



Instructions for Use for gammaCore Sapphire™ CV

(non-invasive Vagus Nerve Stimulator) authorized for emergency use in the acute treatment of adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, using non-invasive VNS on either side of the patient’s neck during the COVID-19 pandemic.

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

1. EMERGENCY USE AUTHORIZATION

FDA has issued an Emergency Use Authorization for the emergency use of the gammaCore Sapphire CV for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their Healthcare Provider, by using non-invasive Vagus Nerve Stimulation (nVNS) on either side of the patient's neck during the Coronavirus Disease 2019 (COVID-19) pandemic.

gammaCore Sapphire CV has neither been cleared nor approved for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive Vagus nerve Stimulation (nVNS) on either side of the patient's neck during the Coronavirus Disease 2019 (COVID-19) pandemic.

gammaCore Sapphire CV has been authorized for the above emergency use by FDA under an Emergency Use Authorization.

gammaCore Sapphire CV has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked.

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2. INDICATION AND PRODUCT DESCRIPTION

The gammaCore Sapphire™ CV (non-invasive Vagus Nerve Stimulator) is intended for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive Vagus nerve Stimulation (nVNS) on either side of the patient's neck during the Coronavirus Disease 2019 (COVID-19) pandemic. The gammaCore Sapphire CV 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 the gammaCore Sapphire CV lasts 2 minutes. The patient controls the intensity level.

The gammaCore Sapphire CV 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 Sapphire CV is rechargeable and includes a charging case to charge the device. The use of more than 24 stimulations per day has not been evaluated in controlled clinical trials. **Do not use gammaCore Sapphire CV more than 24 stimulations in a 24 hour period.**

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

gammaCore Sapphire CV is supplied non-sterile.



Device Feature	Description / Use
Stimulation Surfaces	Points of contact with patient's skin
Display	Indicates device status (refer to Section 8)
Power Button	Turns power ON/OFF
Control Button	Increase/decrease intensity level
Cap	Covers and protects the stimulation surfaces
Charging Case (Case with Power Cord)	Charges the device (refer to Section 10)

For prescription use only.

3. GAMMACORE SAPPHIRE CV TREATMENT RECOMMENDATIONS

- *The gammaCore Sapphire CV is intended for acute use at home or in healthcare settings to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, using non-invasive vagus nerve stimulation (nVNS) on either side of the patient's neck during the Coronavirus Disease 2019 (COVID-19) pandemic.*
- One treatment consisting of two consecutive 2-minute stimulations
- If the therapy does not provide relief, seek medical attention by consulting your Healthcare Provider.
- 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.



For a detailed treatment guide, please refer to Section 12.9

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4. COMMON SIDE EFFECTS ASSOCIATED WITH GAMMACORE SAPPHIRE CV

The most common side effects (reported in patients who participated in gammaCore Sapphire CV studies) include:

- 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. WILL I STILL NEED TO TAKE MEDICATIONS?

People respond differently to gammaCore Sapphire CV. 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.

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6. 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 gammaCore Sapphire CV has neither been cleared nor approved for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive Vagus nerve Stimulation (nVNS) on either side of the patient's neck during the Coronavirus Disease 2019 (COVID-19) pandemic.
- The safety and efficacy of gammaCore Sapphire CV has not been formally evaluated in any patients with COVID-19
- **The gammaCore Sapphire CV is contraindicated for:**
 - Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
 - Patients with a metallic device, such as a stent, bone plate, or bone screw, implanted at or near your neck
 - Patients with an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on their neck at the treatment location
- **Patients should not use the gammaCore Sapphire CV:**
 - While they are driving, operating machinery, or during any activity that may put the patient at risk of injury
 - If they have any planned surgeries that may involve implants. The Patient should advise their HCP accordingly
 - Near microwave machines, magnetic resonance imaging, radio frequency surgical, or computer-aided tomography machine
 - In an explosive atmosphere or in the presence of flammable gas mixtures
 - If the patient has wet skin, is in water, or just stepped out of the water (e.g. shower, bath, pool)
 - If the patient is using another device at the same time (e.g. TENS Unit, muscle stimulator) or any portable electronic device

Contact your HCP if your symptoms continue or worsen.

Treatment is intended to be given (administered) as directed by an HCP. Your HCP must train you on the proper use of gammaCore Sapphire CV.



Precautions

- Only use gammaCore Sapphire CV as described in these *Instructions for Use*, or as otherwise directed by your 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 Sapphire CV. Please contact electroCore Customer Service for an electroCore-approved gel that works with the device.
- Do not share your gammaCore Sapphire CV with another person.
- gammaCore Sapphire CV 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.

