



  
**CEFALY**  
*DUAL*

**USER MANUAL**



NON-INVASIVE



PORTABLE



COMFORTABLE



WEARABLE



DRUG-FREE

CEFALY® DUAL is the first FDA-cleared medical device of its kind for the treatment of migraine.

**CEFALY DUAL is indicated to be used for:**

- The acute treatment of migraine with or without aura in patients 18 years of age or older.
- The preventative treatment of episodic migraine in patients 18 years of age or older.

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

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 DUAL has not been demonstrated for patients with medication overuse headache or chronic tension-type headaches.

For assistance, please contact us as follows:



Website: [www.cefaly.com](http://www.cefaly.com)



Email: [info@cefaly.us](mailto:info@cefaly.us)



Phone: 1-844-475-7100

To view this user manual in Español, please visit  
[cefaly.com/start](http://cefaly.com/start)

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## Critical CEFALY DUAL Facts

Read this user manual thoroughly before using CEFALY DUAL.

### Uses

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

### Who Should Use CEFALY DUAL

- The acute treatment of migraine with or without aura in patients 18 years of age or older.
- The preventative treatment of episodic migraine in patients 18 years of age or older.

*See page 68 of this manual on how to differentiate migraine from other types of headaches.*

### **Operating and Storage Conditions**

#### **Use CEFALY DUAL**

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 DUAL**

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 (500hPa to 1060hPa).

**If further assistance is required, contact Customer Service at [cs@cefaly.com](mailto:cs@cefaly.com) or 1-844-475-7100.**

# 1. Safety Information

## 1.1. Purpose

---

This user manual describes the proper use of CEFALY DUAL.

## 1.2. Indications for Use

---

CEFALY DUAL is for patients diagnosed by a physician with migraines per the FDA cleared indications for use.

CEFALY DUAL is the first FDA-cleared medical device of its kind for the treatment of migraine.

CEFALY DUAL is indicated to be used for:

- The acute treatment of migraine with or without aura in patients 18 years of age or older.
- The preventative treatment of episodic migraine in patients 18 years of age or older.

### *Safety Information*

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 DUAL has not been demonstrated for patients with medication overuse headache or chronic tension-type headaches.

#### **Notes:**

- Episodic migraine is defined as 1-14 headache days per month with associated migraine symptoms (nausea, photophobia, phonophobia, etc).

### **1.3. Contraindications**

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#### **Contraindications**

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

Do not use CEFALY DUAL 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.
- Some important information has been provided as footnotes. The respective text for which the footnote has been added contains superscript reference numbers.

## Safety Information



It is important that you read all the precautions and warnings included in the manual before using CEFALY DUAL 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 DUAL. Standard warnings relate to significant harm to the user and not to CEFALY DUAL.



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

## 1.5. General Warnings and Cautions



### WARNINGS

- Do not use CEFALY DUAL while sleeping.
- Do not use CEFALY DUAL in a wet environment, such as in the bath or shower.
- Do not use CEFALY DUAL 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 DUAL and electrodes are designed for and should be used only in the forehead region.
  - Do not use CEFALY DUAL in the neck region.

### *Safety Information*

- While CEFALY DUAL's design prevents this, do not use CEFALY DUAL close to the thorax (chest region).
- Use CEFALY DUAL 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 DUAL if there has been any loss of feeling in the skin of your forehead or scalp until the normal feeling is resumed.
- Use CEFALY DUAL only with the electrodes and accessories recommended by CEFALY Technology.



- Keep the CEFALY DUAL 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 DUAL 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.

### *Safety Information*

- 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 DUAL 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 DUAL 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.

### *Safety Information*



#### **CAUTION**

- You should ask your doctor before using the CEFALY DUAL device if you have ever had a seizure. You should ask your doctor before using the CEFALY DUAL device if you have been diagnosed with epilepsy.
- The CEFALY DUAL device will not cure your migraines.
- The long-term effects of chronic use of the unit are unknown.
- You should use this unit only with the electrodes and accessories recommended by the manufacturer.
- Do not use CEFALY DUAL in close proximity (less than 3.5 feet) to shortwave or microwave therapy equipment, as it may produce instability in the CEFALY DUAL output.
- Use is incompatible with the simultaneous use of high-frequency surgical equipment.
- It may be dangerous to connect the CEFALY DUAL with devices not identified in this user manual.

