electroCore™

gammaCore™

Instructions for Use for gammaCore-S™

(non-invasive vagus nerve stimulator)

Caution: Rx Only. US Federal Law restricts this device to sale by or on the order of a licensed healthcare provider.

1. INDICATIONS AND PRODUCT DESCRIPTION

gammaCore-S™ (non-invasive vagus nerve stimulator) is indicated for:

- The preventive treatment of migraine headache in adolescent (age 12 and older) and adult patients.
- The acute treatment of pain associated with migraine headache in adolescent (age 12 and older) and adult patients.
- Adjunctive use for the preventive treatment of cluster headache in adult patients.
- The acute treatment of pain associated with episodic cluster headache in adult patients.
- Treatments of hemicrania continua and paroxysmal hemicrania in adults.

FDA review is based on a clinical comparison of probable risks and benefits to health. The FDA has determined probable benefits to health based on clinical evidence submitted to the FDA and patient preference information. The safety and effectiveness of this device is based on a comparison of its low risks and probable benefit to health.

gammaCore™ provides a mild electrical stimulation to the vagus nerve, which runs through the neck and carries information to the central nervous system. Each stimulation with gammaCore lasts 2 minutes. After 2 minutes, the device automatically stops delivering the stimulation and turns itself off. The patient controls the intensity level.

gammaCore delivers up to 30 stimulations in a 24-hour period, starting when the device is turned on and the intensity level is increased above 3. Once the maximum daily number of stimulations has been reached, the device will not deliver any more stimulations until the following 24-hour period. The number of remaining stimulations available in a 24-hour period is indicated on the display (refer to Section 7). gammaCore is rechargeable and includes a charging case to charge the device.

NOTE: gammaCore's 24-hour cycle begins the first time the intensity level is increased past 3.

NOTE: This is a pre-loaded device that contains a specific number of consecutive days of therapy. **gammaCore is supplied non-sterile.**

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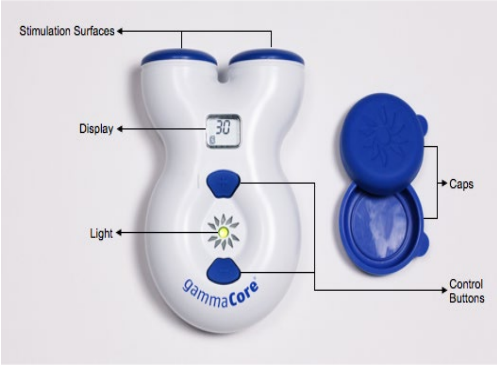


Device Feature	Description / Use
Stimulation Surfaces	Points of contact with patient's skin
Light	Indicates device status (refer to Section 8)
Display	Indicates device status (refer to Section 8)
Control Button	Turns power ON/OFF Increase/decrease stimulation intensity
Caps	Cover and protect the stimulation surfaces

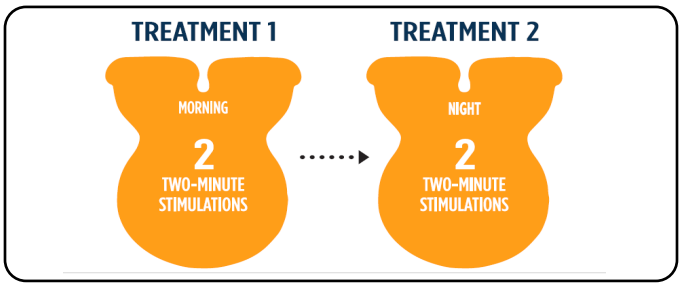
For prescription use only.

2. GAMMACORE TREATMENT RECOMMENDATIONS

PREVENTIVE TREATMENT

Daily: Morning and Night

A treatment consisting of 2 two-minute stimulations on the same side of the neck at morning and night. *

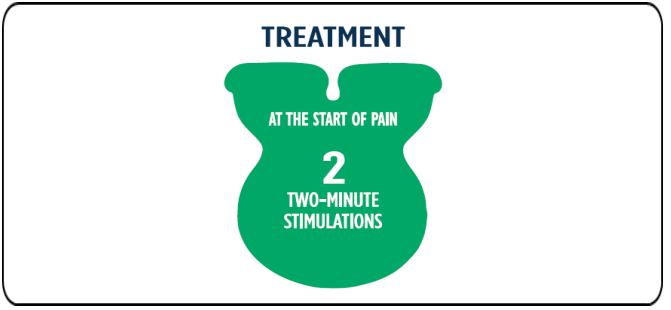


***Additional treatments may be recommended by a Healthcare Provider (HCP) for Cluster Headache and other Trigeminal Autonomic Cephalalgias.**

ACUTE TREATMENT

At the earliest sign of pain:

A treatment consisting of 2 two-minute stimulations on the same side of the neck as needed; repeat treatment if pain persists.



