![electroCore logo]

![gammaCore Sapphire logo]

Instructions for Use for gammaCore Sapphire™ SLC
(non-invasive vagus nerve stimulator)

CAUTION: HEALTHCARE PROVIDER (HCP) AUTHORISATION REQUIRED.

1. INDICATIONS AND PRODUCT DESCRIPTION

gammaCore Sapphire™ (non-invasive vagus nerve stimulator, gammaCore) is intended to provide non-invasive vagus nerve stimulation (nVNS) on the side of the neck. gammaCore is indicated for the treatment and/or prevention of primary headache (migraine, cluster headache, and hemicrania continua) and medication overuse headache in adults.

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 8). gammaCore is rechargeable and includes a charging case to charge the device. A gammaCore refill card is used to load the device with days of therapy based on a healthcare provider (HCP) authorisation.

NOTE: Once activated with a refill card, the course of therapy will decrease by one day as every 24-hour period passes. This daily countdown will occur regardless of use, so only activate a refill card when you intend to use the full course of therapy.

gammaCore is supplied non-sterile.

Device Feature	Description / Use
Stimulation Surfaces	Points of contact with patient's skin
Display	Indicates device status (refer to Section 9)
Power Button	Turns power ON/OFF
Control Button	Increase/decrease stimulation intensity
Cap	Covers and protects the stimulation surfaces
Refill Card	Loads device with therapy when a refill is required (refer to Section 13)
Charging Case (Case with Power Cord)	Charges the device (refer to Section 10)

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.

*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.

3. CONTRAINDICATIONS

Contraindications include:
- 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 (e.g., shower, bath, pool)

4. COMMON SIDE EFFECTS ASSOCIATED WITH GAMMACORE

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.

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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 long-term effects of the chronic use of gammaCore have not been evaluated.
- 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 a 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)
    - Paediatric patients
    - 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

⚠️ Precautions

Before 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 electroCore 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
- An "E" with a numeric code is displayed on the screen when the device is turned on. This means that there is an error (refer to Section 14)
- 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 Device:
- 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 0°C to 38°C (32°F to 100°F). 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 24).

6. WILL I STILL NEED TO TAKE MEDICATIONS?

You and your healthcare provider (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. ADDITIONAL INFORMATION FOR HEALTHCARE PROVIDERS

gammaCore Sapphire™ (non-invasive vagus nerve stimulator) is a hand-held, rechargeable, portable device consisting of a rechargeable battery, signal-generating and -amplifying electronics, and a control button for the patient to control the signal amplitude. It is intended for single patient use and can deliver multiple stimulations a day. The device provides visible (display) and audible (beep) feedback on the device and stimulation status. A pair of stainless-steel surfaces, which are the skin contact surfaces ("stimulation surfaces"), allow the delivery of a proprietary electrical signal. The patient applies electroCore-approved gel to the stimulation surfaces to maintain an uninterrupted conductive path from the stimulation surfaces to the skin on the neck. Tubes of electroCore-approved gel are provided with each unit and refill kit for this purpose. The stimulation surfaces are capped when not in use.

gammaCore produces a low-voltage electric signal consisting of five 5,000-Hz pulses that are repeated at a rate of 25 Hz. The waveform of the gammaCore pulse is approximately a sine wave with a peak voltage limited to 24 Volts when placed on the skin and a maximum output current of 60mA.

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.

8. DISPLAY SYMBOLS

Icon Description	Icon	Example Display	Description
Stimulations Remaining			6 stimulations remaining within a 24-hour period
Intensity Level			Intensity level is at 23
Months Remaining			3 months of therapy remaining*
Days Remaining			30 days of therapy remaining* The display will begin flashing when there are 31 days remaining.
Intensity Level at Last Use			Last delivered intensity level was 23
Battery			Battery is charging
Reload			Refill card is being read
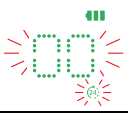
*When the device is first loaded with a refill card, the display will show months of therapy remaining. The display will show the number of months of treatment left until day 31, where it will begin counting down the number of days remaining.

