



CEFALY
DUAL

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TABLE OF CONTENTS

INDICATIONS FOR USE	6
CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS	7
1. Contraindications	7
2. Warnings	7
3. Precautions	8
4. Adverse reactions	9
DESCRIPTION OF THE CEFALY® DUAL AND ACCESSORIES	10
1. Set Cefaly® Dual	10
2. Cefaly® Dual device	10
3. Cefaly® electrode	11
DIRECTIONS FOR USE	12
1. Practical use	12
<i>Preparing the session</i>	<i>12</i>
1. Cleansing and degreasing the skin	12
2. Removing an electrode	13
3. Positioning the electrode	13
4. Positioning the Cefaly® Dual device	14
<i>Selecting and starting the program</i>	<i>15</i>
1. Program 1: Acute treatment	15
2. Program 2: Prevention	15

<i>During the session</i>	16
1. Conducting the session	16
2. Controlling the intensity	16
3. Interrupting the session	17
4. Accidental interruption: defective electrode	17
<i>After the session</i>	18
1. Removing the device	18
2. Detaching and stowing the electrode	18
2. Sensations	19
3. Frequency and timing of sessions	20
<i>Treating attacks</i>	20
<i>Preventive treatment</i>	20
PRACTICAL INFORMATION	21
1. Electrodes	21
2. Operating conditions	21
3. Storage conditions	21
4. Charging the battery	22
5. Cleaning your unit and device maintenance	23
6. Guarantee	23
TROUBLESHOOTING	24
TECHNICAL INFORMATION	25

INDICATIONS FOR USE

The Cefaly® Dual device is indicated for:

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

Caution: Federal law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

1. CONTRAINDICATIONS

1. Subjects with implanted metallic or electronic device in the head.
2. Subjects suffering from pain of unknown origin.
3. Subjects who have a cardiac pacemaker or implanted or wearable defibrillator. This may cause interference with pacing, electric shock, or death.

2. WARNINGS

1. Use the Cefaly® Dual device and Cefaly® electrode only on the forehead.
2. Do not apply on the neck.
3. Do not apply on the chest.
4. Do not apply over open wounds. Do not apply over swollen, infected or inflamed areas. Do not apply over skin eruptions.
5. Do not apply over, or close to, cancerous lesions (skin abnormalities that could be cancer).
6. Do not use in the presence of electronic monitoring equipment (e.g., cardiac monitors, electrocardiogram (ECG) alarms).
7. Do not use in the bath or shower.
8. Do not use while sleeping.
9. Do not use while driving. Do not use while operating machinery. Do not use during any activity that can put you at risk of injury.
10. Apply stimulation only to normal, intact, clean skin.
11. The long-term effects of using the Cefaly® Dual are unknown.
12. Migraines may indicate that you have a serious medical condition. You should have them checked by a doctor.
13. If the frequency of your headache is not reduced after 2 or 3 months of daily use of Program 2 (prevention), ask your doctor.

14. 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.

3. PRECAUTIONS

1. You should ask a doctor before using the Cefaly® Dual device if you are, could be or could become pregnant.
2. You should ask your doctor before using the Cefaly® Dual device if you suspect or know that you have problems with your heart.
3. 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.
4. If you have had a recent head injury, you should not use the Cefaly® Dual device until you have fully recovered.
5. You should use caution if there has been any loss of feeling in the skin of your forehead or scalp.
6. The safety and effectiveness of the Cefaly® Dual device has not been demonstrated for subjects with medication overuse headache, chronic tension-type headache, and refractory migraine.
7. The Cefaly® Dual device will not cure your migraines.
8. The long-term effects of chronic use of the unit are unknown.
9. You should use this unit only with the electrodes and accessories recommended by the manufacturer.

4. ADVERSE REACTIONS

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.

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.

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.

Nausea

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

Headache after a session

Approximately 0.5% of subjects reported a headache after a session of preventive treatment (Program 2).

Tooth pain

In very rare cases, some patients have reported transitory tooth pain during a session.