3. CONTRAINDICATIONS

Contraindications include but are not limited to:

- Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
- Patients who are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)

Patients should not use gammaCore:

- While driving, operating machinery, or during any activity that may put patient at risk of injury
- Near microwave machines, magnetic resonance imaging, radio frequency surgical, or computer-aided tomography machines
- In an explosive atmosphere or in the presence of flammable gas mixtures
- If patient has an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on the neck at the treatment location
- If patient has wet skin, is in the water, or just stepped out of the water (eg, shower, bath, pool)

4. COMMON SIDE EFFECTS ASSOCIATED WITH GAMMACORE-S

The most common side effects (occurring in less than 2% of patients) include the following:

- Application site discomfort
- Application site irritation/redness
- Local pain, face/head/neck area (including toothache)
- Muscle twitching and/or contractions, face/head/neck area (including facial droop and/or lip pull)
- Headache/migraine
- Dizziness
- Tingling, pricking, or a feeling of “pins and needles” on the skin where the device is applied (paresthesia/dysesthesia)

These side effects typically resolve immediately after the stimulation is complete.

5. WARNINGS AND PRECAUTIONS

	**Warnings indicate instructions, which, if not followed, may result in serious injury or death to the device user or to the patient.**
	**Precautions indicate instructions, which, if not followed, may result in damage to the equipment or degradation in the quality of treatment.**

Warnings

- The safety and effectiveness of gammaCore (nVNS) have not been established in the acute treatment of chronic cluster headache.
- The long-term effects of the chronic use of the device have not been evaluated.
- Safety and efficacy of gammaCore have not been evaluated and therefore is NOT indicated for:
  - Adolescent patients with congenital cardiac issues
- Safety and efficacy of gammaCore have not been evaluated in the following patients:
  - Patients with uncontrolled hypertension, hypotension, bradycardia, or tachycardia

- Patients with a history of baseline cardiac disease or atherosclerotic cardiovascular disease, including congestive heart failure, known severe coronary artery disease, or recent myocardial infarction (within 5 years)
- Patients with metallic device such as a stent, bone plate or bone screw implanted at or near their neck
- Patients with a history of abnormal baseline ECG, prolonged QT interval or arrhythmia
- Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
- Pediatric patients (less than 12 years of age)
- Pregnant women
- Patients with active cancer or cancer in remission
- Patients with an abnormal cervical anatomy
- Patients with a history of brain tumor, aneurysm, bleed or head trauma
- Patients with a history of syncope or seizures

- Contact your HCP if your symptoms continue or worsen.
- Treatment is intended to be given (administered) as directed by an HCP. Your HCP or an electroCore Customer Service Representative must train you in the proper use of gammaCore (refer to Section 20).

Precautions

- The long-term safety and effectiveness of the gammaCore device has not been demonstrated in adolescents 12-17 years of age. Due to hormonal and cognitive development changes in adolescents, this population should be closely monitored while using the device. The use of the device in this population is based on extrapolated data from a clinical study in adults.

Before Use:

- You must carefully read the gammaCore Instructions for Use.
- Only use gammaCore as described in the Instructions for Use, or as otherwise directed by the HCP.
- The use of more than 24 stimulations per day has not been evaluated in controlled clinical trials. Do not use more than 24 stimulations in a 24-hour period.
- Only use an electroCore-approved gel with gammaCore. Please contact Customer Service for an electroCore-approved gel that works with the device.
- Do not share gammaCore with another person.
- gammaCore should not be applied across or through the head, directly on the eyes, covering the mouth, on the chest or the upper back, or over the heart.
- Remove jewelry that may touch the treatment location (necklaces, earrings, etc.).
- Carefully examine the device for any signs of damage or defects.

