



CEFALY
DUAL

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SAFETY PRECAUTIONS, CONTRAINDICATIONS AND SIDE EFFECTS

1. SAFETY PRECAUTIONS

- Do not use the Cefaly® Dual while driving, or in conjunction with a dangerous activity that needs to be alert and focused.
- In the hour following a Cefaly® Dual session, do not drive a vehicle or perform a dangerous activity that needs to be alert and focused.
- Do not use the Cefaly® Dual on any other areas apart from the forehead.
- The Cefaly® Dual is meant to be used by a person from the age of 15 (having the required education level to understand this manual). It can be used by a child from the age of 8 but under the supervision of an adult for the first sessions. There is however no available clinical trial demonstrating the efficacy of the Cefaly® in subjects below the age of 18.

2. CONTRAINDICATIONS

- Recent brain or facial trauma (less than 3 months).
- Skin abrasion on the forehead in the area of application of the electrode.
- Allergy to acrylate.
- Cutaneous hypersensitivity: +/- 5% of people present a hypersensitivity of the forehead skin and do not tolerate the sensation induced by the Cefaly® Dual.
- Implanted electronic device in the head.
- Trigeminal neuralgia.
- Ophthalmic shingles.

3. SIDE EFFECTS

Sedative effect

During a treatment session, there is a sedative effect which is accompanied by a reduction in vigilance and a tendency to fall asleep. This prohibits the use of Cefaly® Dual while driving or during a dangerous activity that needs to be alert and focused.

Skin reaction

At the end of the session, the skin on the forehead may become reddened where the electrode was placed. This is caused by stimulation of the blood circulation. Depending on the individual, this redness can last for a few minutes or more after the session.

In very rare cases an allergy to the acrylate of the electrode gel can arise. A temporary rash gradually

develops on the forehead. If this should occur, stop using Cefaly® Dual and contact the manufacturer CEFALY Technology to order special electrodes. The skin rash will gradually disappear within a few days. The use of an anti-inflammatory cream can accelerate the disappearance of the rash.

Pain during the session

A portion of people may perceive the sensation produced by the Cefaly® Dual during the session as painful. In most cases habituation and tolerance to the feeling settle in a few days or weeks. However, there is still a small percentage of subjects for whom the feeling is painful despite regular use.

Headache after the session

Very rarely a headache can occur at the end of a preventive treatment session (Programme 2). This is casual and fleeting but prevents some patients from making effective use of Programme 2.

Persistence of sensation

The perceived sensation during the session may extend beyond it. In most subjects tingling quickly disappears within the tens of minutes after the session. But for some subjects the feeling persists for several hours or even more. While this may be perceived as unpleasant, it is harmless and inconsequential.

Neck pain

Some subjects, especially in the early stages of use, tend to unconsciously contract neck muscles during a session. It can then lead to a pain in the neck. In this case, it is advisable to do sessions with the back of head resting on a pillow in order to relax the muscles of the neck.

Nausea

Rare occurrence of nausea during a treatment session has been reported.

Tooth pain

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

INDICATIONS

Cefaly® Dual is designed to prevent and treat frequent episodic and chronic migraines.

Programme 1 is designed to treat the migraine attack, i.e. during the bout of pain. It is applied either when the migraine is already present or, preferably, when the first signs of the next migraine attack are felt.

However, a part of migraine patients (+/- 10%) suffer from allodynia during migraine attacks. It is a hypersensitivity that makes normal sensations felt as painful. In this case, tingling sensations on the forehead are perceived as very painful and prevent the application of Cefaly® Dual during migraine attacks.

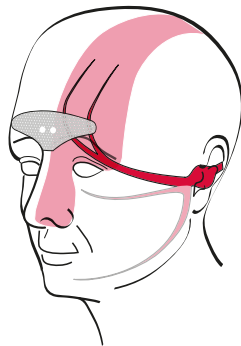
Programme 2 is designed to act as a prophylaxis. Its regular use helps to reduce the frequency of migraine attacks.

FUNCTIONAL PRINCIPLE

Like the majority of headaches, migraines involve the trigeminal nerve. Its superior branch (V1) exits the orbit under the skin of the forehead. The very specific design of the Cefaly® electrode enables it to make contact with the nerve endings of the trigeminal nerve. Consequently, the Cefaly® Dual, through its electrode, delivers neurostimulation to the trigeminal system via its superior branch V1.

Trigeminal nerve stimulation using Programme 1 of the Cefaly® Dual (high frequency) induces a sedative effect on the nervous system that causes headache pain relief during migraine attacks.

Trigeminal nerve stimulation using Programme 2 of the Cefaly® Dual (low frequency) has an action on the central nervous system. Clinical trials showed that the regular repetition of Programme 2 sessions restores a normal metabolism in the fronto-temporal cortex of migraineurs, leading to an improvement of the migraine-triggering threshold, which consequently reduces the frequency of migraine attacks.



DIRECTIONS FOR USE

1. PRACTICAL USE

Preparing the session

Before first use, make sure to charge the Cefaly® Dual (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 of the contact between the electrode and the skin. Take a Cefaly® Prepare™ wipe (see **Figure 1**) or water and soap; but do not under any circumstances use make-up removal products because they leave a greasy film on the skin.

