rare

• *Forehead Skin Allergy*

In rare cases an allergy to the electrode gel can arise. A temporary rash develops on the forehead. If this should occur, stop using CEFALY Enhanced and contact your doctor or the manufacturer CEFALY Technology. The skin rash will gradually disappear within a few days. The use of an anti-inflammatory cream can accelerate the disappearance of the rash. Less than 1 out of 1000 subjects reported a skin allergic reaction.

CAUTION
If any side effects persist for more than a few weeks, stop use of CEFALY Enhanced and see your healthcare provider.

1.7. A Note for New Users

- In clinical studies, CEFALY demonstrated efficacy and safety for acute and preventative treatment of episodic migraines at the highest intensity levels.
- Individual tolerance for CEFALY stimulation intensity may vary and CEFALY treatments should never feel painful.
- New users should start at an intensity where they feel a strong vibration or stimulation sensation that is not painful. In the first 14 minutes of a session, briefly press the device button to set the stimulation at a tolerable level.
- Gradually increase the intensity over time until you find your sweet spot - the intensity level that's comfortable and effective for you. You don't need to reach full intensity to benefit from treatment with CEFALY. Refer to Section 7.1.

2. About CEFALY Enhanced

2.1. What's Included in the CEFALY Enhanced Package

When you receive and open your CEFALY Enhanced migraine treatment kit, you should find the following items numbered 1-7:



Fig. 1 Contents of the Package

1. CEFALY Enhanced: The CEFALY Enhanced generates the treatment signal that is sent to stimulate and desensitize the trigeminal nerve. It includes a device button that is used to activate treatment sessions and manage treatment intensity, and an indicator light that is used for treatment monitoring and as a battery charge indicator.

2. Electrode(s): The electrode adheres to the skin on the forehead and allows the treatment signal from the CEFALY Enhanced to pass through the trigeminal nerve.

3. Resealable Electrode Storage Bag: Use for storage of electrodes between treatments.

4. Quick Start Guide: Learn the features and functions of your CEFALY Enhanced in an easy-to-digest format to get you started quickly.

5. Instruction Manual: The manual includes instructions to help you set up and use your CEFALY Enhanced.

6. Charging Dock and USB Cable: These are used to recharge the CEFALY Enhanced battery.

7. Storage Case: Use for storage of CEFALY Enhanced, electrodes, charging dock, and USB cable.

2.2. Physical Description of CEFALY Enhanced and Electrode

CEFALY Enhanced comes with three electrodes, charging dock, and USB cable. The charging dock and USB cable are only used for charging the CEFALY Enhanced.

CEFALY Enhanced

CEFALY Enhanced is a single device with two program settings (ACUTE and PREVENT) that help users to overcome migraine pain.

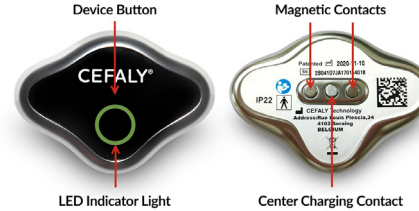


Fig. 2 Description of CEFALY Enhanced

Table 1 - Parts of the CEFALY Enhanced

Part	Location	Functionality
Device button	Front	Used to turn on CEFALY Enhanced and activate the treatment programs (ACUTE and PREVENT).
LED indicator light	Front	Used to indicate the status of the CEFALY Enhanced to user.
Magnetic Contacts	Rear	Used to connect CEFALY Enhanced to the electrode that transmits the stimulations to the user.
Center Charging Contact	Rear	Used for connecting the charging dock to charge CEFALY Enhanced.

Electrode

The CEFALY Enhanced electrode is 3.7 in. (9.4 cm) long and 0.78 in. (2 cm) high, and comes in a Resealable Storage Bag. It acts as the interface between the CEFALY Enhanced and the skin. The electrode has two contact zones that connect with the CEFALY Enhanced through magnets.



Fig. 3 Description of Electrode

Table 2 - Parts of the Electrode

Part	Location	Functionality
Conductive gel	Front	Used for effective contact between the electrode and the user.
Magnetic contact zone	Rear	Used for contact between CEFALY Enhanced and the electrode.

Notes:

- Use electrodes before the “Use-By-Date” printed on the electrode packaging.
- Do not use the same electrode on multiple people. For important reasons of hygiene, each user must have his or her own electrode.

2.3. Understanding CEFALY Enhanced Status

The CEFALY Enhanced makes use of alarms and LED flashes as feedback to the user for various operations on the device. See table for details.

Table 3 - Alarms and Indicators to Show the Status of the CEFALY Enhanced

Device Operation	Action	Feedback	
Low Battery (Device is not connected to Charging Dock for recharge or an electrode for treatment.)	Press CEFALY Enhanced device button once to see feedback. If low battery, connect to the Charging Dock for recharge.	 Series of beeps.	 Solid yellow glow in the LED indicator.

Device Operation	Action	Feedback	
Charging	USB Cable is connected to the Charging Dock and CEFALY Enhanced is placed on the Charging Dock.	 Low battery charging: Slow intermittent green flashes on the LED indicator.	 Almost fully charged: Flashing frequency of green LED indicator will increase with charge level.
Fully Charged	USB Cable is connected to the Charging Dock and CEFALY Enhanced is placed on the Charging Dock.	 Solid green glow on the LED indicator.	

Device Operation	Action	Feedback	
ACUTE Program	Press the device button once.	 Single beep indicates activation of the program.	 Single turquoise flash throughout the treatment.
ACUTE Program (low battery charge)	Program has been activated and battery charge is too low to complete one treatment.	 Chime that repeats four times.	
PREVENT Program	Press the device button twice, with a slight pause in between each press.	 Two beeps indicate activation of the program.	 Two intermittent purple flashes throughout the treatment.

Device Operation	Action	Feedback
PREVENT Program (low battery charge)	Program has been activated and battery charge is too low to complete one treatment.	 Chime that repeats four times.
Stabilize Intensity	During the first 14 minutes of treatment when the intensity is increasing, press the device button once to stabilize the intensity.	 Intensity of the treatment stabilized with a single beep.
Increase Intensity (for experienced CEFALY users)	Long press device button anytime during the first 14 minutes of the treatment.	Intensity of the treatment gradually increases until the device button is released. Series of beeps will be heard when button is pressed.

Device Operation	Action	Feedback
Intensity is 10 mA	When the treatment intensity reaches a 10 mA output current.	 Series of three successive beeps.
Increase to Maximum Intensity	Long press device button for 30 seconds anytime during the first 14 minutes of the treatment.	 Series of rapid beeps to indicate that the device has reached maximum intensity.

