



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

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

1. INDICATIONS AND PRODUCT DESCRIPTION

gammaCore™ Emerald is intended to provide non-invasive vagus nerve stimulation (nVNS) on the side of the neck. gammaCore 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
- Treatment 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 delivers gentle electrical stimulation to the vagus nerve at the neck, helping relieve multiple types of headache pain. Each stimulation lasts 2 minutes, and the device automatically turns off after. You can adjust the intensity to a level that is comfortable for you.

gammaCore allows up to 30 stimulations in a 24-hour period, starting when the device is turned on, and the intensity level is set above 3. Once the daily limit is reached, the device will not deliver more stimulations until the next 24-hour cycle begins. The display shows how many stimulations remain (see Section 8).

gammaCore is rechargeable and comes with a charging pad. To continue therapy after your prescribed days run out, you will need a refill card or a new device prescribed by your health care provider (HCP).

NOTES:

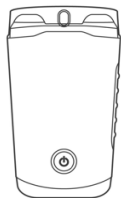
- The 24-hour cycle begins the **first time** the intensity level is set above 3.
- gammaCore comes pre-loaded with a set number of **consecutive** therapy days. Contact the electroCore Customer Experience team for help (see Section 22).

gammaCore may be used independently by patients or with assistance from a health care provider.

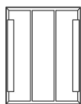
For prescription use only.

gammaCore is supplied non-sterile.

gammaCore Emerald Components



gammaCore Emerald Handset

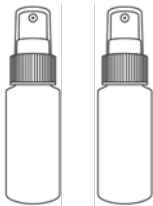


Charging Components:

- Charging Pad
- USB Power Supply
- USB Power Cord

Note: Only use cables and accessories supplied by electroCore, Inc. Using cables and accessories NOT provided by electroCore, Inc., may negatively affect EMC performance

(All charging components are 60601 Certified)



Conductive Spray included with kit: 2 Bottles



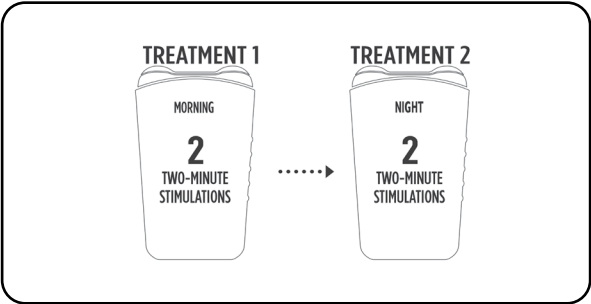
Conductive Gel included with kit: 2 Tubes

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 in the morning and night.*



*Additional treatments may be recommended by a health care 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 microwaves, 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 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 gammaCore 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 devices 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 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. To ensure safety and maximum efficacy, your HCP or an electroCore Customer Experience team member should train you in the proper use of gammaCore (see Section 22).



Precautions

The long-term safety and effectiveness of gammaCore have 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 your HCP.
- For reloadable devices, you must carefully read the Refill Card Instructions to reload your device with therapy.
- Do not use more than 24 stimulations in a 24-hour period, as this has not been tested.
- Only use the included spray or gel with gammaCore. Contact the electroCore Customer Experience team for more information.
- Do not share gammaCore with another person.
- Do not apply gammaCore to your head, eyes, mouth, chest, upper back, or over your heart.
- Remove jewelry that may touch the treatment area (e.g., necklaces, earrings).
- Check gammaCore for any signs of damage.

Do not use gammaCore if:

- The stimulation surfaces are cracked or damaged.
- The device casing is damaged.
- An error message ("E" with a numeric code) is shown on the screen when the device is turned on (see Section 8).
- The device is past its expiration date. Please refer to Section 14 for the Service Life.

During Treatment:

Stop using gammaCore if you experience:

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

If the device malfunctions, stop using it immediately, continue taking your medications, and seek medical care if needed. When possible, contact electroCore Customer Experience for help with your device; electroCore Customer Experience cannot provide medical assistance.

Caring for Your Device:

- Keep gammaCore dry. Avoid 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 extreme temperatures below 32°F or above 100°F (0°C to 38°C), which can cause malfunctions.
- Do not attempt to replace the device battery.
- Do not open, repair, or modify the device. There are no user-serviceable parts.
- The device contains a lithium-ion battery. Avoid damaging, burning, or puncturing the device.
- Keep gammaCore at least 3.3 m (10.8 ft) away from wireless equipment while in use.