FIGURE 1



Then cleanse the skin on the forehead (see **Figure 2**). 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 the subsequent effectiveness of the session.

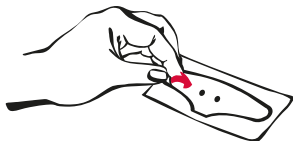
FIGURE 2



2. Removing an electrode

Remove an electrode from its plastic support, holding it by one of its two tips (see **Figure 3**). 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 3



3. Positioning the electrode

Use a mirror to correctly position the electrode (see **Figure 4**).

FIGURE 4



The pointed part is placed downwards with the lower edge placed exactly on the horizontal line that joins both eyebrows (see **Figure 5**). 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 5



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 6**).

FIGURE 6



Selecting and starting the programme

The main button that enables you to select the programme and start the session simultaneously is only active when the device is in place (see **Figure 7**). For the central button to be functional, the Cefaly® Dual needs to detect that the device is placed on an electrode stuck on the skin. Otherwise it does not allow the start-up.



Press 1 x : Start prg. ①

Press 2 x : Start prg. ②

When the device is in place on the forehead and in function, an indicator light above the button flashes. You should therefore place yourself in front of a mirror if you want to observe this indicator light. If the device emits a long beep when you press the button, this means the battery charge is too low and you must therefore first charge the Cefaly® Dual.

1. Programme 1

Press the button once to select and start **Programme 1**. You will hear a single beep.

Programme 1 is designed to treat migraine attacks.

2. Programme 2

Press the button twice in succession to select and start **Programme 2**. You will hear two successive beeps.

As **Programme 2** is designed to prevent migraine it is used during pain-free periods.

FIGURE 7

During the session

1. Conducting the session

A session of Programme 1 lasts sixty minutes and a session of Programme 2 lasts twenty minutes. The programme selected (1 or 2) 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. If this sensation becomes too intense, pressing the button once allows to stabilise the intensity. The intensity reduces at the end of the sixty (Programme 1) or twenty (Programme 2) minutes and the programme stops automatically.

2. Controlling the intensity

The intensity will gradually increase during the first 14 minutes of treatment. When the sensation becomes too intense, press the button just once and the intensity stops increasing.

About ten seconds after the selection and start-up of a programme, it is possible to increase the intensity faster by pressing continuously on the button. If you press the button and keep it pressed, the intensity will increase rapidly. If you release the button, the intensity stabilises and stays constant. By pressing again the button, the intensity increases again as long as you keep the button pressed. The maximum intensity is reached after a total of 30 seconds of pressure on the button.

The effectiveness of the treatment depends on the intensity used. It is consequently advisable to work with the maximum intensity possible. The sensations will feel unusual at first but you will soon become accustomed to them after a few sessions. Our limit is purely psychological as we are capable, for most people, of tolerating the full intensity of Cefaly® Dual, in other words it is possible to let it run for sixty (Programme 1) or twenty (Programme 2) minutes of treatment without restricting the intensity.

3. Link a new session

When the session is over, there is a gradual decrease in intensity for thirty seconds. During this phase, pressing the button just once will immediately start a new session of the same programme.

4. Interrupting the session

To interrupt the session before its programmed end, just remove the Cefaly® Dual which will stop at once when it loses contact with the electrode (see **Figure 8**). Four series of 3 successive beeps indicate the disconnection of the device and the interruption of the session.



FIGURE 8

5. Accidental interruption: defective electrode

The sophisticated electronic system used in Cefaly® Dual constantly measures the impedance of the electrode, skin and subcutaneous tissues. If the impedance of these tissues is not compatible with the treatment, Cefaly® Dual will interrupt the session automatically. In this case, 4 series of 3 successive beeps are emitted to signal the interruption of the session.

This unintentional spontaneous interruption means that either the skin has not been cleansed thoroughly or the electrode has been positioned incorrectly or is no longer intact, or may even mean that the two magnets of the device need to be cleansed.

After the session

1. Removing the device

The session ends after sixty (Programme 1) or twenty (Programme 2) minutes and the device automatically switches off. Remove the device by pulling it forward to detach it from the electrode.

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. But the treatment is completely safe. The majority of the users need several sessions to get used to the sensation. Only 5% of the population present a hypersensitivity, cannot tolerate the sensation and are therefore unable to carry out the treatment effectively.

In addition, during the migraine attack, +/- 10% of the patients suffer from allodynia (hypersensitivity) of the forehead skin and cannot tolerate the sensation during the attack. These patients can therefore only use the Cefaly® Dual in prevention (Programme 2), between the migraine attacks.

During the session

- 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 fibres.
- The sensation may be more pronounced on one side than the other because our sensitivity is not symmetrical. This difference of sensation is mainly felt during the first minutes of the session when the intensities are low.
- Tingling sensations are then felt in the skull, making you feel as if your hair is standing on end.

- With the intensity increase, 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 14 minutes, the intensity stabilises and remains constant until the treatment session is over.