9. DEVICE STATUS INDICATORS

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

Status	Display	Sound	User Action
Start Up / Ready for Use	1. Months/Days Remaining 2. Stimulations Remaining 30 ⟷ 06 (2 seconds)	1 beep after power ON	Follow "How to Use" Instructions (refer to Section 12)
Device in Use	Intensity Level (min 1 – max 40) 23	Short beep each time intensity is increased/ decreased	Follow "How to Use" Instructions (refer to Section 12)
Stimulation Complete	Last Intensity Level Used Will Show 23 **THEN THE DISPLAY WILL SWITCH BETWEEN** 1. Months/Days Remaining 2. Stimulations Remaining 30 ⟷ 06 (2 seconds)	2 short beeps	NONE: Device turns off automatically

Status	Display	Sound	User Action
Maximum number of stimulations reached within 24 hours.	00	None	gammaCore turns off automatically Wait until next 24-hour period
Expired/No Days Left	00	None	gammaCore turns off automatically Reload with refill card
Low Battery	Lo	Repeated long beeps	Place in charging case
Dead Battery	None	None	Place in charging case
Charging	Battery Charge Indicator Bars Flash and Increase Ch	None	Allow device to fully charge
Charging Complete	Ch	None	Remove gammaCore from charging case gammaCore is ready to use

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10. CHARGING INSTRUCTIONS

1. Plug the power cord of the charging case into a power outlet. Only use the provided power cord with the charging case.

2. Place the device into the charging case with the power button facing up. The device should fit into the charging case with ease. Do not force the device into the charging case.

NOTE: The cap is designed to position gammaCore correctly in the charging case. If the device is misaligned, "Un" is displayed. Remove the device and try placing gammaCore in the charging case again.
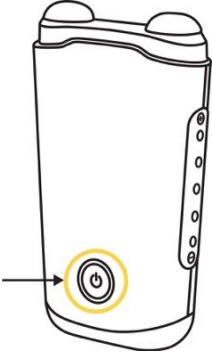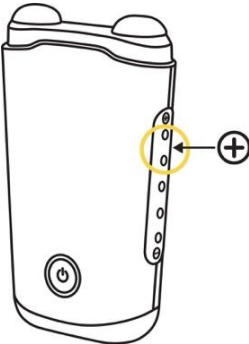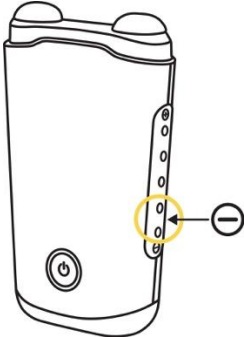
3. The device display will show "Ch" with the battery charge indicator bars flashing and increasing.

4. The device will show "dn" when fully charged.

NOTE: It only takes a few minutes until there is enough charge to deliver 2-3 stimulations.

NOTE: Charge your device before first use. It typically takes 4 to 5 hours for a full charge. High temperatures may increase the charging time. Monitor battery life and charge as needed to maintain an adequate number of stimulations on gammaCore (refer to Section 9 for feedback on the device status indicators).

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11. FUNCTIONS

Power Button	Increase Intensity Level	Decrease Intensity Level
Press power button to turn device ON **Hold power button to turn the device OFF**	**Press upper area of the control button**	**Press lower area of the control button**

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12. HOW TO USE GAMMACORE SAPPHIRE

Set Up
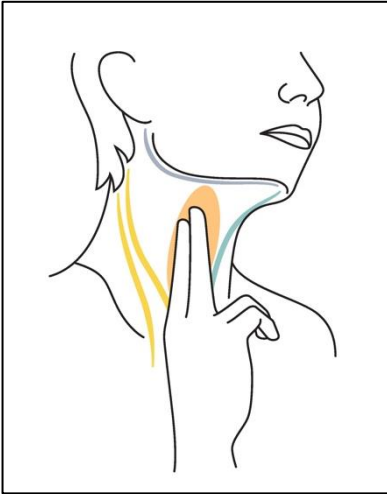
1. Remove any jewelry that may touch the treatment location.