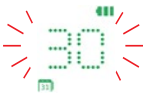
If the device is not working, contact electroCore Customer Experience (see Section 22).

6. WILL I STILL NEED TO TAKE MEDICATIONS?

Talk to your HCP about your treatment plan, including other therapies or medications you use. It is important to always follow your HCP's advice about your medications. gammaCore can be used with your current medications, as no interactions have been reported.

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7. 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 flash when there are 31 days (or less) remaining
Intensity Level at Last Use			Last delivered intensity level was 23
Battery			Battery is charging

8. DEVICE STATUS INDICATORS

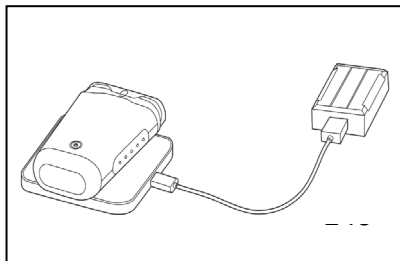
gammaCore has a visual indicator (display) and an auditory signal (beep) to indicate device status.

Status	Display	Sound	User Action
Start-Up/ Ready for Use	1. Months/Days Remaining 2. Stimulations Remaining 	1 Beep After Power ON	Follow “How to Use” Instructions (see Section 11)
Device in Use	Intensity Level (min 1 – max 40) 	Short Beep Each Time Intensity is Increased/ Decreased	Follow “How to Use” Instructions (see Section 11)
Stimulation Complete	Last Intensity Level Used Will Show  THEN THE DISPLAY WILL SWITCH BETWEEN 1. Months/Days Remaining 2. Stimulations Remaining 	2 Short Beeps	NONE: Device turns off automatically

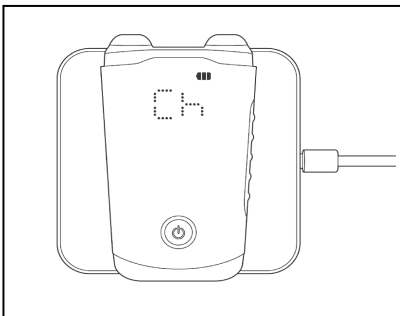
Status	Display	Sound	User Action
Maximum Number of Stimulations Reached Within 24 Hours		None	gammaCore turns off automatically Wait until next 24-hour period
Expired/No Days Left		None	gammaCore turns off automatically Reload with refill card
Low Battery		Repeated Long Beeps	Place on charging pad
Dead Battery	None	None	Place on charging pad
Charging	Battery Charge Indicator Bars Flash and Increase 	None	Allow device to fully charge
Charging Complete		None	Remove gammaCore from charging pad gammaCore is ready to use
gammaCore Not Correctly Placed on Charging Pad		None	Ensure gammaCore is placed in the center of the charging pad
Start-Up Error	An example of an error code:  Errors may have different numeric codes	Repeated Long Beeps	Restart device (Turn off and on again)* If same error occurs, the device should be returned

*If the error is not resolved, contact the electroCore Customer Experience team.

9. CHARGING INSTRUCTIONS



1. Plug the micro USB end of the charging cable into the charging pad, and the larger USB end into the power adapter. Ensure that the power adapter is securely plugged into an outlet.
2. Place the device in the center of the charging pad with the power button facing up.
3. When charging begins, the battery icon on the screen will blink, and after 5–10 seconds, “Ch” will appear.
4. The screen will display “dn” when it’s fully charged. It typically takes approximately 5 hours for a full charge.