- Do not modify this equipment without written authorization from the manufacturer.
- The CEFALY DUAL 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.

## **1.6. Side Effects**

---

CEFALY DUAL 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 DUAL and consult your healthcare provider or seek immediate medical attention.

## Safety Information

### Common

- *Sleepiness*

The main side effect is a tendency towards sleepiness. This means that CEFALY DUAL 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 DUAL 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 DUAL 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.

## *Safety Information*



### **CAUTION**

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



## 2. About CEFALY DUAL

### 2.1. What's Included in the CEFALY DUAL Package

---

When you receive and open your CEFALY DUAL migraine treatment kit, you should find one of each of the following items numbered 1-5:

## About CEFALY DUAL



Fig. 1 Contents of the Package

### *About CEFALY DUAL*

- 1. CEFALY DUAL:** The CEFALY DUAL 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:** The electrode adheres to the skin on the forehead and allows the treatment signal from the CEFALY DUAL to pass through the trigeminal nerve. The electrode is reusable for up to 20 applications.
- 3. Instruction Manual:** The manual includes instructions to help you set up and use your CEFALY DUAL.
- 4. Power Adapter and Cable:** These are used to recharge the CEFALY DUAL battery.
- 5. Storage Case:** Use for storage of CEFALY DUAL, electrode, power adapter, and cable.

## About CEFALY DUAL

### 2.2. Physical Description of CEFALY DUAL and Electrode

CEFALY DUAL comes with two accessories, the electrode and the power adapter and cable. The power adapter and cable are only used for charging CEFALY DUAL.

#### CEFALY DUAL

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

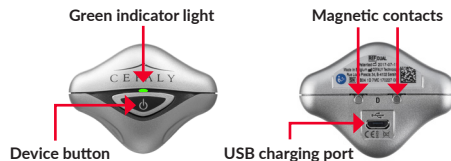


Fig. 2 Description of CEFALY DUAL

Table 1 - Parts of the CEFALY DUAL

Part	Location	Functionality
Device button	Front	Used to turn on CEFALY DUAL and activate the treatment programs (ACUTE and PREVENT).
Green indicator light	Front	Used to indicate the status of the CEFALY DUAL to user.
USB charging port	Rear	Used for connecting the charger to charge CEFALY DUAL.
Magnetic contacts	Rear	Used to connect CEFALY DUAL to the electrode that transmits the stimulations to the user.

## About CEFALY DUAL

### Electrode

The CEFALY DUAL electrode is 3.7 in. long and 0.78 in. high, and comes in a silver packet. It acts as the interface between the CEFALY DUAL and the skin. The electrode has two contact zones that connect with the CEFALY DUAL 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 DUAL and the electrode.



**Notes:**

- Use electrodes before the “Use-By Date” printed on the silver packet.
- 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 DUAL Status

The CEFALY DUAL 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 DUAL




Device Operation	Action	Feedback
Charging	Charging cable is connected to CEFALY DUAL.	 Intermittent flashing of the LED indicator.
Fully Charged	Charging cable is connected to CEFALY DUAL.	 Solid glow on the LED indicator.



Device Operation	Action	Feedback
ACUTE Program	Press the device button once.	 Single beep indicates activation of the program.   Single flash throughout the treatment.
PREVENT Program	Press the device button twice.	 Two beeps indicate activation of the program.   Two intermittent flashes throughout the treatment.

### About CEFALY DUAL

Device Operation	Action	Feedback
Increase Intensity	Long press device button after the first 10 seconds of the treatment.	Intensity of the treatment slowly increases until the device button is released.
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.
Maximum Intensity	Long press device button for 30 seconds after the first 10 seconds of the treatment.	 Series of rapid beeps to indicate that the device has reached maximum intensity.