Do not use gammaCore if:

- The stimulation surfaces are broken or cracked.
- The casing is cracked, dented, or appears to be damaged.
- The light is flashing green and “Err” is displayed on the screen when the device is turned on. Flashing green and “Err” means that there is an error (refer to Section 8).
- It has passed its expiration date. The expiration date is indicated on the device packaging.

During Treatment:
Discontinue treatment if you experience:

- Light-headedness, dizziness, or chest pain
- Excessive skin irritation

If the device seems to malfunction, discontinue use immediately, continue taking usual medications, and seek medical care as needed. When possible, contact electroCore Customer Service for assistance with your device; electroCore Customer Service cannot provide medical assistance.

Caring for Your gammaCore:

- Keep gammaCore away from water or other liquids, including cleaning liquids.
- Moisture may damage the device. Keep gammaCore away from items such as nebulizers and steam kettles.
- Store gammaCore in a safe location out of reach of children.
- Avoid exposure to extreme hot or cold temperatures outside the range of 32°F to 100°F (0°C to 38°C). Exposure to such conditions may cause the device to malfunction.
- Do not attempt to replace the device battery. If the device is not working, contact electroCore Customer Service.
- Do not open or take apart the case or attempt to repair or modify the device. There are no user-serviceable parts. If the device is not working, contact electroCore Customer Service.
- As the device contains a lithium-ion battery, do not intentionally damage, burn, or puncture the device.
- Wireless communications equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies, can affect this equipment. Keep gammaCore at least 3.3 m (10.8 ft) away from these items while in use.

If the device is not working, contact electroCore Customer Service (refer to Section 20).

6. WILL I STILL NEED TO TAKE MEDICATIONS?

You and your HCP should discuss your ongoing treatment routine, including the use of any additional therapies and/or medications. It is important to always follow your HCP's recommendations about your medications. gammaCore can be used with existing medications as there have been no reported device-drug interactions.

7. DISPLAY SYMBOLS

Icon Description	Icon	Example Display	Description
Stimulations Remaining			9 remaining
Intensity Level			Intensity level is at 20
Days Remaining			15 days remaining until device will not deliver stimulations
Intensity Level at Last Use			Last delivered intensity level was 20

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8. DEVICE STATUS INDICATORS

gammaCore has a visual indicator (display) and an auditory signal (beep) to indicate device status.

Status	Light	Display	Sound	User Action
Start Up / Ready for Use	Green Light On 	1. Days Remaining  2. Stimulations Remaining 	1 short beep after power ON	Follow “How to Use” Instructions (refer to Section 10)
Device in Use	Green Light On (is not an indicator that there is a signal at stimulation surfaces) 	Intensity Level (min 1 – max 40) 	Short beep each time intensity is increased/ decreased	Follow “How to Use” Instructions (refer to Section 10)

Stimulation Complete	None 	1. Number of Days Remaining  2. Number of Stimulations Remaining  3. Last Intensity Level Used 	2 short beeps	NONE: Device turns off automatically
Error	Flashing Green Light 		Repeated long beeps	Device turns off automatically after 10 seconds Restart device (Turn off and on again) *

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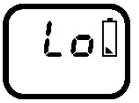
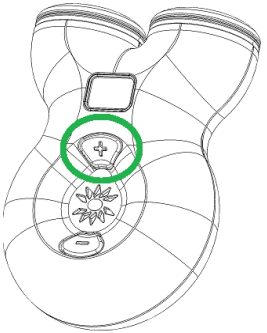
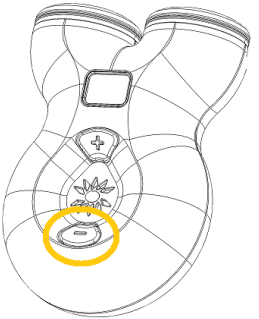
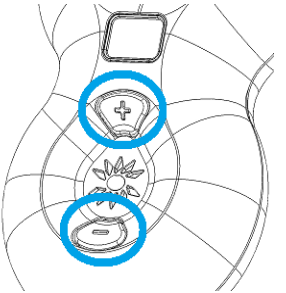
No Stimulations Remaining	Flashing Green Light 		Repeated long beeps	gammaCore turns off automatically *Replace gammaCore
Expired/No Days Left	Flashing Green Light 		Repeated long beeps	gammaCore turns off automatically *Replace gammaCore
Low Battery	Flashing Green Light 		Repeated long beeps	Replace gammaCore
Device Does Not turn On	None 	None	None	Press the (+) and (-) buttons at the same time for 10 seconds and then release. Wait 5 seconds and press the top (+) button again to turn the device on