DESCRIPTION OF THE CEFALY® DUAL AND ACCESSORIES

1. SET CEFALY® DUAL

The set Cefaly® Dual has the following elements:

- 1 Storage case
- 1 Instruction manual
- 1 Cefaly® electrode
- 1 Cefaly® Dual device
- 1 Power adapter
- 1 Cable



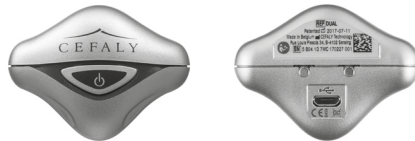
2. CEFALY® DUAL DEVICE

Cefaly® Dual device is in PC plastic having the following characteristics:

- Silver color painted
- Dimensions: 55 mm x 40 mm x 15 mm
- Weight: 12 g

Front side: The front side has a single button to switch on the device, select the stimulation program and adjust the intensity.

Rear side: The backside has two magnets for the connection with the electrode and a connector for charging the battery.



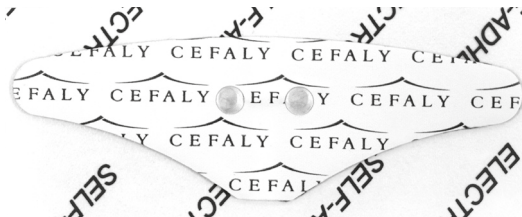
3. CEFALY® ELECTRODE

Cefaly® Dual works with a unique self-adhesive electrode applied on the forehead.

Only the Cefaly® electrode is appropriate to work with the Cefaly® Dual device because of a specific connection between the device and the electrode.

Cefaly® electrode is 94 mm long and 30 mm high. It makes the interface between the device and the skin. It's a reusable electrode designed to be used 20 times.

The electrode has two contact zones that connect with the Cefaly® Dual device through magnets.



DIRECTIONS FOR USE

1. PRACTICAL USE

Preparing the session

Before first use, please fully charge the device (see p. 22).

1. Cleansing and degreasing the skin

It is essential to cleanse and degrease the skin thoroughly before the session to ensure a good quality skin-electrode interface. Use water and soap to cleanse and degrease the forehead skin. Do not use make-up removal products because they leave a greasy film on the skin.

Cleanse the skin on the area between the eyebrows and forehead (see **Figure 1**). Pay special attention to the whole of the area where the electrode will be placed: the main part of the forehead and between the eyebrows. This step is essential to ensure that the electrode grips and that the session is effective.

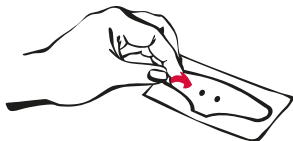
FIGURE 1



2. Removing an electrode

Remove an electrode from its plastic support, holding it by one of its two tips (see **Figure 2**). The quality of the treatment depends on the quality of the electrodes. They are designed to be used 20 times, providing that the skin has been cleansed thoroughly and degreased before the electrode is applied. Electrodes that have been overused lose their capacity to transmit electrical impulses and the treatment is consequently ineffective.

FIGURE 2



3. Positioning the electrode

Use a mirror to correctly position the electrode (see **Figure 3**).

FIGURE 3



The pointed part is placed downwards with the lower edge placed exactly on the horizontal line that joins both eyebrows (see **Figure 4**). Press your fingers several times along the entire surface of the electrode so that it grips your skin firmly. The effectiveness of the treatment depends on the quality of the contact between the electrode and the skin.

FIGURE 4



4. Positioning the Cefaly® Dual device

Two magnets allow to fix the device on the electrode. Hold the device and bring the rear side of the device with the two magnets against the central part of the electrode. The device is attracted by the two contact zones of the electrode and gets automatically into position (see **Figure 5**).

FIGURE 5



Selecting and starting the program

Press the button (see **Figure 6**) to select and start the session. An indicator light above the button will begin to flash signaling the device is working properly.



FIGURE 6

Press 1 x : Start prg. ①

Press 2 x : Start prg. ②

1. Program 1: Acute treatment

Press the button once to select and start **Program 1**. You will hear a single beep. **Program 1** is designed to treat migraine attacks.