Device Operation	Action	Feedback
End Treatment	Remove the device from the electrode.	 Series of successive beeps indicate that the treatment has been stopped/ interrupted.
Accidental Interruption	If the electrode doesn't fully grip your skin, is worn out, and/ or is nudged by movement, your session may be interrupted.	 Series of successive beeps that repeat four times indicate that the treatment has been stopped/interrupted.

2.4. Best Practices and Recommendations

Read the following sections thoroughly before operating the CEFALY Enhanced: Setting up CEFALY Enhanced, Preparing for Migraine Treatment, Delivering Migraine Treatment, and Care Information. Refer to page 10 for the Critical CEFALY Enhanced Facts.

Cleanse and dry your skin before every treatment session. This will ensure the electrode attaches securely to the skin.
CEFALY Enhanced is designed to function with the CEFALY electrodes and genuine CEFALY accessories.
Electrodes must be used before the expiration date printed on the outside of the packet.

The magnetic contacts of the CEFALY Enhanced should be kept clean. If those contacts should become dirty, clean them with a soft duster and an alcohol-based cleaning product.
Handle your cable carefully to avoid tangles. Keep the connectors at the ends of the cables clean.
To ensure optimal use of your electrode for future sessions, place it back on the plastic backing and put in the Resealable Electrode Storage Bag.
After successfully completing your treatment, pack your CEFALY Enhanced and electrode away in the storage case until you are ready for your next treatment.

2.5. Electrode Care

A visual inspection and quick stickiness check helps determine if it is time for a new electrode. If you experience any of the following with your current electrode, you should dispose of it and use a new one:

- Your electrode is not sticky to the touch or looks dried out.
- The two pads of the electrode are not fully covered with gel.
- After washing your forehead with soap and water, and drying it thoroughly, the electrode does not stick uniformly to your forehead, and peels at the ends or center.
- With the device on the electrode, the electrode slips or separates in any way from your forehead.

If you are not able to verify the above, you should use a new electrode. If you have any questions about reusing your electrode, please contact CEFALY for assistance.

Good Electrode



Electrode with Gel Missing



Dried Out Electrode



3.1. Open the CEFALY Enhanced Package

Open the package and remove the components (see Fig. 4), including:



Fig. 4 Contents of the Package

1. CEFALY Enhanced
2. Electrode(s)
3. Resealable Electrode Storage Bag
4. Quick Start Guide
5. Instruction Manual
6. Charging Dock & USB Cable
7. Storage Case

Confirm your package contains all of the listed components and proceed to the next step.

3.2. Charge the Battery

- Prior to your first CEFALY Enhanced treatment session, fully charge the battery (this typically takes 4 hours to complete).
- As shown in Fig. 5, connect the micro-USB plug to the charging dock and place your CEFALY Enhanced onto the top side of the charging dock. The silicon pad should be facing down, and the silver ring with the gold pin should be facing up. Then, connect the USB plug to the power adapter (Fig. 6) and plug the adapter into a power source. Please refer to section 11.3 USB Power Adaptor for the requirements of the adaptor. Only USB Power Adapters that meet the requirements specified in section 11.3 shall be used.
- While charging, the LED indicator will have a flashing green glow. The flashing frequency will increase with charging level. Once fully charged, the indicator light will turn solid green (Fig. 7).

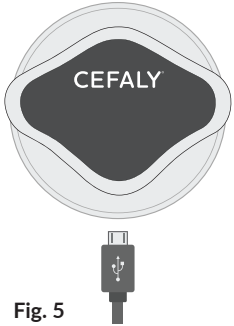


Fig. 5

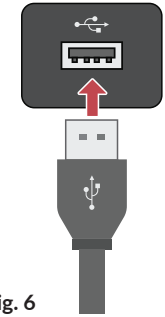


Fig. 6

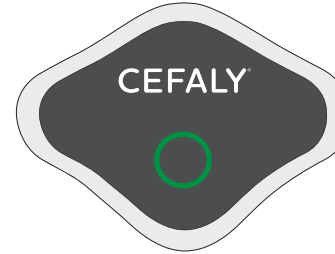


Fig. 7

See table for feedback from CEFALY Enhanced during charging and completion of charging.

Status	Action	Feedback from the CEFALY Enhanced	
Low Battery (Device is not connected to Charging Dock for recharge or an electrode for treatment.)	Press CEFALY Enhanced device button once to see feedback. If low battery, connect to the Charging Dock for recharge.	 Series of beeps.	 Solid yellow glow in the LED indicator.
Charging	USB Cable is connected to the Charging Dock and CEFALY Enhanced is placed on the Charging Dock.	 Low battery charging: Slow intermittent green flashes on the LED indicator.	 Almost fully charged: Flashing frequency of green LED indicator will increase with charge level.
Fully Charged	USB Cable is connected to the Charging Dock and CEFALY Enhanced is placed on the Charging Dock.	 Solid green glow on the LED indicator.	



Fig. 8

4.1. Clean Your Skin

- It is important to cleanse your skin before every CEFALY Enhanced session. This will help ensure the electrode attaches securely to your forehead.

CAUTION
Do not apply the electrode to wet or moist skin.

- Use soap and water to wash between and above your eyebrows (Fig. 8). Afterward, be sure to dry your skin thoroughly.
- The use of makeup-removing products, moisturizing facial cleansers, or alcohol wipes are NOT recommended as a substitute for soap and water.

WARNING
Do not use CEFALY Enhanced in or around the neck or chest. It should only be applied to normal, intact, clean skin on the forehead.

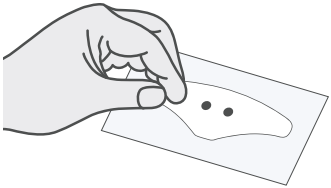


Fig. 9

4.2. Open the Electrode

- Open the Resealable Electrode Storage Bag, slide out the electrode, then peel it from the clear plastic backing (Fig. 9).
- Save the plastic backing for later use to store your electrode in the Resealable Electrode Storage Bag.

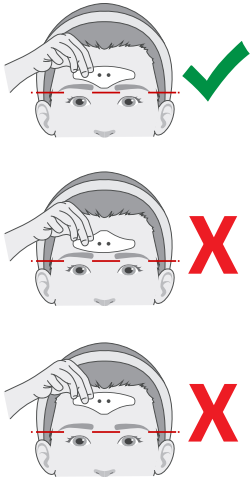


Fig. 10

4.3. Position the Electrode on Your Skin

- Use a mirror to help place the electrode on your forehead. Place the electrode so the curved area is between your eyebrows and wings are just above the eyebrows as seen in Fig. 10.
- Once in place, run your fingers along the electrode several times to check that it's flat and firm against your skin.

WARNING

Incorrect application and placement of the electrode may lead to serious injury. Contact CEFALY for assistance in questions related to the placement of the electrode before using the device.