Device Operation	Action	Feedback
Restart Treatment Session During Last 45 Seconds Of Treatment	Press the device button once during the last 45 seconds of the treatment when the treatment is ending.	 <p>Single beep indicates that the treatment session has been restarted.</p>
End Treatment	Remove the device from the electrode.	 <p>Series of successive beeps indicate that the treatment has been stopped/interrupted.</p>
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.	 <p>Series of successive beeps indicate that the treatment has been stopped/interrupted.</p>

## 2.4. Best Practices and Recommendations

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Read the following sections (i.e. Setting up CEFALY DUAL, Preparing for Migraine Treatment, Delivering Migraine Treatment, and Care Information) thoroughly before operating the CEFALY DUAL. Refer to page 8 for the Critical CEFALY DUAL Facts.

Cleanse your skin before every treatment session. This will ensure the electrode attaches securely to the skin.

CEFALY DUAL 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.

### About CEFALY DUAL

The magnetic contacts of the CEFALY DUAL 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 sleeve and slide the sleeve back into the original packet.

After successfully completing your treatment, pack your CEFALY DUAL and electrode away in the storage case until you are ready for your next treatment.

## 3. Setting Up CEFALY DUAL

### 3.1. Open the CEFALY DUAL Package

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



Fig. 4 Contents of the Package

1. CEFALY DUAL
2. Electrode
3. Instruction Manual
4. Power Adapter and Cable
5. 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 DUAL treatment session, fully charge the battery (this typically takes 3 hours to complete).
- As shown in Fig. 5, connect the micro-USB plug to the back side of your CEFALY DUAL. Then, connect the USB plug to the power adapter (Fig. 6) and plug the adapter into a power source.
- While charging, the indicator light on the front of the CEFALY DUAL will flash intermittently. The flashing will accelerate as the battery comes closer to a full charge. Once fully charged, the indicator light on the front will remain on (Fig. 7).



Fig. 5



Fig. 6

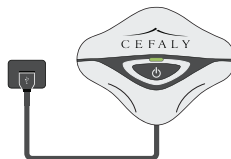




Fig. 7

### Setting Up CEFALY DUAL

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

Status	Action	Feedback from the CEFALY DUAL
Charging	Charging cable is connected to CEFALY DUAL.	 Intermittent flashing of the LED indicator.
Fully Charged	Charging cable is connected to CEFALY DUAL.	 Solid glow on the LED indicator.



## 4. Preparing for Migraine Treatment



Fig. 8

### 4.1. Clean Your Skin

- It is important to cleanse your skin before every CEFALY DUAL session. This will help ensure the electrode attaches securely to your forehead.
- 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 is NOT recommended as a substitute for soap and water.



#### WARNING

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

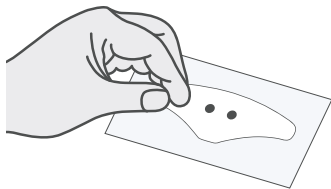
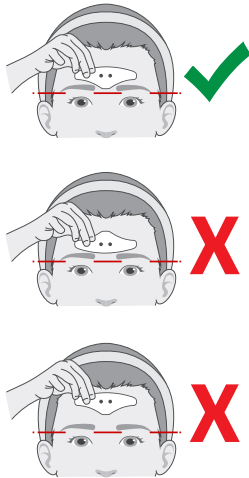


Fig. 9

## 4.2. Open the Electrode

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- Open the electrode packet and slide out the plastic sleeve and peel the electrode from the clear plastic sleeve (Fig. 9).
- Save both the packet and sleeve for later use and storage of your electrode.



**Fig. 10**

### **4.3. Position the Electrode on Your Skin**

- Use a mirror to place the electrode on your forehead with the pointed edge down and in line with the bottom of your forehead as shown 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.