After the session

- The forehead skin may remain red for several tens of minutes.
- The tingling may persist after the session for several tens of minutes, up to several hours for some.

3. CHOICE OF PROGRAMME, FREQUENCY, DISTRIBUTION OF THE SESSIONS AND THEIR EFFECTIVENESS

Treating attacks

Programme 1 should be used for a 60-minute session during a migraine attack or when the early signs of an attack become noticeable. The pain may either disappear, be reduced or continue. If the migraine pain is not relieved within two hours or if another migraine attack occurs, Programme 1 can be used the same day for a second 60-minute session.

During the first few sessions, the results may not be striking. However, the more you get used to it, and the more you continue using Cefaly® Dual with more intensity, the more noticeable its effectiveness will become.

Preventive treatment

Programme 2 should be used once or twice a day outside the attacks. A daily session of 20 minutes is the minimum.

The effectiveness of this preventative action is determined by a dose/response relationship. Improvement is gradual, as the daily sessions of 20 minutes are repeated. Patients who respond best have an improvement after just a few weeks. Other patients respond more slowly and need several months to obtain a significant improvement. At the beginning, during the first few weeks, individuals may notice either an improvement, no difference or, occasionally, a worsening in their symptoms because the neurostimulation is still inadequate.

After several months, once an improvement has been noticed, you can try reducing the number of sessions carried out. In case this dose reduction is inadequate, start increasing the number of sessions again.

WARRANTY

The CEFALY Technology company warrants the purchaser of the Cefaly® Dual device against faulty workmanship and defective components. The warranty is valid for 2 (two) years commencing from the purchase date of the device. **Please keep the invoice or sales receipt since this is your proof of purchase on the date stated.**

This warranty, which is valid for 2 (two) years, does not cover accessories, such as electrodes, charging system and the preparation product (Cefaly® Prepare™).

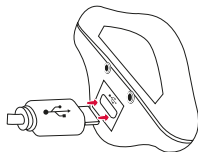
This warranty does not cover damage caused by shocks, falls and other knocks, which are likely to damage the device. The warranty does not apply to devices whose cases are cracked, broken, buckled or show signs of knocks.

During the warranty period, the device will either be repaired free of charge by an approved service or replaced, depending on the degree of severity of the defect.

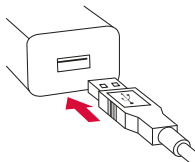
TECHNICAL ASPECTS

Charging the battery:

Connect the micro-USB plug to the connector on the rear side of the Cefaly® Dual device.



Then connect the USB plug to the power adapter and plug the power adapter into mains.



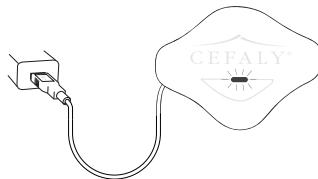
While charging, the indicator light above the button flashes. The flashing rate will increase as the battery becomes more fully charged; when fully charged, the indicator light will remain lit.

The use duration at full charge is ranging from 5 to 10 hours of stimulation depending on the programme used for each session. It is therefore recommended to charge the battery at least every 5 sessions.

Power supply: a rechargeable 3.7 V Lithium-ion Polymer battery. The device is charged thanks to the provided cable and power adapter.

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

Maximum input voltage (micro-USB connection): 5,25 Vdc.



Electrodes and wipes: Electrodes and wet wipes have to be used before the date printed on their sachet.

Device maintenance: The magnetic contacts of the device should be kept clean. If those contacts are covered by a dirty layer, clean them with Cefaly® Prepare™ wipe.

The Cefaly® Dual device does not require any maintenance operation. It is not necessary to disinfect or sterilize the device between uses on different patients.

Adapter and cable maintenance: 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.

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.



Operating conditions:

Temperature: +10°C to +35°C

Relative humidity: 30% to 75%

Atmospheric pressure: 700 hPa to 1060 hPa

Transport and storage conditions:

Temperature: -5°C to +35°C

Relative humidity: 45% to 75%

Atmospheric pressure: 500 hPa to 1060 hPa

Case: PC plastic, painted

Dimensions: 55 mm x 40 mm x 15 mm

Weight: 12 g

Electrical specifications for a charge between 0 and 1000 ohms

Constant amplitude intensity predefined automatically, depending on the programme

Rectangular impulses

Compensated constant current preventing any galvanic direct component

Stimulation parameters:

	Programme 1	Programme 2
Maximum intensity	16 mA	16 mA
Pulse frequency	100 Hz	60 Hz
Pulse width	250 μ s	250 μ s
Pulse duration	500 μ s	500 μ s
Session duration	60 minutes	20 minutes

Maximum quantity of electricity per impulse: 5 μ C

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

Number of programmes: 2

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 can be dangerous to connect the Cefaly® Dual 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.

Notes

In case you wear an implantable stimulator, ask your doctor before applying Cefaly® Dual.

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 35°C, the temperature of the electrode will stay below 40°C.

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 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

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 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	
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

The Cefaly® Dual device is a patented model and is protected by an international patent. Cefaly® is a trademark that has been registered internationally.

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

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.

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

CEFALY
TECHNOLOGY



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