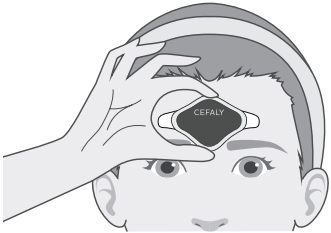


Fig. 11

4.4. Attach CEFALY Enhanced to the Electrode

- On the back of your CEFALY Enhanced there are two magnets that allow the device to securely attach to the electrode.
- Hold your CEFALY Enhanced on the edge, so these magnets are exposed, and bring the device toward your forehead. Take care to avoid accidentally pressing the button on the front of the device. The CEFALY Enhanced will pull itself toward the electrode and automatically settle into its proper place.

5.1. Choose the ACUTE Treatment Program

Once your CEFALY Enhanced is securely attached to the electrode on your forehead, you're ready to select your treatment program. For the acute treatment of migraine with or without aura, select Program 1 the ACUTE Treatment Program.

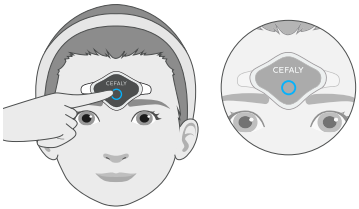


Fig. 12

Selecting the ACUTE Treatment Program

The ACUTE treatment program is intended for treatment during a migraine attack or at the onset of a migraine and is activated by pressing your device button once. (Fig. 12)

This is a 60-minute program designed to **treat migraine attacks** when they begin, to stop or relieve your migraine pain. For best results, use this therapy at the beginning of an acute migraine attack. When using the ACUTE migraine treatment program, you will observe the following:

- You will hear a single beep to indicate your ACUTE program selection.
- The CEFALY Enhanced LED indicator will have a single turquoise flash throughout the program to aid in treatment monitoring. It may take several seconds for flashing to begin.

See table for feedback from the CEFALY Enhanced when the ACUTE treatment program is selected.

Status	Action	Feedback from CEFALY Enhanced
ACUTE Program	Press the device button once.	 Single beep indicates activation of the program.  Single turquoise flash throughout the treatment.

Notes:

- For best results, the ACUTE program should be used for its full 60-minute session.



CAUTION

The acute treatment for CEFALY Enhanced (Program 1 - 60-minute ACUTE session) can be used the same day for a second 60-minute session if the migraine pain is not relieved within two hours or if another migraine attack occurs; however, the effectiveness of the second 60-minute session has not been established.

5.2. Monitoring Your ACUTE Treatment

- Throughout this 60-minute program, the CEFALY Enhanced light will flash a turquoise color once repeatedly to indicate the program is active.
- This flash of the indicator light will aid in treatment monitoring. It may take several seconds for flashing to begin.

5.3. What to Expect During Your ACUTE Treatment

For the first few minutes of your ACUTE treatment session, the sensation is light and it's possible you may not feel anything. The stimulation intensity will gradually increase, and you may feel vibrations or a tingling effect on your forehead and near your eyes. You may begin to feel like your hair is standing on end or your eyebrows are twitching, but this is only a sensation.

IMPORTANT: During the first 14 minutes of the ACUTE treatment session, the intensity will automatically increase until the device reaches maximum intensity. As the intensity increases to maximum intensity, you may hear 3 successive beeps during your session. This indicates the treatment intensity has reached a 10 mA output current.

The intensity will remain at maximum intensity after the first 14 minutes for the remainder of your 60 minute treatment. During the first 14 minutes, the stimulation intensity may become slightly uncomfortable however it should not be painful. You may stabilize the device intensity, within the first 14 minutes, by pressing the device button once during the treatment session. Please reference section 7.1 for stabilizing intensity.

At the end of the treatment, when you remove the electrode, your skin may appear reddened where the electrode was placed. This redness is expected and will resolve after a few minutes. The skin redness is due to local blood flow to the forehead after a treatment session.

Notes:

- For the best results, you should aim to use CEFALY Enhanced at the highest intensity level. Gradually increase the intensity with each treatment for your skin to get used to the stimulation. New users are encouraged to stabilize the treatment intensity at any point during the first 14 minutes if they experience painful sensations. CEFALY should be used at an intensity level that is comfortable to you; it should never be painful.
- The electrode gel is the conductive material that transmits the stimulation impulses. Avoid touching the gel during the treatment session.

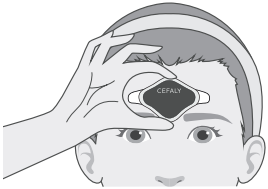


Fig. 13

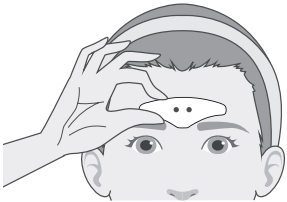


Fig. 14

5.4. Ending Your ACUTE Treatment

- At the end of the ACUTE 60-minute treatment session, the CEFALY Enhanced device will play a series of successive beeps then automatically shut off. You may continue to feel sensations over the stimulation area lasting for several minutes after the treatment session is complete.
- You can now remove the CEFALY Enhanced by pulling it away from the electrode (Fig. 13). Then gently detach the electrode from your skin (Fig. 14).
- To ensure optimal use of your electrode for future sessions, place it back on the plastic backing and store inside the Resealable Electrode Storage Bag.
- After successfully completing your treatment, pack your CEFALY Enhanced and electrode away in the storage case until you are ready for your next treatment.

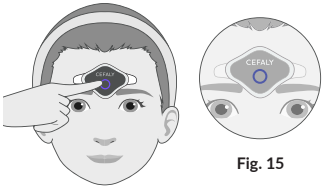


Fig. 15

6.1. Choose the PREVENT Treatment Program

Once your CEFALY Enhanced is securely attached to the electrode on your forehead, you're ready to select your treatment program. For the preventative treatment of migraine, select Program 2 the PREVENT Treatment Program.

Selecting the PREVENT Treatment Program

The PREVENT treatment program is meant for daily preventative treatment and is activated by pressing your device button twice, with a slight pause in between each press.

This is a 20-minute program designed for the preventative treatment of migraines. When using the PREVENT migraine treatment program, you will observe the following:

- You will hear two beeps to indicate your PREVENT program selection.

- The CEFALY Enhanced LED indicator will have two intermittent purple flashes throughout the program to aid in treatment monitoring. It may take several seconds for flashing to begin.

See table for feedback from the CEFALY Enhanced when the PREVENT treatment program is selected.

Status	Action	Feedback from CEFALY Enhanced
PREVENT Program	Press the device button twice, with a slight pause in between each press.	 Two beeps indicate activation of the program.  Two intermittent purple flashes throughout the treatment.

Notes:

- For new CEFALY users, please review section 7.1 Stabilizing Intensity During First 14 Minutes.
- The PREVENT Treatment (Program 2 - 20-minute PREVENT session) should be used daily for 20-minute sessions. More than one 20-minute session per day is not recommended because the safety and effectiveness of Program 2 when used more than once per day has not been studied.