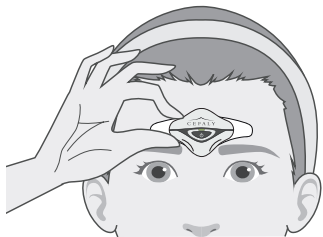


Fig. 11

#### 4.4. Attach CEFALY DUAL to the Electrode

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- On the back of your CEFALY DUAL there are two magnets that allow the device to securely attach to the electrode.
- Hold your CEFALY DUAL so these magnets are exposed and bring it toward your forehead. The CEFALY DUAL will pull itself toward the electrode and automatically settle into its proper place. (Fig. 11)

## 5. Delivering Acute Migraine Treatment (Program 1 – ACUTE)

### 5.1. Choose the ACUTE Treatment Program

Once your CEFALY DUAL 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.

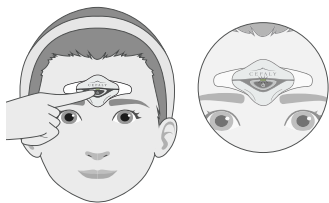


Fig. 12

### 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)



### *Delivering Acute Migraine Treatment*

This is a 60-minute program designed to **treat migraine attacks when they begin**, to stop or relieve your migraine pain. 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 DUAL green indicator light will flash once throughout the program to aid in treatment monitoring. It may take several seconds for flashing to begin.

### *Delivering Acute Migraine Treatment*

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

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

#### **Notes:**

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

## *Delivering Acute Migraine Treatment*



### **CAUTION**

The acute treatment session for CEFALY DUAL (Program 1 - ACUTE Treatment) 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**

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- Throughout this 60-minute program, the CEFALY DUAL light will flash 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. Gradually, the intensity will increase and you'll start to feel vibrations or a tingling effect 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.

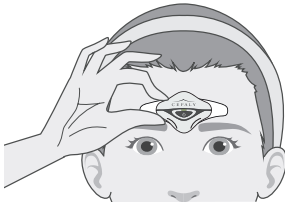
### *Delivering Acute Migraine Treatment*

During the first 14 minutes of the ACUTE treatment session, the intensity will automatically increase and then stabilize for the remainder of your treatment.

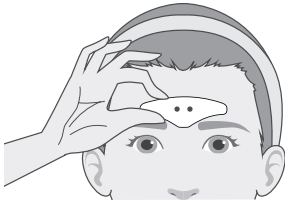
At the end of the treatment, when you remove the electrode, your skin may appear reddened where the electrode was placed. This redness may last a few minutes and is an indication the device has stimulated blood flow to the area.

#### **Notes:**

- For the best results, you should aim to use CEFALY DUAL at the highest intensity level. Gradually increase the intensity with each treatment for your skin to get used to the stimulation.



**Fig. 13**



**Fig. 14**

## **5.4. Ending Your ACUTE Treatment**

- At the end of your selected treatment session, you will stop feeling sensations from your CEFALY DUAL and it will automatically shut off.
- You can now remove the CEFALY DUAL 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 sleeve and slide the sleeve back into the packet.
- After successfully completing your treatment, pack your CEFALY DUAL and electrode away in the storage case until you are ready for your next treatment.

## 6. Delivering Preventative Migraine Treatment (Program 2 – PREVENT)

### 6.1. Choose the PREVENT Treatment Program

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Once your CEFALY DUAL is securely attached to the electrode on your forehead, you're ready to select your treatment program. For the preventative treatment of episodic 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.

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 DUAL green indicator light flashes twice throughout the program to aid in treatment monitoring. It may take several seconds for flashing to begin.

### *Delivering Preventative Migraine Treatment*

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

Status	Action	Feedback from CEFALY DUAL
PREVENT Program	Press the device button twice.	 Two beeps indicate activation of the program.   Two intermittent flashes throughout the treatment.

#### **Notes:**

- With proper daily use of the PREVENT program, you may see a reduction in your number of migraine days.