Before Use:

- Carefully read the gammaCore Sapphire CV *Instructions for Use*. Ask your HCP or electroCore Customer Service if you have any questions about how to use the device or require any further clarification on the *Instructions for Use*.
- Remove jewelry that may touch the treatment location (necklaces, earrings, etc.).
- Carefully examine the device for any signs of damage or defects; if present contact your HCP and when possible, contact electroCore Customer Service using the information provided in Section 25.

Do not use gammaCore Sapphire CV if:

- The stimulation surfaces are broken or cracked.
- The casing is cracked, dented, or appears to be damaged.
- It has passed its expiration date. The expiration date is indicated on the device packaging.
- Error code "C4" is displayed. (refer to Section 9)

Discontinue treatment if you experience:

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

If gammaCore Sapphire CV seems to malfunction, discontinue use immediately. Contact your HCP and seek medical care as needed. When possible, contact electroCore Customer Service for assistance with your gammaCore Sapphire CV; electroCore Customer Service cannot provide medical assistance.

Caring for Your gammaCore Sapphire CV:

- Turn off gammaCore Sapphire CV when it is not being used. If gammaCore Sapphire CV is not turned off, the battery may become depleted and the device may not deliver treatment when needed.
- If the battery becomes depleted, place gammaCore Sapphire CV in the charging case to recharge.

- Moisture may damage the gammaCore Sapphire CV. Keep the device away from items such as nebulizers and steam kettles.
- Store gammaCore Sapphire CV 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.
- Do not open or take apart the case or attempt to repair or modify the device. There are no user serviceable parts.
- Do not intentionally damage, burn, or puncture the device.
- Wireless communications equipment, such as wireless home network devices, mobile phones, walkie-talkies, cordless telephones and their base stations can affect gammaCore Sapphire CV. Keep gammaCore Sapphire CV at least 3.3 m (10.8 ft) away from these items while in use (refer to Section 24 for additional information).

If the device is not working, contact electroCore Customer Service (refer to Section 25).

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7. POTENTIAL RISKS AND COMPLICATIONS ASSOCIATED WITH OTHER VAGUS NERVE STIMULATION DEVICES













The following risks and complications have been associated with other nVNS devices and may potentially occur with gammaCore Sapphire CV:

- Pain
- Skin irritation
- Headache
- Muscle twitching and/or contractions of head/neck/face
- Gastrointestinal discomfort
- Hoarseness or change in voice
- Irregular heartbeat (arrhythmia)
- Light-headedness/dizziness
- Metallic taste
- Coughing
- Nausea
- Shortness of breath (dyspnea)
- Tingling, pricking, or a feeling of “pins and needles” (paresthesia/dysesthesia)

Please refer to Section 4 for common side effects associated with gammaCore Sapphire CV use.





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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			9 months of therapy remaining
Days Remaining			30 days of therapy remaining* *The display will begin flashing when there are 31 or fewer days remaining.
Intensity Level at Last Use			Last delivered intensity level was 23
Battery			Battery is charging

9. DEVICE STATUS INDICATORS

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

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

*If error is not resolved, contact electroCore Customer Service (refer to Section 25).

Status	Display	Sound	User Action
Maximum number of stimulations reached within 24 hours.		None	gammaCore Sapphire CV turns off automatically Wait until next 24-hour period
Expired/No Days Left		None	gammaCore Sapphire CV turns off automatically
Low Battery		Repeated long beeps	Place in charging case
Dead Battery	None	None	Place in charging case
Charging	Battery Charge Indicator Bars Flash and Increase 	None	Allow device to fully charge
Charging Complete		None	Remove gammaCore Sapphire CV from charging case gammaCore Sapphire CV is ready to use
gammaCore Sapphire CV Not Correctly Placed in Charging Case		None	Ensure gammaCore Sapphire CV is placed correctly in charging case
Card error or wrong card version		None	Remove card from front of device; not a reloadable device

*If error is not resolved, contact electroCore Customer Service (refer to Section 25).

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 Sapphire CV correctly in the charging case. If the device is misaligned, “Un” is displayed. Remove the device and try placing gammaCore Sapphire CV in the charging case again.