6.2. Monitoring Your PREVENT Treatment

- Throughout this 20-minute program, the CEFALY Enhanced light will flash a purple color twice repeatedly to indicate the program is active.
- This flash of the indicator light will aid in treatment monitoring. It may take several seconds for flashing to begin for the remainder of the session.

6.3. What to Expect During Your PREVENT Treatment

At the beginning of therapy, you may not feel the stimulation. The initial stimulation intensity can be low for some users. The stimulation intensity will gradually increase and you may feel vibrations or a tingling on your forehead and near your eyes. You may even begin to feel like your hair is standing on end or your eyebrows are twitching, but this is only a sensation.

During the first 14 minutes of the PREVENT treatment session, the intensity will gradually increase to the maximum intensity. As the intensity increases to maximum intensity, you may hear 3 successive beeps during your session. This indicates the treatment intensity has reached a 10 mA output current. After 14 minutes, the stimulation intensity will plateau for the remainder of your session. The stimulation intensity may become slightly uncomfortable in the first 14 minutes however it should not be permitted to become painful. You may stabilize the device intensity by pressing the device button once during the first 14 minutes of stimulation. Please refer to section 7.1 Stabilizing Intensity During First 14 Minutes.

At the end of the treatment, when you remove the electrode, your skin may appear reddened where the electrode was placed. This redness may last a few minutes and is an indication the device has stimulated blood flow to the area.

Note:

- For the best results, you should aim to use CEFALY Enhanced at the highest intensity level. Gradually increase the intensity with each treatment for your skin to get used to the stimulation. New users are encouraged to stabilize the treatment intensity at any point during the first 14 minutes if they experience painful sensations. CEFALY should be used at an intensity level that is comfortable to you; it should never be painful.
- The electrode gel is the conductive material that transmits the stimulation impulses. Avoid touching the gel during the treatment session.

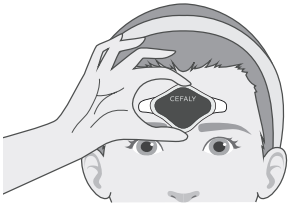


Fig. 16

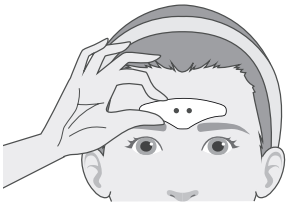


Fig. 17

6.4. Ending Your PREVENT Treatment

- At the end of your PREVENT treatment session, you will stop feeling sensations from your CEFALY Enhanced and it will automatically shut off.
- If at any point you need to stop your treatment session, simply remove your CEFALY Enhanced device from the electrode and your session will end. For more information, review section 7.3 Stopping Your Session Early.
- You can now remove the CEFALY Enhanced by pulling it away from the electrode (Fig. 16). Then gently detach the electrode from your skin (Fig. 17).

- To ensure optimal use of your electrode for future sessions, place it back on the plastic backing, then store inside the Resealable Electrode Storage Bag.
- After successfully completing your treatment, pack your CEFALY Enhanced and electrode away in the storage case until you are ready for your next treatment.

7.1. Stabilizing Intensity During First 14 Minutes

- Migraine relief in clinical studies were demonstrated at maximum stimulation intensity, however the tolerance for stimulation intensity may vary among users. New CEFALY users are encouraged to stabilize the device intensity during the first 14 minutes until they become accustomed to the treatment. Over time, consider allowing stimulation intensities to increase based on individual tolerance of the stimulation.
- You will hear a single beep as confirmation. See table for feedback from CEFALY Enhanced.

Status	Action	Feedback from CEFALY Enhanced
Stabilize Intensity	During the first 14 minutes of treatment when the intensity is increasing, press the device button once to stabilize the intensity. Should you press and hold the device button again, the intensity will increase again.	 Intensity of the treatment stabilized with a single beep.

7.2. Manually Increasing the Intensity During First 14 Minutes

At any point during the first 14 minutes of either treatment program, you can manually increase your intensity.

- To manually increase intensity, long press your device button until you reach your desired intensity level. When you release the device button, the intensity will stabilize for the remainder of the session.
- You can repeat this if you would like to increase the intensity again. Maximum intensity is reached after long pressing the device button for about 30 seconds.
- You will hear a series of rapid beeps that will end once you release the device button or at the end of 30 seconds.
- You can manually increase the intensity any time within the first 14 minutes of the cycle.
- The intensity of the stimulation reaches its maximum level at the end of the first 14 minutes. See table for feedback from CEFALY Enhanced.
- As you ramp up the intensity, you may hear a series of three successive beeps. This

indicates the treatment intensity has reached a 10 mA output current. See section 2.3 Understanding CEFALY Enhanced Status for more information.

Status	Action	Feedback from CEFALY Enhanced
Increase Intensity	Long press device button anytime during the first 14 minutes of the treatment.	Intensity of the treatment slowly increases until the device button is released.
Maximum Intensity	Long press device button for 30 seconds anytime during the first 14 minutes of the treatment.	 Series of rapid beeps to indicate that the device has reached maximum intensity.

7.3. Stopping Your Session Early

- If at any point you need to stop your treatment session, simply remove your CEFALY Enhanced from the electrode and your session will end.
- You will hear a series of beeps indicating that your device has been disconnected and your treatment interrupted. See table for feedback from CEFALY Enhanced.

Status	Action	Feedback from CEFALY Enhanced
End Treatment	Remove the CEFALY Enhanced from the electrode.	 Series of successive beeps indicate that the treatment has been stopped/interrupted.

7.4. Accidental Interruptions

The electronics involved in CEFALY Enhanced constantly check that your device is in contact with the electrode. If the electrode doesn't fully grip your skin, is worn out, and/or is nudged by movement, your session may be interrupted. In this case, a series of successive beeps will indicate the device has been disconnected. See table for feedback from CEFALY Enhanced.

Status	Action	Feedback from CEFALY Enhanced
Accidental Interruption	If the electrode doesn't fully grip your skin, is worn out, and/or is nudged by movement, your session may be interrupted.	 Series of successive beeps that repeat four times indicate that the treatment has been stopped/ interrupted.

8. Care Information

8.1. Cleaning and Maintenance

The magnetic contacts of the CEFALY Enhanced should be kept clean. If those contacts should become dirty, clean them with a soft duster and an alcohol-based cleaning product. It is not necessary to disinfect or sterilize the CEFALY Enhanced between uses and/or between users.

Electrodes

Electrodes must be used before the expiration date printed on the outside of the packet. Electrodes may be reused as long as they effectively stick to your forehead. Electrodes that have been overused or are dirty lose their capacity to transmit electrical impulses and will be ineffective.