2. Find a comfortable position. (A place where you can see your neck in a mirror may 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.
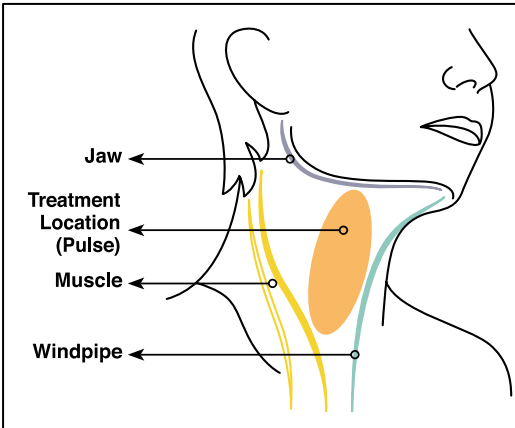
The stimulation surfaces of the device will line up with the following landmarks:

- 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)
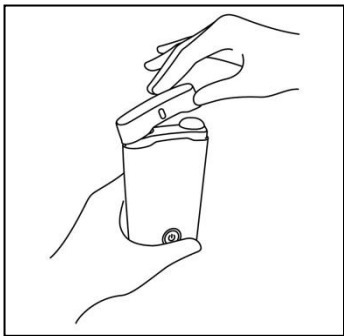
4. Remove the cap.

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 not effective.
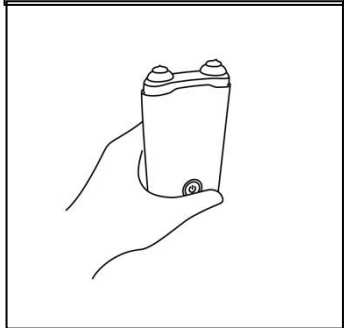
CAUTION: Only use an electroCore-approved gel with gammaCore. Please contact electroCore Customer Service for an electroCore-approved gel that works with the device (refer to Section 24).

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.

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 beep twice, and the stimulation will automatically stop.

NOTE: The months/days and stimulations remaining can be viewed by turning gammaCore 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.

10. Clean gammaCore by wiping the leftover gel off the stimulation surfaces with a soft, dry cloth (refer to Section 15).

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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13. RELOADING INSTRUCTIONS
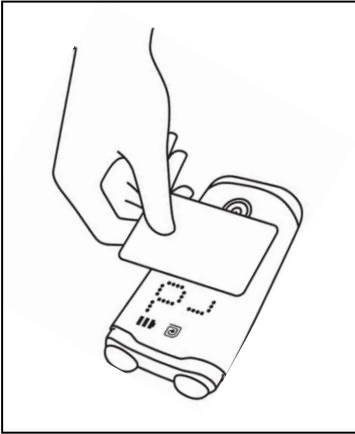
1. Once you have received your gammaCore Refill Card, you can now load your device.

2. Turn gammaCore on by pressing the power button. Have your refill card ready.

3. Once gammaCore is turned on, place the device on a hard surface with the display screen facing up. Place the refill card across the device so you can see the display (as shown in the diagram).

4. Leave the refill card on the device for a minimum of 10 seconds. (Do not move the refill card as it may disrupt the loading process).

5. gammaCore will display "rd" and the 🔄 icon (refer to Section 8 for displayed details) while gammaCore is reading the refill card.

6. gammaCore will *beep twice* when therapy has been loaded. The reading and loading process may take a minimum of 10 seconds.

7. The number of months/days loaded onto your gammaCore will be displayed (Refer to Section 8). The device is now ready to be used for treatment.

NOTE: If a "C" (warning) or "H" (error) with a numeric code is displayed, an error has occurred during the reloading process. Turn the device off, then back on and try to reload a second time. If the error continues, contact electroCore Customer Service.

NOTE: If 5 card reloading "H" errors occur during a 24-hour period, "H2" will be displayed. Wait 24 hours and retry or contact electroCore Customer Service.

NOTE: If 10 card loading attempts are made during a 24-hour period, "H1" will be displayed. Wait 24 hours and retry or contact electroCore Customer Service.

14. DEVICE ERROR CODES

Status	Display	Sound	User Action
Start-Up Error	An example of an error code: ▪▪▪ E7 Errors may have different numeric codes	None	Wait 24 hours and restart device (Turn off and on again)*
Too many attempts to reload the device in 24-hour period	H1	Repeated Long Beeps	Wait 24 hours and try again*
Too many reload errors in 24-hour period	H2	Repeated Long Beeps	Wait 24 hours and try again*
Card already used	C3	None	Locate unused refill card and try again*
Wrong Card Version for this Device	C5	None	Card has already been used or wrong version card for this device*
gammaCore Not Correctly Placed in Charging Case	Un	None	Ensure gammaCore is placed correctly in charging case

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

NOTE: If you see a code displayed that is not listed above or if the error has a different numeric code, contact electroCore Customer Service (refer to Section 24).