## *Delivering Preventative Migraine Treatment*

- The PREVENT Treatment program 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**

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- Throughout this 20-minute program, the CEFALY DUAL light will flash 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**

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For the first few minutes of your PREVENT treatment session, the sensation is light and it's possible you may not feel anything. Gradually, the intensity will increase and you'll start

### *Delivering Preventative Migraine Treatment*

to feel vibrations or a tingling effect 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 automatically increase and then stabilize for the remainder of your treatment.

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.

#### **Notes:**

- For the best results, you should aim to use CEFALY DUAL at the highest intensity level. Gradually increase the intensity with each treatment for your skin to get used to the stimulation.

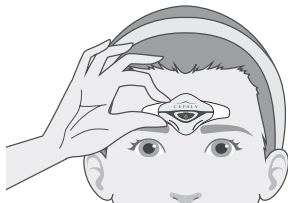


Fig. 15



Fig. 16

## 6.4. Ending Your PREVENT Treatment


- At the end of your PREVENT treatment session, you will stop feeling sensations from your CEFALY DUAL and it will automatically shut off.
- You can now remove the CEFALY DUAL by pulling it away from the electrode (Fig. 15). Then gently detach the electrode from your skin (Fig. 16).
- To ensure optimal use of your electrode for future sessions, place it back on the plastic sleeve and slide the sleeve back into the packet.
- After successfully completing your treatment, pack your CEFALY DUAL and electrode away in the storage case until you are ready for your next treatment.



## 7. Controlling Your Treatment (ACUTE or PREVENT)

### Pausing Intensity During First 14 Minutes

- During either treatment program, if you feel any discomfort while the intensity increases during the first 14 minutes, you may press your device button once to stabilize the intensity level for the remainder of the treatment session.
- You will hear a single beep as confirmation. See table for feedback from CEFALY DUAL.


Status	Action	Feedback from CEFALY DUAL
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.

## **Manually Increasing the Intensity During First 14 Minutes**


Once 10 seconds have elapsed since the start 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 DUAL.

## Controlling Your Treatment


Status	Action	Feedback from CEFALY DUAL
Increase Intensity	Long press device button after the first 10 seconds of the treatment.	Intensity of the treatment slowly increases until the device button is released.
Maximum Intensity	Long press device button for 30 seconds after the first 10 seconds of the treatment.	 Series of rapid beeps to indicate that the device has reached maximum intensity.

### *Controlling Your Treatment*

Status	Action	Feedback from CEFALY DUAL
Restart Treatment Session During Last 45 Seconds Of Treatment	Press the device button once during the last 45 seconds of the treatment when the treatment is ending.	 Single beep indicates that the treatment session has been restarted.

### **Stopping Your Session Early**


- If at any point you need to stop your treatment session, simply remove your CEFALY DUAL 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 DUAL.

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

## Accidental Interruptions

The electronics involved in CEFALY DUAL 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 DUAL.

### *Controlling Your Treatment*

Status	Action	Feedback from CEFALY DUAL
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 indicate that the treatment has been stopped/interrupted.

## 8. Care Information

### 8.1. Cleaning and Maintenance

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The magnetic contacts of the CEFALY DUAL 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 DUAL 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. With proper use and storage, an electrode may last up to 20 sessions.

#### **Power Adapter & 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.

## **8.2. Operating and Storage Conditions**

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Use CEFALY DUAL 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 the CEFALY DUAL 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 (500hPa to 1060hPa)

## **8.3. Disposal**

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When your CEFALY DUAL 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 DUAL or your use. Check the troubleshooting table for a solution if a problem should arise with your CEFALY DUAL. **If further assistance is required, contact Customer Service at [cs@cefaly.com](mailto:cs@cefaly.com) or 1-844-475-7100.**

Table 7 - Troubleshooting

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

**Possible Cause:**

- The battery charge is too low.

**Solution:**

- Recharge the battery for at least 5 minutes to complete a full session; ideally, charge for 3+ hours to charge the CEFALY DUAL fully.