2. Program 2: Prevention

Press the button twice in succession to select and start **Program 2**. You will hear two successive beeps. As **Program 2** is designed to prevent migraine it is used during pain-free periods.

During the session

1. Conducting the session

A session of Program 1 lasts sixty minutes and a session of Program 2 lasts twenty minutes. It runs automatically and step by step. During the first few minutes, the sensation is very weak, even imperceptible. Nothing or almost nothing is felt as the impulses are very light. A vibration or tingling sensation then appears which increases. When this sensation becomes sufficiently intense, pressing the button once will stabilize it. The intensity reduces at the end of the sixty (Program 1) or twenty (Program 2) minutes and the session stops automatically.

2. Controlling the intensity

The intensity will gradually increase during the first 14 minutes. When the sensation becomes too intense, press the button just once to stabilize the intensity. The session always ends after sixty (Program 1) or twenty (Program 2) minutes, but the intensity remains at the same level until it stops. You can as well increase again the intensity by pressing continuously on the button: as long as you press on the button the intensity increases, and it stabilizes as soon as you release the pressure on the button.

The sensations will feel unusual at first but you will soon become accustomed to them after a few sessions, and consequently be able to work with the maximum intensity possible (i.e. without restricting the intensity).

3. Interrupting the session

To stop the session before its end, just remove the device by pulling it forwards (see **Figure 7**) and the session automatically stops. Four series of 3 successive beeps indicate the disconnection of the device and the interruption of the session.

FIGURE 7



4. Accidental interruption: defective electrode

Cefaly® Dual could interrupt the session by itself. This unintentional spontaneous interruption means that either the skin has not been fully cleansed or the electrode has not been placed correctly or is not intact. It may also mean that the two magnets of the device need to be cleaned. In this case, four series of 3 successive beeps indicate the disconnection of the device and the interruption of the session.

After the session

1. Removing the device

The session ends after sixty (Program 1) or twenty (Program 2) minutes, and the device automatically switches off. Remove the device by pulling it forwards (see **Figure 8**).

FIGURE 8



2. Detaching and stowing the electrode

Detach the electrode from your skin by holding one of its tips (see **Figure 9**). Replace the electrode on its transparent plastic support sheet. Then store it in its bag. Do not leave the electrode uncovered in a dry place to prevent it from becoming dehydrated. Once the gel loses its moisture, its properties deteriorate and the electrode ceases to be effective.

FIGURE 9



2. SENSATIONS

The sensations induced by the Cefaly® Dual are unusual and unexpected.

- Cefaly® Dual generates electrical impulses very gradually. During the first two minutes, either nothing is felt or a slight tingling sensation under the electrode. A lack of sensation for one or two minutes does not mean that the device is not working; it simply means that the impulses produced are below the stimulation threshold of the nerve fibers.
- Tingling sensations are then felt in the skull, making you feel as if your hair is standing on end.
- The sensation of vibration or massage increases and spreads very gradually to the whole of the forehead and the front part of the skull. The Cefaly® Dual increases the intensity very gradually. After about fourteen minutes, the intensity stabilizes and remains constant until the treatment session is over.
- The sensation can last for several minutes to several hours after the session.

3. FREQUENCY AND TIMING OF SESSIONS

Treating attacks

Program 1 should be used for a 60-minute session during a migraine attack. The session can be done anytime during the day or evening. During the session, simple tasks as reading or watching TV can be done.

Program 1 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.

Preventive treatment

Program 2 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. The session can be done anytime during the day or evening. During the session, simple tasks as reading or watching TV can be done.

PRACTICAL INFORMATION

1. ELECTRODES

- Electrodes have to be used before the date printed on their sachet.
- Once you open the bag, the electrode can be used during up to one month.
- The same electrode can be used for 20 sessions.
- To keep the electrode quality it is essential to cleanse and degrease the forehead skin thoroughly before the session. Use water and soap to cleanse and degrease the forehead skin. After a session, place the electrode on its transparent plastic support sheet. Then store it in its bag.
- Do not use the same electrode on several different people. For important reasons of hygiene, each user must have his or her own electrode.
- You can get new electrodes by placing an order on the www.cefaly.us website.