Dead Battery	None 	None	None	Replace Device*

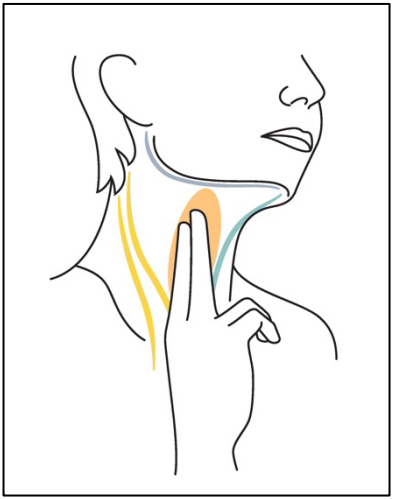
*If error is not resolved, contact electroCore Customer Service.

9. FUNCTIONS

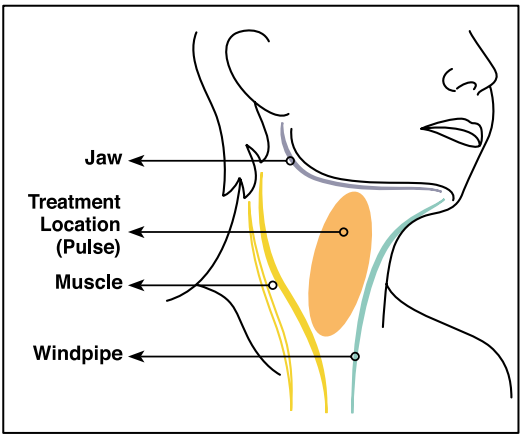
Power On / Increase Intensity	Decreases Intensity	Turns Device Off
		
Press the (+) button to turn gammaCore on; Press the (+) button again to increase stimulation intensity	Press the (-) button to decrease stimulation intensity	Press the (+) and (-) buttons at the same time to turn gammaCore off

10. HOW TO USE gammaCore-S

Set Up



1. Remove any jewelry that may touch the treatment location.
2. Find a comfortable position. (A place where you can see your neck in a mirror would be helpful.)
3. Locate the treatment location by finding the pulse on the side of the neck. The vagus nerve is in the same area. Make sure the treatment location is clean and dry.



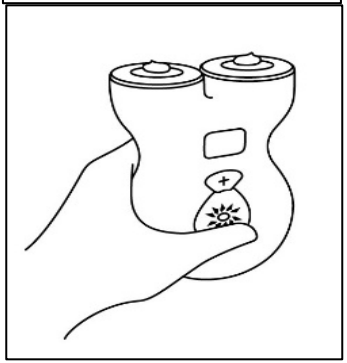
The stimulation surfaces of the device will line up with the following

- Over the pulse (orange); this is the treatment location
- In front of the large muscle at the side of the neck (yellow)
- Just below the lower jaw (grey)
- Lined up next to the windpipe (green)

4. Remove the cap.

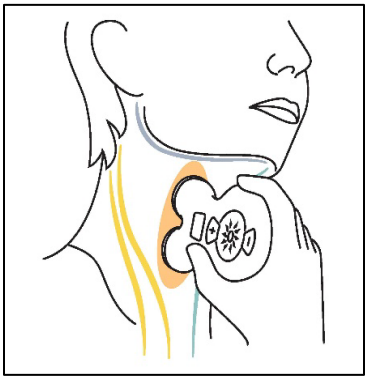
5. Apply a small (pea-size) amount of gel to both of the stimulation surfaces. Not applying the gel as described may cause the stimulation to be uncomfortable or less effective.

CAUTION: Only use an electroCore-approved gel with gammaCore. Please contact electroCore Customer Service for an electroCore-approved gel that works with the device (refer to Section 20).