Charging Dock and USB Cable

USB Cable: Handle your cable carefully to avoid tangles. Keep the connectors at the ends of the cables clean. If those contacts should become dirty, clean them with a soft duster and an alcohol-based cleaning product.

Charging Dock: Keep the front surface and connection pin of the charging dock clean. Please ensure the charging dock is disconnected from its power source before cleaning.

8.2. Operating and Storage Conditions

Use and charge CEFALY Enhanced at room temperature between 50° F and 95° F (10° C and 35° C) in a dry environment (relative humidity between 30% to 75%) and at normal atmospheric pressures (700 hPa to 1060 hPa). This device is intended for use at altitudes lower than 9842.5 ft (3000 m).

Store the CEFALY Enhanced at temperatures between 23° F and 95° F (-5° C to 35° C) in a dry environment (relative humidity 45% to 75%) and at normal atmospheric pressure (500 hPa to 1060 hPa).

8.3. Disposal

When your CEFALY Enhanced reaches the end of its service life, dispose of it and its battery in accordance with your local regulations.

9. Troubleshooting

When a problem occurs, troubleshooting will help you to determine if the problem is with the CEFALY Enhanced or your use. Check the troubleshooting table for a solution if a problem should arise with your CEFALY Enhanced. **If further assistance is required, contact Customer Service (see page 3).**

Table 4 - Troubleshooting

Problem #01 - The CEFALY Enhanced emits one long beep when the device button is pressed.

Possible Cause:

- The battery charge is too low.

Solution:

- Recharge the battery fully for about 4 hours so you may complete a full treatment session.

Problem #02 - The CEFALY Enhanced turned off during my session.

Possible Cause:

- Your electrode is not sticking well to your forehead.
- Your CEFALY Enhanced is not properly secured to the electrode.
- The battery charge is too low.

Solution:

- Cleanse your skin again with soap and water, and pat dry. Then reposition the electrode, attach the CEFALY Enhanced and try powering it on again. To reposition the electrode, start from the center and work your way outward toward each corner, running your fingers several times along the entire surface of the electrode. You want the electrode to be flat and firm against your forehead skin.
- Use a mirror to make sure your CEFALY Enhanced is properly positioned on the electrode. The magnetic contacts on the CEFALY Enhanced must be properly secured by the corresponding magnetic contact zone on the electrode for the CEFALY

Enhanced to work properly. If the electrode is not positioned correctly and is not flat against your forehead, the contacts may not connect properly. To reposition the electrode, start from the center of and work your way outward toward each corner, running your fingers several times along the entire surface of the electrode. You want the electrode to be flat and firm against your forehead skin.

- Recharge the battery fully for about 4 hours so you may complete a full treatment session.

Problem #03 - I cannot feel any stimulation.

Possible Cause:

- Your electrode is not sticking well to your forehead.
- Your CEFALY Enhanced is not properly secured to the electrode.
- Experienced CEFALY users may be desensitized to lower-strength pulses at the beginning of a session.
- You accidentally pressed the device button to stabilize your treatment at a low

intensity level, prohibiting it from increasing.

- Your CEFALY Enhanced is not turned on.

Solution:

- Cleanse your skin again with soap and water, and pat dry. Then reposition the electrode, attach the CEFALY Enhanced and try powering it on again. To reposition the electrode, start from the center and work your way outward toward each corner, running your fingers several times along the entire surface of the electrode. You want the electrode to be flat and firm against your forehead skin.
- Use a mirror to make sure your CEFALY Enhanced is properly positioned on the electrode. The magnetic contacts on the CEFALY Enhanced must be properly secured by the corresponding magnetic contact zone on the electrode for the CEFALY Enhanced to work properly. If the electrode is not positioned correctly and is not flat against your forehead, the contacts may not connect properly. To reposition the electrode, start from the center of and work your way outward toward each corner, running your fingers several times along the entire surface of the electrode. You

want the electrode to be flat and firm against your forehead skin.

- Wait 2-3 minutes while using CEFALY Enhanced for the intensity to increase. It's possible you are becoming used to the sensation.
- Wait until at least 4 minutes into your session, then press and hold the device button to manually ramp up the intensity of the session. When you release the device button, the intensity will stabilize at the new level and remain constant. Should you press and hold the device button again, the intensity will increase again. The maximum intensity is reached after pressing and holding the device button for 30 consecutive seconds. You should increase the intensity to a tolerable level, but you should stop before the sensation becomes intolerable or painful.
- Push the device button once to start the ACUTE program and twice in a row to begin the PREVENT program once the electrode and device are properly positioned on your forehead. If the CEFALY Enhanced does not power on, use the micro-USB cable and the charging dock to charge it for 4+ hours. If this is your first time using the CEFALY Enhanced it must be fully charged. Once your CEFALY Enhanced is fully charged, a green indicator light will remain turned on.

Problem #04 - The treatment intensity feels too high and is painful.

Possible Cause:

- The sensations experienced while using the CEFALY Enhanced are novel to most people and can take some adjustment.

Solution:

- IMPORTANT: Please use the stabilization feature of the device when first starting treatments - Refer to section 7.1 Stabilizing Intensity During the First 14 Minutes.

  Each user will have a different pain threshold to stimulation. The stimulation intensity may be slightly uncomfortable but should not be painful. Stabilize the device at the point prior to painful sensations until your skin and nerves become accustomed to the stimulation intensities.

- If you experience any zapping or shocking sensation during treatment, stop treatment immediately. Zapping and shocking sensations are not expected during treatment and may result in injury if allowed to continue. Once you stop treatment,

ensure that you have thoroughly cleansed the forehead area with soap and water and dry thoroughly. Ensure you use an electrode with a moist and cool gel surface without cracks or dry areas. Reapply the electrode, ensuring full adhesion to the skin by running your fingers along the entire length of the electrode. Ensure there are no air bubbles under the electrode. If you still experience shocking or zapping after these procedures, stop treatment immediately and contact CEFALY for further information.

Problem #05 - The intensity feels too low.

Possible Cause:

- Once you're accustomed to the sensations experienced while using the CEFALY Enhanced you may feel desensitized to its lower-strength pulses at the beginning of a session.

Solution:

- You may press and hold the device button anytime during the first 14 minutes of

program selection to manually increase intensity to your desired strength. When you release the device button, the intensity will stabilize and remain constant. Should you press and hold the device button again, the intensity will increase again. The maximum intensity is reached after pressing and holding the device button for 30 consecutive seconds. You should increase the intensity to a tolerable level, but you should stop before the sensation becomes intolerable or painful.

Problem #06 - My skin is reddened when I remove the electrode.

Possible Cause:

- The skin on the forehead may at times become reddened where the electrode was placed.
- This may indicate an allergy to the acrylate used in the electrode.

Solution:

- This redness may last a few minutes or more after your session, and is usually harmless. It indicates the CEFALY Enhanced has stimulated blood flow to the area.