2. OPERATING CONDITIONS

Do not use the Cefaly® Dual device in a very damp atmosphere as a bathroom. The operating conditions must not exceed the following figures:

- Temperature: +50°F to +95°F
- Relative humidity: 30% to 75%
- Atmospheric pressure: 700 hPa to 1060 hPa

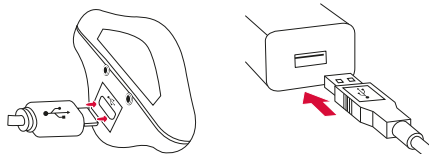
3. STORAGE CONDITIONS

The storage conditions must not exceed the following figures:

- Temperature: +23°F to +95°F
- Relative humidity: 45% to 75%
- Atmospheric pressure: 500 hPa to 1060 hPa

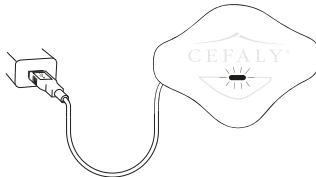
4. CHARGING THE BATTERY

The Cefaly® Dual device is operated by a rechargeable 3.7V LiPo battery. The battery operating life is ranging from 5 to 10 hours of stimulation depending on the program used for each session. When the power supplied by the battery is not enough for the device to deliver the programmed parameters and intensity, the device stops automatically and sends out a long beep for 2 seconds. After this interruption, you can no longer switch on the device as long as the battery has not been charged.



The battery has to be charged when the device is not used. For battery charging, use the power adapter and cable provided with the Cefaly® Dual device. Connect the micro-USB plug to the connector on the rear side of the Cefaly® Dual device and connect the USB plug to the power adapter. Plug the power adapter into mains.

While charging, the indicator light above the button flashes. The flashing rate will increase as the battery becomes more fully charged; when fully charged, the indicator light will remain lit.



5. CLEANING YOUR UNIT AND DEVICE MAINTENANCE

To clean your unit, use a soft duster and an alcohol-based cleaning product, which does not contain any solvents.

Never put the unit in water.

The magnetic contacts of the device should be clean. If those contacts are covered by a dirty layer, clean them with a soft duster and an alcohol-based cleaning product.

The Cefaly® Dual device does not require any maintenance operation.

Avoid the cable to be intertwined. The connectors at the ends of the cable should be clean. If those connectors are covered by a dirty layer, clean them with a soft duster and an alcohol-based cleaning product.

6. GUARANTEE

The guarantee starts at the date of delivery. Please keep the invoice or sales receipt since this is your proof of purchase on the date stated.

Its duration and requirements are specified in the general sale's terms specific to the United States.

TROUBLESHOOTING

Before you contact the technical service, please check the following solutions.

Symptoms	Solutions
When I press the button, I do not hear a sound and the device does not start.	<ul style="list-style-type: none">• Make sure the battery is charged• Charge the battery
When I press the button, I hear a continuous beep for 2 seconds and the device does not start.	<p>The battery is empty:</p> <ul style="list-style-type: none">• Charge the battery
When the device starts, it stops directly with a repeated sound.	<p>The connection between the device and the skin is not good:</p> <ul style="list-style-type: none">• Make sure to clean the skin before applying the electrode• Try again with a new electrode• In front of a mirror, check that the device is placed correctly
While the device is running, it suddenly stops with a repeated sound.	<p>The connection between the device and the skin has been lost:</p> <ul style="list-style-type: none">• Make sure that the device has not moved from its position• Try again with a new electrode after cleaning the forehead skin

TECHNICAL INFORMATION

Power supply: A rechargeable 3.7V LiPo battery.

Battery operating life: 5 to 10 hours of stimulation depending on the program used for each session. It is therefore recommended to recharge the device at least every 5 sessions.

Battery shelf life: 300 cycles of complete charge-discharge.

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

Device and charging system elimination: At the end of the lifetime, the apparatus and its charging system should not be thrown in a dustbin reserved for the household refuse but be the subject of a selective collection.