6. Turn gammaCore on by pressing the power button. When the device is ready for use, the device will beep once. The number of stimulations available for that 24-hour period and months/days remaining will be displayed.

Delivering Treatment



7. Position the device on the side of the neck over the treatment location. Use mild to moderate pressure so both stimulation surfaces make good contact with the skin; however, do not apply excessive pressure to the neck.

8. Increase the intensity level to the maximum level ***you*** can tolerate by repeatedly pressing the top area of the control button. Once you have found **your** maximum level, hold gammaCore in place for the remainder of the 2-minute stimulation. You may experience a lip pull. The device will beep every time the control button is pushed, and the display will indicate a numerical value between 1 and 40, which signifies the intensity level. You will likely feel muscle contractions at the treatment location. These muscle contractions are normal and should stop after the stimulation is complete. The appropriate intensity level is different for every person and may vary from stimulation to stimulation.

NOTE: Neck muscle contractions during the stimulation that are not painful are normal and not a reason to stop the stimulation. If muscle contractions are too strong or uncomfortable, try:

- Lowering the intensity level by pressing the bottom area of the control button.
- Repositioning gammaCore on the neck over the pulse and slowly increasing the intensity level again by pressing the top area of the control button.

If the stimulation is still intolerable, remove gammaCore from the neck and turn the device off by pressing and holding the power button and discontinue the stimulation.

NOTE: The device has a limited number of stimulations it can deliver in a 24-hour period.

NOTE: The length of each stimulation, 2-minutes, provides enough time for correct positioning of gammaCore and for setting the appropriate intensity level.

NOTE: Make sure that both stimulation surfaces are in contact with the skin during the stimulation Checking in a mirror may help until you become familiar with the device and its correct positioning.

9. At the end of each stimulation, the device will display the last intensity level that was used for approximately 7 seconds, then revert to display the number of stimulations and months/days remaining. You may then place the device back on the treatment location for another stimulation. Additional gel may be applied between each stimulation.

NOTE: After 2 minutes, the device will make 2 short beeps and the stimulation will automatically stop.

NOTE: The days and stimulations remaining can be viewed by turning the device on. However, do not turn the intensity level higher than three (3) until preparing for a stimulation. The device counts each time the intensity level is higher than three (3) as a stimulation. gammaCore delivers a limited number of stimulations in a 24-hour period.

NOTE: Some users who attempt multiple doses in a row could experience an issue where the device will not turn on immediately. gammaCore has a delay feature to prevent accidental starts due to an unintentional button press. To resolve, wait 10 seconds before turning the device on again.

NOTE: If you have trouble turning on the device, press the (+) and (-) buttons at the same time for 10 seconds and then release. Wait 5 seconds and press the top (+) button again to turn on the device.

10. Clean gammaCore by wiping the leftover gel off the stimulation surfaces with a soft, dry cloth (refer to Section 12).

11. Clean the excess gel off your neck with a cloth or tissue. The gel is not intended to be left on the skin and may cause skin irritation for some people.

12. Put the cap back on the device after use.

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11. ADDITIONAL INFORMATION FOR HEALTHCARE PROVIDERS

The HCP must brief the patient on the following items:

- The HCP must inform the patient using gammaCore to notify them of any changes in health status. The HCP must re-evaluate the patient's suitability for treatment using gammaCore based on the patient's new health information.
- The HCP should train patients in the proper use of gammaCore, inform them of all potential risks and complications of treatment, and provide accompanying device labeling.

12. CLEANING

- Clean the device after each use by gently wiping the case and the stimulation surfaces with a soft, dry cloth to remove leftover gel.
- Put the caps back on the device after use to protect the stimulation surfaces from dirt, debris, and damage.

PRECAUTIONS:

- Do not submerge the device in water; it is not water resistant.
- Do not use soap, hand sanitizer, detergents, or other cleansers when cleaning the device.

13. PRODUCT HANDLING

Operating Conditions – gammaCore-S

- Range: 32°F to 100°F (0°C to 38°C)
- Only use the device indoors
- Maximum Output: 30V (peak), 60mA (peak)
- Load Impedance: 450 to 550 Ohms
- gammaCore produces an electrical signal consisting of five 5,000-Hz pulses, repeating at a rate of 25 Hz. The waveform of the gammaCore pulse is approximately a sine wave.