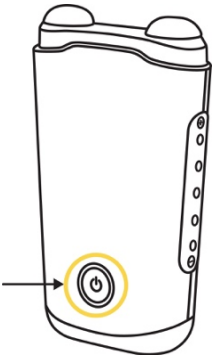
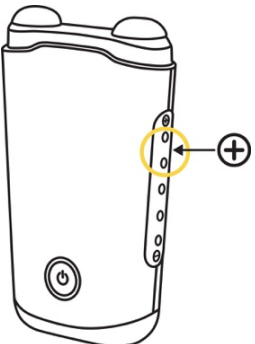
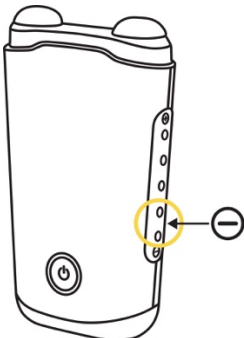
3. The device display will show “Ch” with the battery charge indicator bars flashing and increasing.
4. The device will show “dn” when fully charged.

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 6 to 7 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 Sapphire CV (refer to Section 9 for feedback on the device status indicators).

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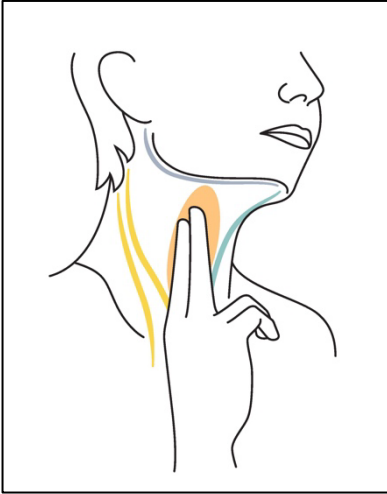
11. FUNCTIONS

Power Button	Increase Intensity Level	Decrease Intensity Level
 A line drawing of a handheld device with a power button at the bottom. The power button is a circle with a power symbol (a circle with a vertical line and a horizontal line) inside. A yellow circle highlights the power button, and an arrow points to it from the left.	 A line drawing of the device showing the control buttons on the right side. The upper area of the control buttons is highlighted with a yellow circle. An arrow points from a plus sign (+) to this area.	 A line drawing of the device showing the control buttons on the right side. The lower area of the control buttons is highlighted with a yellow circle. An arrow points from a minus sign (-) to this area.
<p>Press the power button to turn device ON</p>	<p>Press the upper area of the control button</p>	<p>Press the lower area of the control button</p>
<p>Hold the power button to turn the device OFF</p>		

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12. HOW TO USE GAMMACORE SAPPHIRE CV

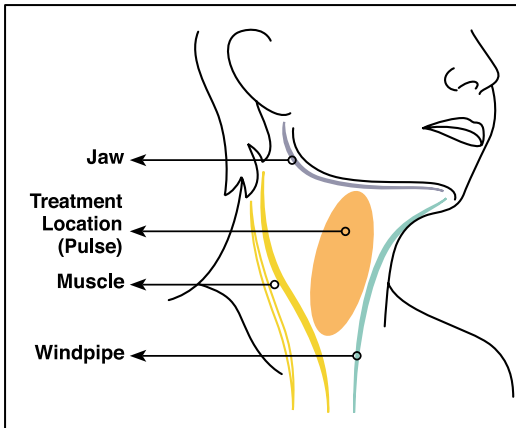
Set Up



12.1 Remove any jewelry that may touch the treatment location.

12.2 Find a comfortable sitting position. (A place where you can see your neck in a mirror may be helpful.)

12.3 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:

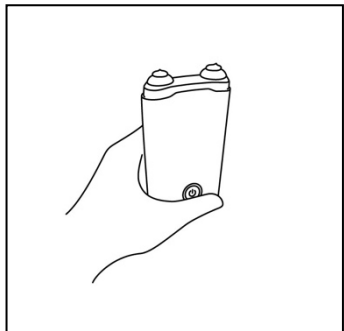
- Over the pulse (orange); this is the treatment location
- In front of the large muscle at the side of the neck (yellow)
- Just below the lower jaw (grey)
- Lined up next to the windpipe (green)



12.4 Remove the cap.

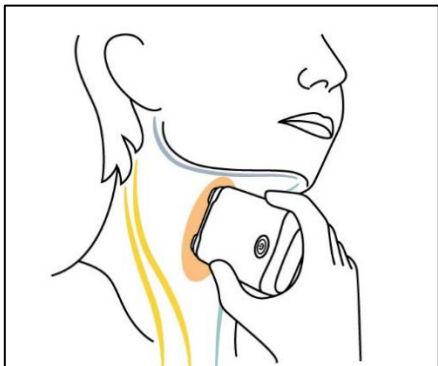


12.5 Apply a small (pea-size) amount of gel to both of the stimulation surfaces. Not applying the gel as described may cause the stimulation to be uncomfortable or less effective.



CAUTION: Only use an electroCore-approved gel with gammaCore Sapphire CV. Please contact electroCore Customer Service for an electroCore-approved gel that works with the device (refer to Section 25).