- In rare cases, you may experience an allergy to the acrylate used in the electrode adhesive and a temporary rash may cause. You may experience small blistering, burning, itching, or swelling in the areas where the electrode comes in contact with the skin. If this should happen, stop using the CEFALY Enhanced and wash the area with soap and water, gently. The skin rash should gradually disappear within a few days and can be helped along by applying an anti-inflammatory cream.

If your condition does not improve, stop using the CEFALY Enhanced and speak with your healthcare provider. Before using your CEFALY Enhanced after such an event, contact CEFALY Technology to ask about the alternate hypoallergenic electrodes.

Problem #07 - I experience painful headaches, nausea, tooth pain, tinnitus (noise or ringing in the ears), or hyperlacrimation (overproduction of tears) that persist after a session is over.

Possible Cause:

- These may indicate that you are experiencing an uncommon side effect of using the CEFALY Enhanced.

- You may be experiencing what is known as a Trigeminal Autonomic Cephalalgia (TAC), which can occur with migraine.

Solution:

- Some users have reported experiencing painful headaches, nausea, tooth pain, tinnitus or hyperlacrimation during and after CEFALY Enhanced sessions. If you continue to experience any one or more of these conditions despite attempts to stabilize treatment intensity or if the symptoms persist for more than a few days after treatment, stop use and consult your healthcare provider. Users are also encouraged to contact Customer Service (see page 3).
- Consult your healthcare provider about experiencing these symptoms with your migraine.

Problem #08 - The CEFALY Enhanced does not power on.

Possible Cause:

- The CEFALY Enhanced does not have enough charge.

- Your electrode is not sticking well to your forehead.
- Your CEFALY Enhanced is not properly secured to the electrode.
- Device is not responding when trying to switch ON.

Solution:

- Use the micro-USB cable to connect the Charging Dock, then place the CEFALY Enhanced onto the Charging Dock and let it charge for 4+ hours. If this is your first time using the CEFALY Enhanced it must be fully charged. Once fully charged, the indicator light will have a solid green glow.
- Cleanse your skin again with soap and water, and pat dry. Then reposition the electrode, attach the CEFALY Enhanced and try powering it on again. To reposition the electrode, start from the center and work your way outward toward each corner, running your fingers several times along the entire surface of the electrode. You want the electrode to be flat and firm against your forehead skin.
- Use a mirror to make sure your CEFALY Enhanced is properly positioned on the electrode. The magnetic contacts on the CEFALY Enhanced must be properly secured

by the corresponding magnetic contact zone on the electrode for the CEFALY Enhanced to work properly. If the electrode is not positioned correctly and is not flat against your forehead, the contacts may not connect properly. To reposition the electrode, start from the center of and work your way outward toward each corner, running your fingers several times along the entire surface of the electrode. You want the electrode to be flat and firm against your forehead skin.

- If further assistance is required, contact Customer Service (see page 3).

10.1. How Do I Differentiate Headache from Migraine?

Migraine headache is a disorder that should be diagnosed by a physician.

- The key symptoms of migraine headaches are duration, characteristics of pain, and associated symptoms.
- Migraines generally last from about 4 to 72 hours and are typically located on one side of the head.
- The pain increases and decreases in a pulse-like manner.
- Associated with the pain, you may also experience nausea/vomiting, increased sensitivity to light, and/or increased sensitivity to sounds.
- Some people with migraine also develop aura symptoms (refer to definitions). For migraine with aura, these symptoms are fully reversible and last from about 5-60 minutes prior to headache onset (see Fig. 18).

Non-Migraine Headaches

- Each specific type of non-migraine headache has unique characteristics.
- The most common non-migraine headache that people experience is the tension-type headache (TTH). TTH has pain on both sides of the head and a constant pain often described as someone 'squeezing' the head.
- The headaches are not worsened with walking, movement, exercise, etc., and rarely have associated symptoms like nausea.
- Unlike migraine headaches, non-migraine headaches may have either sensitivity to light or sensitivity to sound, but not both.

HOW DO I KNOW I HAVE MIGRAINES?

MIGRAINE HEADACHE

Headache pain with associated symptoms



GENERAL CHARACTERISTICS

- Duration of 4-72 hours
- Pain located on one side of the head (unilateral)
- Pulsating or throbbing pain
- Physical activity increases pain and symptoms
- Pain is associated with:
  - Nausea/vomiting
  - Sensitivity to light
  - Sensitivity to sound

WITH AURA

- Reversible aura symptoms (visual, sensory, speech, motor or retinal)
- Aura spreads over >5 minutes
- Aura lasts 5-60 minutes
- Headache follows within 60 minutes of aura

NON-MIGRAINE HEADACHE

Headache pain is not associated with other symptoms



GENERAL CHARACTERISTICS

- Duration of 30 mins to 7 days
- Pain on both sides of the head (bilateral)
- Constant pain (tightening or pressure)
- Activity does not change the pain
- Only one of the following:
  - Sensitivity to light
  - Sensitivity to sound
- No nausea
- Touching skin of the head is painful (pericranial tenderness)

Fig. 18 Difference between Migraine and Headache

10.2. What Should I Do to Avoid Migraine Attacks?

Migraine Triggers

Triggers are environmental conditions, foods, and/or activities that may precipitate a migraine. One of the most common triggers is stress. Coping with stress can be as simple as having a friend to talk with regularly, seeing a therapist, or scheduling regular, moderate exercise. Life can be difficult; add suffering with migraines to the mix, and it gets even more challenging. Find some practices and habits that help you cope with stress and better treat your migraines.

Another commonly reported trigger for migraines is food. As to which foods trigger a migraine, science cannot seem to agree. Studies have found very few foods that are triggers commonly held by migraine sufferers. It appears each person with migraine has different foods or combinations of foods that may be triggers, much like allergies. To identify if certain foods trigger your migraines, keep a food and migraine diary, and review it regularly for patterns.

The following are some commonly reported migraine triggers:

- Stress
- Fasting/hunger
- Significant changes in weather
- Dehydration
- Changes in sleep routine
- Artificial sweeteners
- Medication overuse
- Hormonal changes (menses, hormone replacement therapy, etc.)
- Alcohol
- Over-exertion (excessive exercise, etc.)
- Strong, noxious odors
- Altitude changes
- Tyramines (aged cheese, fermented foods)
- Specific foods (varies largely among individuals)

Daily Practices to Help Avoid Migraine Attacks

Research shows there are some daily habits and non-pharmacological treatments that help reduce the burden of migraine.