Storage/Transport Conditions

- gammaCore should be stored at room temperature away from moisture
- Range: 32°F to 100°F (0°C to 38°C)
- Replace caps after each use
- Store the device in such a way (e.g., drawer or shelf) that the caps remain in place and are not accidentally removed.

Service Life

- The service life of gammaCore is 1.5 years after the date the device of manufacture (refer to the package label for expiration date).
- The expiration date of the conductive gel is 5 years after the date of manufacture.

14. PRODUCT DISPOSAL

Regulations require that disposal of electrical and electronic equipment, including used and unused medical devices, is handled in a controlled manner. A product that may be contaminated after use or that may contain chemicals or elements that may present hazards to people, or the environment must be disposed of in accordance with the applicable government regulations. Contact electroCore Customer Service (refer to Section 20) if you have questions.

NOTE: gammaCore contains a lithium-ion battery that cannot be removed by the user.

NOTE: Please dispose gammaCore as you would a cell phone or other electronic device. Check with your local municipality to do this according to your local electronic waste regulations.

15. PRODUCT ORDERS AND RETURNS

Prescription by an HCP is required.

Please refer to the device label and contact electroCore Customer Service to place an order for gammaCore or electroCore-approved gel.

Requests to return a device, including a non-working device, must be made to, and approved by electroCore Customer Service.

Refer to Section 20 for electroCore Customer Service Contact Information.

16. CLINICAL STUDIES

- Please visit www.gammacore.com/prescribing-gammacore/clinical-efficacy for additional Clinical Study information.

17. ELECTRICAL CLASSIFICATION

- UL 60601-1 Class III; EN 60601-1 Internally Powered Equipment
- Type BF Applied part
- Only the manufacturer should change the battery
- Protection from solid foreign objects ≥12.5 mm and ingress of water at 15°

18. ELECTROMAGNETIC COMPATIBILITY GUIDANCE

- All Engineering specifications have passed the required test levels. All specifications are available upon request.

19. SYMBOLS AND NOMENCLATURE DESCRIPTION

	Expiration date		Follow operating instructions
	Lot number		Manufacturer
	Catalog number / Reference number	IP22	Protection from solid foreign objects ≥12.5 mm and ingress of water at 15°
	Electric shock hazard		Type BF applied part
	Serial number		Storage temperature
	Non-sterile	xxyyGzzzz (package label)	Date of manufacture on package label, where: yy is the year of manufacture, eg, 2523G1001 indicates the year of manufacture is 2023
	**WARNING** Failure to follow instructions may result in serious injury or death to the patient or user		Non-ionizing electromagnetic radiation
	**PRECAUTION** Failure to follow instructions may result in damage to the equipment or degradation in the quality of treatment		Magnetic resonance unsafe
	Refer to instruction manual		Authorized representative
	Information or additional information available		Keep away from sunlight
	Separate collection for waste of electrical and electronic equipment		Do not use if package is damaged
	Date of Manufacture		Medical device

20. CONTACT INFORMATION

Customer Service:

E-mail: customerservice@electrocore.com
electroCore, Inc.
200 Forge Way, Suite 205
Rockaway, NJ 07866
United States
Telephone: 1 (888) 903-2673

Manufacturer:

E-mail: customerservice@electrocore.com
electroCore, Inc.
200 Forge Way, Suite 205
Rockaway, NJ 07866
United States
Telephone: 1 (888) 903-2673

UK / EU Customer Service:
Email:
customerserviceUK@electrocore.com

EU Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Product Complaint Reports and/or related issues may be submitted directly to electroCore, Inc.:

Telephone: +1 (973) 355-6708
E-mail: complaints@electrocore.com

CH REP

MDSS CH GmbH
Laurenzenvorstadt 61
5000 Aarau, Switzerland

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CE 2797

For patent information, please visit electroCore.com

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Customer Service Limited Liability:
electroCore guarantees against any out of box failures and warrants that the Products shall meet the Product Standard. The warranty does not apply to any Product that: (i) has been subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper installation, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions, or use contrary to any instructions issued by electroCore; or (ii) has been reconstructed, repaired, or altered by persons other than electroCore or its authorized Representative. Customer shall not service, repair, modify, alter, replace, reverse engineer, or otherwise change any Products.

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