Delivering Treatment



12.6 Turn gammaCore Sapphire CV 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.

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

12.8 Increase the intensity level by repeatedly pressing the top area of the control button to the maximum level you can tolerate. Once you have found your maximum level, hold gammaCore Sapphire CV in place for the remainder of the 2-minute stimulation. 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. For the majority of individuals, the appropriate level of stimulation will be between 15-25 on the numerical display.

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:

- Removing gammaCore Sapphire CV from the neck.
- Lowering the intensity level by pressing the bottom area of the control button.
- Repositioning gammaCore Sapphire CV 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, turn the device off by pressing and holding the power button and discontinue the stimulation.

CAUTION: Do not turn gammaCore Sapphire CV on again until preparing for the next treatment. The device has a limited number of stimulations it can deliver.

12.9. Treatment Guide

The gammaCore Sapphire CV is intended for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive Vagus nerve Stimulation (nVNS) on either side of the patient's neck during the Coronavirus Disease 2019 (COVID-19) pandemic.

Each treatment should consist of *two* consecutive 2-minute stimulations at the onset of respiratory distress or shortness of breath. Stimulations may be applied to either side of the neck.

Please refer to Section 3 for an example.

The HCP must brief the patient on the following items:

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

NOTE: The length of each stimulation, 2-minutes, provides enough time for correct positioning of gammaCore Sapphire CV 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.

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12.10 Remove gammaCore Sapphire CV after each stimulation. At the end of each stimulation, the device will display the number of stimulations and months/days remaining and the last intensity level before automatically turning off.

NOTE: After 2 minutes, the device will beep twice, and the stimulation will automatically stop.

NOTE: The days and stimulations remaining can be viewed by turning gammaCore Sapphire CV 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 Sapphire CV delivers a limited number of stimulations in a 24-hour period.

12.11 Clean gammaCore Sapphire CV by wiping the leftover gel off the stimulation surfaces with a soft, dry cloth (refer to Section 13).

12.12 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.

12.13 Put the cap back on the device after use.

13. 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.

14. PRODUCT HANDLING

Operating Conditions – gammaCore Sapphire CV

- Range: 0°C to 38°C (32°F to 100°F)
- Humidity: 10% to 90%
- Barometric Pressure: 80 to 101 kPa
- Altitude: Use below 2000 m
- Maximum Output: 30V (peak), 60mA (peak)
- Load Impedance: 450 to 550 Ohms
- gammaCore Sapphire CV produces an electrical signal consisting of five 5,000-Hz pulses, repeating at a rate of 25 Hz. The waveform of the gammaCore Sapphire CV pulse is approximately a sine wave.

Operating Conditions – Charging Case

- Range: 0°C to 38°C (32°F to 100°F)
- Humidity: 10% to 90%
- Barometric Pressure: 80 to 101 kPa
- Altitude: Use below 2000 m
- Only use the charging case indoors
- Do not place any object except gammaCore Sapphire CV 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 Sapphire CV should be stored at room temperature away from moisture
- Range: 0°C to 38°C (32°F to 100°F)
- Humidity: 10% to 90%
- Barometric Pressure: 80 to 101 kPa
- 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 Sapphire CV is 3 years after the date of manufacture (refer to package label for the expiration date).

- The service life of the conductive gel is 5 years.

15. TROUBLESHOOTING

gammaCore Sapphire CV does not turn on

- gammaCore Sapphire CV is not charged. Charge gammaCore Sapphire CV by placing the device in the charging case (refer to Section 10).
- Restart gammaCore Sapphire CV. Turn gammaCore Sapphire CV off and on again.

gammaCore Sapphire CV does not charge

- If “Un” is displayed, remove gammaCore Sapphire CV and place back in charging case. If “Un” continues to be displayed, move device around in the charging case.
- Ensure the AC power cord is plugged into a live power outlet.
- Ensure AC power cord wire is plugged into the charging case.

gammaCore Sapphire CV has no stimulations left/days left

- Contact electroCore Customer Service to order a new device.

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

16. 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 25) if you have questions about the appropriate disposal of this device.

NOTE: gammaCore Sapphire CV contains a lithium battery that cannot be removed by the user.

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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
	Non-sterile	xyyGzzzz (package label)	Date of manufacture on package label, where: <u>yy</u> is the year of manufacture, <u>gg</u> , 2519G1001 indicates the year of manufacture is 2019
	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		Atmospheric pressure range
	Refer to instruction manual		Relative humidity range
	Information or additional information available		Magnetic resonance unsafe
	Separate collection for waste of electrical and electronic equipment		Authorized representative

18. ORDERING INFORMATION

Authorization by your HCP is required.