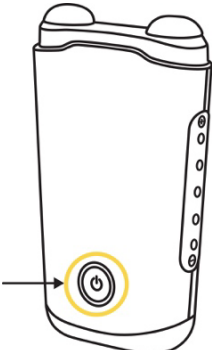
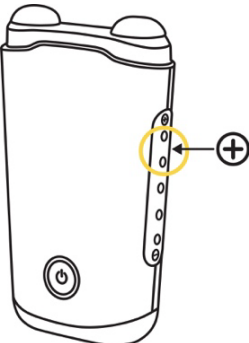
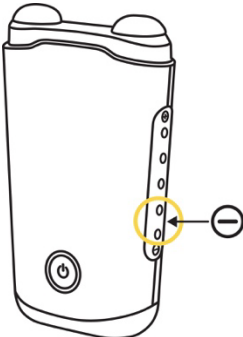
Note: If the device isn’t placed correctly on the charging pad, it will show “Un”. Adjust the position of the device until the battery icon blinks and “Ch” is displayed. Wait a few seconds to confirm it is placed correctly and charging.

Note: Moving the device from the charging pad may restart charging and slow down the full charge. You can still use the device for treatment even if “dn” is not displayed. Check the battery icon to see how much charge remains.

Quick Tips:

- Just a few minutes of charging gives enough power for 2-3 uses.
- Fully charge the device before your first use. This usually takes 4–5 hours but may take longer in high temperatures.
- Check battery life regularly and charge as needed to ensure the device is ready for use (see Section 8 for details on device status).

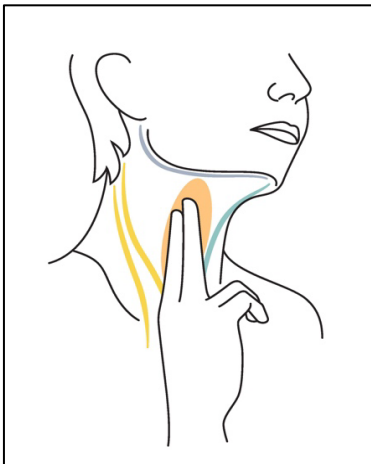
10. FUNCTIONS

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

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11. HOW TO USE GAMMACORE EMERALD

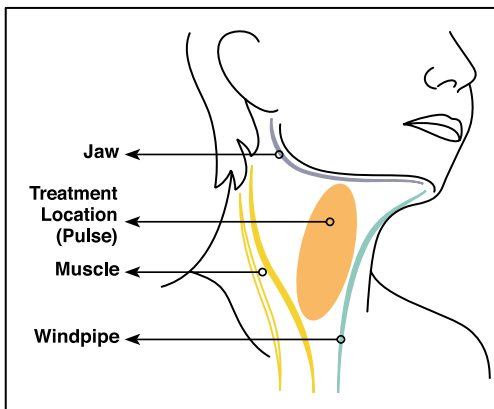
Set-Up



11.1 Remove any jewelry that may touch your neck.

11.2 Sit in a comfortable position where you can easily see your neck in a mirror, if needed.

11.3 Find your pulse on the side of your neck—this is where the vagus nerve is located. Before you start, make sure the skin in this area is clean and dry.



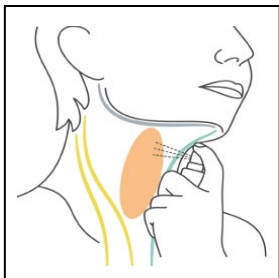
Line up the stimulation surfaces as follows:

- **Orange:** Over your pulse (this is the treatment area).
- **Yellow:** In front of the large neck muscle.
- **Grey:** Just below your jaw.
- **Green:** Next to your windpipe.



11.4 Remove the cap from the device.

11.5 gammaCore comes with 2 gels and 2 sprays. You can choose whether you prefer to use the gel or the spray. Skipping this step could make the stimulation uncomfortable or less effective.



OPTION 1:

Spray 1-2 pumps of the provided spray onto the treatment area.

OR



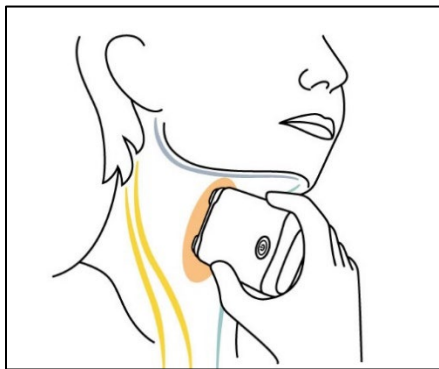
OPTION 2:

Apply a small (pea-size) amount of the provided gel to each stimulation surface.

NOTE: You only need to use one. You do not need to use both the gel and the spray.