Daily Helpful Habits:

- Meditation and mindfulness practices
- Keeping a migraine diary using tools such as the CeCe Migraine Management App
- Daily personal journaling
- Cognitive-behavioral therapy (individual or group therapies)
- Relaxation training
- Endurance and aerobic training
- Staying well hydrated
- Eating balanced, healthy meals

11. Technical Information

11.1. About the CEFALY Enhanced Device

Maximum output current: 16 mA (milliamps)

Pulse width: 250 µs (microseconds)

Maximum phase charge: 5 µC (microcoulombs)

Maximum rise time of an impulse: 5 microseconds at 50% of the maximum

Number of programs: 2

Device service life: 3 years

Device Casing: PC plastic, painted

Dimensions: 2.6 inch x 1.86 inch x 0.68 inch (66 mm x 47 mm x 17 mm)

Weight: 25 grams

Table 5 - Program Parameters

Parameters	ACUTE	PREVENT
Pulse Frequency	100 Hz	60 Hz
Pulse Width	250 µs	250 µs
Pulse Duration	500 µs	500 µs
Maximum Intensity	16 mA	16 mA
Ramp Up Time	14 minutes	14 minutes
Steady Time	46 minutes	6 minutes
Ramp Down Time	45 seconds	45 seconds
Session Duration	60 minutes	20 minutes

Device Electrical Specifications

For a charge between 200 and 1000 ohms.

- Constant amplitude intensity predefined automatically, depending on the program.
- Rectangular impulses.
- Compensated constant current preventing any galvanic direct component.

Any electrode for which the current density is above 2 mA/ cm^2 requires special attention from the operator.

Device Temperature Specifications

When the CEFALY Enhanced is operated at an ambient temperature of 95° F, the electrode's maximum temperature measured in testing is 109.4° F.

Table 6 - IP22: Degree of protection against harmful ingress of particulate matter and water.

Ingress Protection Rating: Degree of protection against harmful ingress of particulate matter and water	IP22
Solids Protection Level	2 protected against particulate matter above 12.5 mm
Liquids Protection Level	2 Protected against dripping water when tilted up to 15° from the vertical



CAUTION
Use is incompatible with the simultaneous use of high-frequency surgical equipment.

11.2. About the Battery

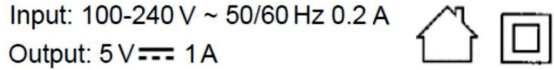
Power supply: CEFALY Enhanced uses a 3.7 V Lithium-Ion Polymer battery that is recharged using the included micro-USB cable and power adapter.

Battery shelf life: 450 cycles of complete charge-discharge.

Maximum input voltage (micro-USB connection): 5.25 Vdc.

11.3. USB Power Adaptor

- The USB adaptor shall be a class II power supply that is IEC 60601-1 Ed 3.1 2012 certified, with two means of operator protection, input 110 V~240 V, 50/60 Hz, max 0.2A and the output is 5 V direct current, 1 A . The USB adaptor shall have below marking



- If you do not have a suitable adaptor, please contact Customer Service for assistance (see page 3).

11.4. Electromagnetic Compatibility

Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 16 cm (5 inches) to any part of the CEFALY Enhanced. Otherwise, degradation of the performance of this equipment could result.

11.5. Guidance and Manufacturer's Declaration- Electromagnetic Emission

The CEFALY Enhanced is intended for use in the electromagnetic environment specified in the table. The customer or the user of the CEFALY Enhanced should ensure that it is used in such an environment.

Electromagnetic Interference

In order to regulate the requirements for ElectroMagnetic Compatibility with the aim of preventing unsafe product situations, the EMC IEC 60601-1-2 4th edition standard has been implemented.



WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it may 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.



WARNING

Use of accessories, transducers and cables other than provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



WARNING

Portable RF communications equipment should be used no closer than 16 cm (5 inches) to any part of the power supply or battery charger, including cables. Otherwise, degradation of the performance of this equipment could result.

Emission test	Compliance	Electromagnetic environment - guidance
Conducted RF emissions - CISPR 11	Not Applicable	
Radiated RF emissions - CISPR 11	Group 1 Class B	The CEFALY Enhanced is suitable for use in all establishments including domestic.
Harmonic current emissions - IEC 61000-3-2	Not Applicable	
Voltage changes, voltage fluctuations and flicker EMISSIONS - IEC 61000-3-3	Not Applicable	

Immunity tests	IEC 60601-1-2 ed.4 Compliance	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD), IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Professional and home healthcare Environment. The humidity shall be at least 30%
Radiated RF electromagnetic field, IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer than 16 cm (5 inches) to any part of CEFALY Enhanced product. Professional and home healthcare Environment.
IMMUNITY to proximity fields from RF wireless communications equipment, IEC 61000-4-3	Levels of table below	Levels of table below	

Conducted RF, IEC 61000-4-6	3V 0.15 — 80 MHz 80% AM at 1kHz 6V in ISM and amateur radio bands between [0.15MHz - 80MHz]	3V 0.15 — 80 MHz 80% AM at 1kHz 6V in ISM and amateur radio bands between [0.15MHz - 80MHz]	Professional and home healthcare Environment.
Electrostatic fast transient / burst, IEC 61000-4-4	Not Applicable	Not Applicable	
Surge, IEC 61000-4-5	Not Applicable	Not Applicable	
Power frequency magnetic field IEC 61000-4-8	30 A/m (50/60 Hz)	30 A/m (50/60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical in all establishments including domestic.
Voltage dips, short interruptions and voltage variations on power supply	Not Applicable	Not Applicable	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Modulation	Immunity test level (V/m)	Applied test level (CEFALY levels allowing to reduce the minimum separation distance to 16 cm instead of 30 cm)
385	380 - 390	Pulse modulation 18 Hz	27	54
450	430 - 470	FM, ± 5 kHz deviation 1 kHz sine	28	54
710	704 - 787	Pulse modulation 217 Hz	9	18
745				18
780				18
810	800 - 960	Pulse modulation 18 Hz	28	54
870				54
930				54

Test Frequency (MHz)	Band (MHz)	Modulation	Immunity test level (V/m)	Applied test level (CEFALY levels allowing to reduce the minimum separation distance to 16 cm instead of 30 cm)
1720	1700 - 1990	Pulse modulation 217 Hz	28	54
1845				54
1970				54
2450	2400 - 2570	Pulse modulation 217 Hz	28	54
5240	5100 - 5800	Pulse modulation 217 Hz	9	18
5500				18
5785				18

11.6. Warranty

90-Day Money-Back Guarantee

CEFALY Enhanced devices purchased directly from www.cefaly.com or CEFALY US, Inc. are covered by a 90-Day Money-Back Guarantee. The guarantee does not include refunds for shipping fees and begins upon the date of your item delivery.

If you decide CEFALY Enhanced is not the right treatment for you, return your CEFALY Enhanced kit postmarked within 90 days from your delivery date, and you will be refunded the purchase price of the CEFALY Enhanced.

To be eligible for a refund, the CEFALY Enhanced and accessories must be in the same condition they were received and in the original packaging. We reserve the right to decline your return if any items have been damaged or modified, or have been in contact with any liquids. If there are any missing parts you will not receive a refund.