Catalog Number	Description
11016-00301	gammaCore Sapphire CV
40000-00103	gammaCore Conductive Gel

19. PRODUCT ORDERS AND RETURNS

To learn more about ordering gammaCore Sapphire CV, call electroCore Customer Service.

Requests to return a device, including a non-working device, when treatment has been completed or when the COVID-19 public health emergency has been terminated should be made to electroCore Customer Service.

When the COVID-19 public health emergency has been terminated, electroCore will attempt to inform recipients of gammaCore Sapphire CV to facilitate the return or disposal of the gammaCore Sapphire CV.

Refer to Section 25 for electroCore Customer Service Contact Information.

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ADDITIONAL INFORMATION FOR HEALTHCARE PROVIDERS

20. DETAILED PRODUCT DESCRIPTION



gammaCore Sapphire™ CV (non-invasive Vagus Nerve Stimulator) is a multi-use, 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. 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 Sapphire CV 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 Sapphire CV 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 signal is transmitted through the skin of the neck to vagus nerve. Each stimulation last 2 minutes allowing the patient to properly position the device, adjust the intensity level, and deliver the dose. After 2 minutes, the device automatically stops delivering the stimulation and turns itself off. Each gammaCore Sapphire CV allows for multiple treatments (Refer to Section 12).

gammaCore Sapphire CV delivers up to 30 stimulations within a 24-hour period (refer to Section 12). Once the maximum daily number of treatments has been reached, the device will not deliver any more stimulations until the following 24-hour period. A charging case is included to charge gammaCore Sapphire CV.

21. ADDITIONAL 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

- Please refer to Section 6 for a complete list of warnings.



Precautions

- Prior to using or prescribing gammaCore Sapphire CV, the HCP should read and understand all instructions and labeling.
- gammaCore Sapphire CV is not to be used outside of its intended use.

Consider all warnings and precautions.

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

22. CLINICAL STUDIES

A summary of the studies that assessed nVNS in patients with asthma is provided in Table 1:

Table 1. Summary of nVNS trials relevant to COVID-19

Study	Design	N	Findings relevant to COVID-19
nVNS for the treatment of acute asthma exacerbations	Prospective, multicenter, open-label study	4	90 minutes after acute nVNS treatment, FEV ₁ improved from baseline by a mean of 73%, and mean VAS dyspnea score decreased from 8 (at baseline) to 1
nVNS for the relief of acute bronchoconstriction due to asthma	Prospective, multicenter, open-label study	30	90 minutes after acute nVNS treatment, 93% of patients reported improvement in VAS dyspnea score, and 86% had improvements in FEV ₁

Abbreviations: COVID-19, coronavirus disease 2019; FEV₁, forced expiratory volume in 1 second; nVNS, non-invasive vagus nerve stimulation; VAS, visual analog scale.

23. ELECTRICAL CLASSIFICATION

- ❖ Electrical Classification (gammaCore Sapphire CV)
 - 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°

24. ELECTROMAGNETIC COMPATIBILITY GUIDANCE

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and gammaCore Sapphire CV

The customer or the user of gammaCore Sapphire CV can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and gammaCore Sapphire CV, 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.

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

gammaCore Sapphire CV is intended for use in the electromagnetic environment specified below.
The customer or the user of gammaCore Sapphire CV should assure 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 Sapphire CV 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	6 Vrms 150 kHz to 80 MHz	6 Vrms	$d = 0.58\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.6 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 Sapphire CV is used exceeds the applicable RF compliance level above, gammaCore Sapphire CV should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating gammaCore Sapphire CV.

^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 Sapphire CV is intended for use in the electromagnetic environment specified below.
The customer or the user of gammaCore Sapphire CV 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	± 2 kV 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 $40\% U_T$ 60 % dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ (95% dip in U_T) for 5 cycles	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycles $40\% U_T$ (60% dip in U_T) for 5 cycles $7\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ (95% dip in U_T) for 5 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.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

25. CONTACT INFORMATION

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

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Customer Service Limited Liability:

gammaCore Sapphire CV is guaranteed against defects in materials, function, and workmanship for the lesser of: (1) one year; or (2) the expiration date of the product, whether it expires due to completion of all of the treatments or expires due to the time limit set on the product. electroCore shall not be liable, expressly or implied, for any damage that might arise or be caused, whether by the customer or by any of the users of the product, as a result of: (a) misuse, mishandling, and/or improper operation; (b) repairs or modifications performed other than by electroCore or an electroCore authorized repair facility; (c) use of the device in any manner other than for which it is intended; or (d) any special, indirect and/or consequential damages of any kind and however caused arising from the sale or use of the product.

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