CAUTION: Only use the included spray or gel with gammaCore. For additional spray or gel, contact the electroCore Customer Experience team (see Section 22).

Delivering Treatment



11.6 Turn on gammaCore by pressing the power button. It will beep once when ready. The display will show how many stimulations are left for the 24-hour period, and the remaining months or days of therapy.

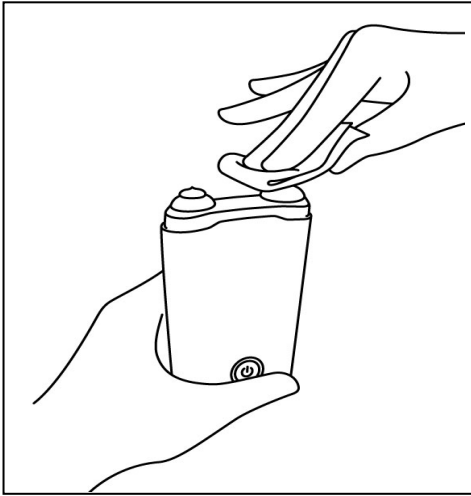
11.7 Place gammaCore on the side of your neck at the treatment area. Use mild to moderate pressure so both stimulation surfaces touch your skin, but avoid pressing too hard.

11.8 Adjust the intensity level by pressing the top of the control button repeatedly. Hold gammaCore in place for the 2-minute stimulation. A slight lip pull or muscle contraction in the treatment area is normal and should stop when the stimulation ends. Slight adjustments to the positioning of the device while on the neck can help achieve a lip pull without having to increase the intensity level

- If muscle contractions feel too strong:
 - Lower the intensity by pressing the bottom of the control button.
 - Adjust gammaCore's position and slowly increase the intensity again.
- If the stimulation is still uncomfortable, remove gammaCore and turn it off by holding the power button.

NOTES:

- **Muscle contractions are normal and should not be painful or uncomfortable.**
- The device has 30 stimulations in a 24-hour period starting when the device is turned on, and the intensity level is set above 3
- Each 2-minute stimulation allows for correct positioning and setting the right intensity.
- Ensure both stimulation surfaces are in contact with your skin; a mirror may help with positioning until you become more familiar.



11.9 After each stimulation, the display will show the last intensity level for 7 seconds, then switch to show the remaining stimulations and months/days remaining. If needed, you can apply more spray or gel between stimulations.

- After 2 minutes, the device will beep twice, and the stimulation will stop.
- To check the remaining stimulations, turn gammaCore on, but avoid setting the intensity above 3 unless you're ready to start as this will count as a stimulation.

11.10 Clean gammaCore by wiping any leftover spray or gel from the surfaces with a soft, dry cloth (see Section 13).

11.11 Wipe off any excess spray or gel from your neck with a cloth or tissue to avoid skin irritation.

11.12 Put the cap back on gammaCore after use.

12. IMPORTANT INFORMATION FOR PATIENTS

Patients using gammaCore should:

- **Discuss Health Changes:** Inform your health care provider if your health changes. They can help decide if gammaCore is still the right treatment for you.
- **Ask About Proper Use and Risks:** Make sure you understand how to use gammaCore correctly, including any potential risks. Your healthcare provider can guide you and provide important information about the device.

13. CLEANING

- After each use, gently wipe the stimulation surfaces with a soft, dry cloth to remove any leftover spray or gel.
- Replace the cap back on the device to keep the stimulation surfaces clean and protected from dirt 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.

14. PRODUCT HANDLING

Operating Conditions – gammaCore Emerald

- Range: 32°F to 100°F (0°C to 38°C)
- Humidity 10% - 90%
- Barometric Pressure: 80 to 101kPa
- Altitude: Use below 2000m
- Maximum Output: 24V (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 Pad

- Range: 32°F to 100°F (0°C to 38°C)
- Humidity 10% - 90%
- Barometric Pressure: 80 to 101kPa
- Altitude: Use below 2000m
- Maximum Output: 15W
- Input: 5V 2A, 9V 2A
- Only use the charging pad indoors
- Do not place any object except gammaCore on the charging pad

Operating Conditions – Power Supply

- Range: 32°F to 100°F (0°C to 38°C)
- Humidity 10% - 90%
- Barometric Pressure: 80 to 101kPa
- Altitude: Use below 2000m
- Maximum Output: 5W
- Input: 100 ~ 240 VAC ($\pm 10\%$)
- Frequency: 50/60Hz

*gammaCore is designed with a safety feature to ensure voltage does not exceed 30V.