15. 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 cap 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.

16. PRODUCT HANDLING

Operating Conditions – gammaCore Sapphire
- Range: -20°C to 60°C (-40°F to 140°F)
- 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.

Operating Conditions – Charging Case
- Range: -20°C to 60°C (-40°F to 140°F)
- Only use the charging case indoors
- Do not place any object except gammaCore on the charging surface
- Maximum Output: 5.5V DC, 5W
- Input: 100 to 240 VAC, 50 to 60 Hz, 0.4A max

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

Service Life
- The service life of gammaCore is 3 years after the date the device has been activated.
- The expiration date of the conductive gel is 5 years after the date of manufacture.

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17. TROUBLESHOOTING

gammaCore does not turn on
• gammaCore is not charged. Charge gammaCore by placing the device in the charging case (refer to Section 10).
• Restart gammaCore by pressing and holding the power button for 3 seconds.

gammaCore does not charge
• If "Un" is displayed, remove gammaCore and place back in charging case. If "Un" continues to be displayed, move device around in the charging case.
• Ensure the power cord is plugged into a live power outlet and into the charging case. Only use the provided power cord with the charging case.

gammaCore has no stimulations left/days left
• A gammaCore Refill Card is needed to reload the device (refer to Section 13). Please contact electroCore Customer Service to order a refill card.

For further assistance, please contact electroCore Customer Service (refer to Section 24).

18. 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 24) 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.

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19. SYMBOLS AND NOMENCLATURE DESCRIPTION

Symbol	Description	Symbol	Description
	Expiration date		Follow operating instructions
LOT	Lot number		Manufacturer
REF	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
SN	Serial number		Storage temperature
NON STERILE	Non-sterile	xxxdyyzzzz (package label)	Date of Manufacture on package label, where "D" is the year of manufacture, e.g. 254DDK1001 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	**MR**	Magnetic resonance unsafe
	Refer to instruction manual	**EC REP**	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	**MD**	Medical device

20. PRODUCT ORDERS AND RETURNS

Authorisation by your HCP is required. Please refer to the device label and contact electroCore Customer Service to place an order for a refill card kit or electroCore-approved gel. Contact electroCore Customer Service for details on local returns policy.

Refer to Section 24 for electroCore Customer Service Contact Information.

21. CLINICAL STUDIES

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

22. ELECTRICAL CLASSIFICATION

❖ Electrical Classification (gammaCore Sapphire)

- UL 60601-1 Class III; EN 60601-1 Internally Powered Equipment
- Type BF Applied part
- IP22 Protected against ingress of solid foreign objects ≥ 12.5 mm diameter and protected against vertically falling water drops when enclosure tilted up to 15°
- Product contains Bluetooth RF transmitter: Frequency range of 2.379 to 2.496 GHz, GFSK Modulation, 1mW max power

❖ Electrical Classification (Charging Case)

- UL 60601-1 Class III
- Accessible Part
- IP22 protected against ingress of solid foreign objects ≥ 12.5 mm diameter and protected against vertically falling water drops when enclosure tilted up to 15°

23. ELECTROMAGNETIC COMPATIBILITY GUIDANCE

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

24. CONTACT INFORMATION

Manufacturer: electroCore, Inc. 200 Forge Way, Suite 205 Rockaway, NJ 07866 United States Telephone: 1 (888) 903-2673 E-mail: customerservice@electrocore.com	**UK Customer Service:** E-mail: customerserviceUK@electrocore.com Telephone: +44 (0) 0800 678 5632 **EU Customer Service:** Email: customerserviceEU@electrocore.com Telephone: +44 (0) 0800 678 5632
Product Complaint Reports and/or related issues may be submitted directly to electroCore, Inc.: Telephone: +1 (973) 355-6708 E-mail: complaints@electrocore.com	**EU Authorized Representative:** Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover, Germany 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.

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