Contact Customer Service for our return address and further instruction (see page 3).

Limited Warranty

Your CEFALY device is protected by a three (3) year limited warranty from the original date of purchase when purchased directly from www.cefaly.com or an authorized retailer. It is important after purchasing your device that you complete the product registration on www.cefaly.com to receive this coverage. This limited warranty ensures your device is free of defects in manufacture and workmanship if used in accordance with the instructions provided. Electrodes, charging cables, and other accessories are excluded from this warranty. Please keep your invoice or sales receipt as your Proof of Purchase date.

This limited warranty does not cover damage caused by misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repairs or modifications; improper use of electrical/power supply; dropped product; malfunction or damage of an operating part from failure to provide manufacturer's recommended maintenance and storage; transportation damage; theft; neglect; vandalism; environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of CEFALY Technology.

These limited warranties are effective only if the product is purchased from www.cefaly.com or CEFALY US, Inc. and the product is only operated in the country in which the product is purchased. A product that requires modifications or adoption to enable it to operate in any other country than the country for which it was designed, manufactured, approved and/or authorized, or repair of products damaged by these modifications is not covered under this warranty.

In no event shall CEFALY Technology's liability with respect to any of the products furnished by the company exceed the charges paid by the Customer to CEFALY Technology for such product(s). Customer's sole remedy for any defective product or any other breach of performance shall be the repair or replacement of any defective product furnished by CEFALY Technology. IT IS EXPRESSLY UNDERSTOOD BY CUSTOMER THAT THE FOREGOING REMEDY IS CUSTOMER'S EXCLUSIVE AND SOLE REMEDY.

EXCEPT AS SPECIFICALLY PROVIDED ABOVE, THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE. IN NO EVENT SHALL CEFALY BE LIABLE UNDER ANY THEORY OF LIABILITY FOR INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES.

12. About CEFALY Technology

CEFALY Technology is a global company that has been transforming people's approach to migraine treatment since 2008. CEFALY Technology's mission is to solve the persistent problem of migraine through advanced therapeutic innovations.

While the causes of migraine are not completely understood, current research shows that the largest and most complex cranial nerve, the trigeminal nerve, is heavily involved in the sensation of migraine headache pain. (One trigeminal nerve runs to the right side of the head, while the other runs to the left. Each of these nerves has three distinct branches.)

CEFALY Enhanced has been specifically engineered to modify pain sensation in the trigeminal nerve through its ophthalmic branch, which runs under the skin of the forehead. CEFALY Enhanced magnetically secures to an electrode positioned on the forehead between the eyebrows. Then, it begins sending tiny electrical impulses to the trigeminal nerve, reducing or eliminating migraine pain.

CEFALY Enhanced is trusted and recommended by leading healthcare professionals, as well as hundreds of thousands of people with migraine worldwide. The ACUTE setting is clinically proven to stop or reduce migraine pain during an attack. With compliant daily use, the PREVENT setting is clinically proven to reduce the frequency of migraine days.

13. Glossary

13.1. Terms & Definitions

Migraine - Migraine is a medical condition that causes severe, disabling headaches. A migraine headache involves a throbbing pain in the head accompanied by nausea, vomiting, sensitivity to light, and/or sensitivity to sound.

Aura - Some people experience temporary sensory disturbances, such as blind spots, zigzag patterns, flashes of light, or stars. Such experiences are called aura.

Headache - A general term for pain in any region of the head, not originating from the skin.

Indications for use - Indications for use for a device include a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

Contraindications - A contraindication is a specific situation in which a device, drug, procedure, or surgery should not be used because it may be harmful to the person.

Warning - Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device. Standard warnings relate to significant harm to the user and not to the device.

Caution - Alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, failure, damage to the device or damage to other property.

ACUTE Program - A 60-minute program designed to treat migraine attacks at the onset, to stop or relieve the pain.

PREVENT Program - A 20-minute program designed for the preventative treatment of migraines.

Service Life - A product's service life is its period of use in service. Service life represents a commitment made by the item's manufacturer and is usually specified as a median. It is the time that any manufactured item can be expected to be "serviceable" or supported by its manufacturer.

13.2. Symbols

Symbols	Title of the Symbol	Description of the Symbol
	Consult instructions for use.	This symbol indicates that the user should refer to the User Manual/Instructions for Use before using the device.
	Consult instructions for use.	This symbol indicates that the user should refer to the User Manual/Instructions for Use before using the device.
	Temperature Limit	Indicates the temperature limit to which the device can be safely exposed.
	Type BF Applied Parts	This symbol on the electrode package means type BF applied parts (electrode).
	WEEE Symbol	Indicates Waste Electrical and Electronic Equipment that can have potentially harmful effects on the environment. Incorrect disposal can cause harmful toxins to build up in the air, water, and soil, and can be harmful to humans.

Symbols	Title of the Symbol	Description of the Symbol
	Use-By Date	Indicates the date after which the electrodes are not to be used.
	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	Lithium-ion Battery	Indicates that the device contains recyclable lithium-ion batteries.
	Manufactured By	Indicates the medical device manufacturer.
	Date of Manufacture	Indicates the date when the medical device was manufactured.

Symbols	Title of the Symbol	Description of the Symbol
	Do not use if the package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
IP22	Ingress Protection	Indicates the degree of protection against harmful ingress of particulate matter and water. In this case: Solid Particle Protection level is 2 (fingers or similar objects) Liquid Ingress Protection level is 2 (dripping water when the device is tilted at 15°)
REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
SN	Serial Number	Indicates the manufacturer's serial number so that the specific medical device can be identified.
LOT	Batch Code	To identify the manufacturer's batch or lot code.

Symbols	Title of the Symbol	Description of the Symbol
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Warning	Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device. Standard warnings relate to significant harm to the user and not to the device.
	Caution	Alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, failure, damage to the device or damage to other property.
	FCC Mark	The FCC Mark indicates that the electromagnetic radiation from the device is below the limits determined by the Federal Communications Commissions. This also indicates the manufacturer has followed the requirements of the Supplier's Declaration of Conformity authorization procedures.

14. Compliance Statement

14.1. FCC - Regulatory Compliance Statement

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.

Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

CAUTION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

14.2. ISED Canada - Regulatory Compliance Statement

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

14.3. FCC & IC Radiation Exposure Statement

This equipment complies with FCC and Canada radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The **CEFALY Enhanced** device Is A Patented Model And Is Protected By An International Patent. CEFALY® Is A Trademark That Has Been Registered Internationally.

The CEFALY Enhanced Is Manufactured In Conformity With ISO 13485 And GMP.

The Manufacturer Is ISO 13485 (Medical) Certified. CEFALY Enhanced Is A Class II Medical Device.

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