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 the 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 spray is 4 years after the date of manufacture.
- The expiration date of the gel is 5 years after the date of manufacture.

15. TROUBLESHOOTING

gammaCore does not turn on

- Make sure gammaCore is charged by placing it on the charging pad (see Section 9).
- Restart gammaCore by pressing and holding the power button for 3 seconds.

gammaCore does not charge

- Adjust the device on the charging pad until the battery indicator light “Ch” is shown.

gammaCore has no stimulations left/days left

- Use a gammaCore refill card to reload the device (See Refill Card Instructions).
- Order a new device.

For further assistance, please contact electroCore Customer Experience (see Section 22).

16. PRODUCT DISPOSAL



Regulations require that the 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 Experience (see Section 22) if you have questions.

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

NOTE: Please dispose of 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.

17. 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
	Barometric Pressure		Humidity
	Non-sterile	xxxfyyzzzz (package label)	Date of Manufacture on package label, where "F" is the year of manufacture, e.g., 254FDK1001 indicates the year of manufacture is 2025
	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

18. PRODUCT ORDERS AND RETURNS

Contact the electroCore Customer Experience team to:

- Order a refill card or a new device
- Order additional conductive spray and/or gel
- Return a device, including one that isn't working

19. CLINICAL STUDIES

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

20. ELECTRICAL CLASSIFICATION

❖ Electrical Classification (gammaCore Emerald)

- 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 the enclosure is tilted up to 15°

❖ Power Supply

- Manufacturer HDP Power, Model HDP05-MD05010U
- Output 5.0V 1000mA Max
- Certified to IEC 62368-1 and IEC 60601 standards
- Maximum Output Power 5W

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21. ELECTROMAGNETIC COMPATIBILITY GUIDANCE

gammaCore has been tested for radiated RF (radio frequency) immunity at certain frequencies. Using it near devices that emit other frequencies could cause it to work improperly.

EMC Precautions

- Stacking of gammaCore or use in proximity of other devices may cause EM disturbances
- gammaCore function may be lost or degraded due to EM disturbances
- Portable RF communications equipment and its peripherals should not be used closer than 30 cm (12 inches) to any part of gammaCore

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
gammaCore is intended for use in the electromagnetic environment specified below. The customer or the user of gammaCore should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	gammaCore must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. gammaCore 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	

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**Recommended Separation Distances between Portable and Mobile
RF Communications Equipment and gammaCore**

The customer or the user of gammaCore can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and gammaCore, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.6 GHz $d = 0.70\sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of gammaCore than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6 ISM and amateur radio bands	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 0.58\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people, and animals.			

^aField strengths from fixed transmitters, such as base stations or radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which gammaCore is used exceeds the applicable RF compliance level above, gammaCore should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating gammaCore.

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2kV for AC Mains ± 1 kV Other	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	± 1 kV for power supply lines ± 2 kV line(s) to earth	± 1 kV for power supply lines ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycles <5% U_T >95% % dip for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (95% dip in U_T) for 250/300 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycles <5% U_T (>95% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25/30 cycles <5% U_T (95% dip in U_T) for 250/300 cycles	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3 (Table 9)	Table 9 – Frequencies and levels Pulse Modulation see IEC60601-1-2	Table 9 – Frequencies and levels Pulse Modulation see IEC60601-1-2	
IMMUNITY to proximity magnetic fields IEC 61000-4-39	30kHz: 80A/m 134.2kHz: 65A/m 13.56 MHz: 7.5A/m	30kHz: 80A/m 134.2kHz: 65A/m 13.56 MHz: 7.5A/m	
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Note: The remainder of this page was intentionally left blank.

22. CONTACT INFORMATION

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United States



Manufacturer:

Telephone: 888-903-2673

Email: customerservice@electrocore.com

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200 Forge Way, Suite 205
Rockaway, NJ 07866
United States

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

Telephone: 973-355-6708

Email: complaints@electrocore.com

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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