Case: Polycarbonate plastic, painted

Dimensions: 55 mm x 40 mm x 15 mm

Weight: 12 g

Electrical specifications for a charge between 0 and 1000 ohms

Biphasic rectangular impulses with electrical mean equal zero

Constant amplitude intensity predefined automatically

Compensated constant current preventing any galvanic direct components

Maximum output current: 16 mA (milliamps)

Pulse width: 250 μ s (microseconds)

Maximum phase charge: 5 μ C (microcoulombs)

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

Number of programs: 2

Program parameters:

Parameters	Program 1	Program 2
Pulse frequency	100 Hz	60 Hz
Pulse width	250 μ s	250 μ 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

Device service life: 7 years

Charging system service life: 7 years

Electrode shelf life: Electrode can be reused as long as it correctly sticks to forehead. If you take care of cleansing correctly the forehead skin before each session, placing the electrode back on its support, placing the support back in the sachet and storing it correctly, the electrode typically lasts for about 20 utilizations. The electrode expiry date is indicated on the electrode sachet.

Applied parts: Electrode.

IP22: Degree of protection against harmful ingress of particulate matter and water:

- 2: protected against particulate matter above 12.5 mm
- 2: protected against dripping water when tilted up to 15° from the vertical

Explanation of the symbols used:



This standardized symbol, applied on the device label, means that you have to consult the instruction manual.



This standardized symbol, applied on the electrode sachet, means that it is recommended that you consult the instruction manual.



Temperature limits: Indicates the limit temperatures for transportation and storage of the package.



This standardized electrical symbol, applied on the electrode sachet, means that the Cefaly® Dual device is of type BF for the applied part.

Additional Warnings

Applying the stimulation using the Cefaly® Dual device and the Cefaly® electrode according to this user manual is perfectly safe.

The Cefaly® Dual use is however incompatible with the simultaneous use of high frequency surgical equipment as it may result in burns at the site of the stimulator electrodes and possible damages to the Cefaly® Dual. Also, do not use the Cefaly® Dual in close proximity (less than 1 meter) to short wave or microwave therapy equipment as it may produce instability in the Cefaly® Dual output.

Though the Cefaly® Dual design prevents this, the application of electrodes close to the thorax may increase the risk of cardiac fibrillation.

It may be dangerous to connect the Cefaly® Dual device with devices not described in this user manual.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: Strangulation risk due to the length of the charging system cable.

WARNING: Suffocation risk in case of swallowing the electrode.

WARNING: The device contains a rechargeable Lithium battery. Misuse could result in fire/explosion/dangerous gas leak.

Notes

Any electrode for which the current density is above 2 mA/cm² requires special attention of the operator.

Do not apply stimulation differently than what is described in this manual (especially from one side to the other or through the head, directly on the eyes, including the mouth, on the front of the neck (especially on the carotid sinus) or using electrodes placed on the thorax and the upper part of the back or traversing the heart).

Temperature information: When the device is operated at an ambient temperature of 95°F, the temperature of the electrode will stay below 104°F.

ELECTROMAGNETIC COMPATIBILITY

List of Cables and Accessories

The only accessories to be used with the Cefaly® Dual are the Cefaly® electrode and the charging system (power adapter and cable) provided with the device.

The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit and could be unsafe.

Warning

Medical Electrical Equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.

Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance 3.3m away from the equipment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Cefaly® Dual device is intended for use in the electromagnetic environment specified below. The customer or the user of the Cefaly® Dual device should assure that it is used in such an environment.

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	

Standards:

- 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 device is manufactured in Europe in conformity with ISO 13485 and GMP.
- The manufacturer CEFALY Technology company is ISO 13485 (medical) certified. The CE marking indicates that the device has been designed and developed in accordance with a strict risk analysis, and that it complies with the provisions of Directive 93/42/EEC on medical devices.
- Cefaly® Dual is a class II device.

In case of device malfunction or unexpected events, contact the manufacturer.

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The logo for Cefaly Technology features a stylized roofline above the company name. "CEFALY" is written in a large, serif, all-caps font, and "TECHNOLOGY" is written below it in a smaller, sans-serif, all-caps font.

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