### *Troubleshooting*

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

##### **Possible Cause:**

- Your electrode is not sticking well to your forehead.
- Your CEFALY DUAL 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 DUAL 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 DUAL is properly positioned on the electrode. The magnetic contacts on the CEFALY DUAL must be properly secured by the corresponding magnetic contact zone on the electrode for the CEFALY DUAL

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 for at least 5 minutes to complete a full session; ideally, charge for 3+ hours to charge the CEFALY DUAL fully.

**Problem #03 - I cannot feel any stimulation.**

**Possible Cause:**

- Your electrode is not sticking well to your forehead.
- Your CEFALY DUAL is not properly secured to the electrode.
- Once accustomed to the sensations experienced while using the CEFALY DUAL you may feel desensitized to its lower-strength pulses at the beginning of a session.

### *Troubleshooting*

- You accidentally pressed the device button to stabilize your treatment at a low intensity level, prohibiting it from increasing.
- Your CEFALY DUAL is not turned on.

#### **Solution:**

- Cleanse your skin again with soap and water, and pat dry. Then reposition the electrode, attach the CEFALY DUAL 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 DUAL is properly positioned on the electrode. The magnetic contacts on the CEFALY DUAL must be properly secured by the corresponding magnetic contact zone on the electrode for the CEFALY DUAL 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 DUAL 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 DUAL does not power on, use the micro-USB cable and the adapter to charge it for 3+ hours. If this is your first time using the CEFALY DUAL it must be fully charged. Once your CEFALY DUAL is fully charged,

### *Troubleshooting*

the indicator light will remain turned on. If this is not your first time using your CEFALY DUAL and it is not powering on, charging for 5 minutes should allow it to turn on and get you through a full session.

#### **Problem #04 - The intensity feels too high.**

##### **Possible Cause:**

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

##### **Solution:**

- To make treatment more enjoyable, we recommend you increase the intensity in small increments of time, over the course of a few weeks. If you feel the intensity is too strong for you, simply press the device button once during a session to stabilize the pulses at a tolerable level for the remainder of the session.

**Problem #05 - The intensity feels too low.**

**Possible Cause:**

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

**Solution:**

- 10 seconds after you've selected your session, you may press and hold the device button to quickly ramp up the 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.

## *Troubleshooting*

### **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 DUAL 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 DUAL 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 DUAL and speak with your healthcare provider. Before using your CEFALY DUAL 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 DUAL.
- 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 DUAL sessions. If you experience any one or more of these conditions and it (they) persists, both during

### *Troubleshooting*

sessions and while not using CEFALY DUAL, for more than a few weeks, stop use and consult your healthcare provider.

- Consult your healthcare provider about experiencing these symptoms with your migraine.

#### **Problem #08 - The CEFALY DUAL does not power on.**

##### **Possible Cause:**

- The CEFALY DUAL does not have enough charge.
- Your electrode is not sticking well to your forehead.
- Your CEFALY DUAL is not properly secured to the electrode.

##### **Solution:**

- Use the micro-USB cable and the adapter to connect your CEFALY DUAL to a power source for 3+ hours. If this is your first time using the CEFALY DUAL it must be fully charged. Once fully charged, the indicator light will remain turned on. If

you've charged your CEFALY DUAL and it is still not powering on, contact CEFALY Technology for further assistance.

- Cleanse your skin again with soap and water, and pat dry. Then reposition the electrode, attach the CEFALY DUAL 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 DUAL is properly positioned on the electrode. The magnetic contacts on the CEFALY DUAL must be properly secured by the corresponding magnetic contact zone on the electrode for the CEFALY DUAL 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.

## 10. Self-Care for Migraines

### 10.1. How Do I Differentiate Headache from Migraine?

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**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. 15).

## **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. 15 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.

### *Self-Care for Migraines*

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
- 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 DUAL Device

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**Maximum output current:** 16 mA (milliamps)

**Pulse width:** 250  $\mu$ s (microseconds)

**Maximum phase charge:** 5  $\mu$ C (microcoulombs)

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

**Number of programs:** 2

**Device service life:** 7 years

**Charging system service life:** 7 years

**Device Casing:** PC plastic, painted

**Dimensions:** ~2.17 in x 1.57 in x 0.59 in ( 55 mm x 40 mm x 15 mm)

**Weight:** 12 g

Table 4 - Program Parameters

Parameters	ACUTE	PREVENT
Pulse Frequency	100 Hz	60 Hz
Pulse Width	250 $\mu$ s	250 $\mu$ s
Pulse Duration	500 $\mu$ s	500 $\mu$ s
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

## *Technical Information*

### **Device Electrical Specifications**

For a charge between 0 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 2mA/ cm<sup>2</sup> requires special attention from the operator.

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

### **Device Temperature Specifications**

When the CEFALY DUAL is operated at an ambient temperature of 95°F the temperature of the electrode will stay below 104°F.

Table 5 - 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.

## *Technical Information*

### **11.2. About the Battery**

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

**Battery shelf life:** 300 cycles of complete charge-discharge. Maximum input voltage (micro-USB connection): 5,25 Vdc.

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

### **11.3. Electromagnetic Compatibility**

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Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CEFALY DUAL. Otherwise, degradation of the performance of this equipment could result.

Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies may affect this equipment and should be kept at least 11 feet away.

#### 11.4. Guidance and Manufacturer's Declaration- Electromagnetic Emission

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

Table 6 - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic environment -guidance
RF emissions CISPR 11	Group 1	The CEFALY DUAL device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CEFALY DUAL device 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 Applicable	
Voltage fluctuations/flicker emissions IEC 61000 - 3 - 3	Not Applicable	

## *Technical Information*

### **11.5. Warranty**

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#### **60-Day Money-Back Guarantee**

CEFALY DUAL devices purchased directly from [www.cefaly.com](http://www.cefaly.com) or CEFALY US, Inc. are covered by a 60-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 DUAL is not the right treatment for you, return your CEFALY DUAL kit post-marked within 60 days from your delivery date, and you will be refunded the purchase price of the CEFALY DUAL.

To be eligible for a refund, the CEFALY DUAL 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.

**Email [cs@cefaly.com](mailto:cs@cefaly.com) or call 1-844-475-7100 for our return address and further instruction.**



## Limited Warranty

Your CEFALY DUAL is protected by a three (3) year limited warranty from the original date of purchase when purchased directly from [www.cefaly.com](http://www.cefaly.com) or CEFALY US, Inc. This limited warranty ensures your CEFALY DUAL 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](http://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

### *Technical Information*

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 DUAL 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 DUAL 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 DUAL 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

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**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.







## Glossary

### 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.
	FDA Registered	This indicates that the organization is registered with the U.S. FDA in order to legally market the device in the United States of America.

Symbols	Title of the Symbol	Description of the Symbol
	CE Mark	Indicates conformity to the requirements of the Medical Device Directive (93/42/EEC). 0459 is the number of the notified body (GMED). The CE mark applied also indicates that this equipment complies with the requirements of the ROHS Directive (2011/65/EU) for the Restriction of Hazardous Substances in Electrical and Electronic Equipment.
	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.




## Glossary

Symbols	Title of the Symbol	Description of the Symbol
	Use-By Date	Indicates the date after which the medical device is 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.
	Green Dot Symbol	Indicates that a financial contribution has been paid to a qualified national packaging recovery organization.



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	<p>Indicates the degree of protection against harmful ingress of particulate matter and water.</p> <p>In this case: Solid Particle Protection level is 2 (fingers or similar objects)</p> <p>Liquid Ingress Protection level is 2 (dripping water when the device is tilted at 15°)</p>
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Serial Number	Indicates the manufacturer's serial number so that the specific medical device can be identified.

## Glossary

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.





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

The CEFALY DUAL Is Manufactured In Conformity With Iso 13485 And GMP.

The Manufacturer Is ISO 13485 (Medical) Certified. The CEFALY DUAL Is CE Marked And Complies With The Provisions Of Directive 93/42/EEC On Medical Devices.

CEFALY DUAL Is A Class II Medical Device.

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