

# FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of gammaCore Sapphire CV During the COVID-19 Pandemic

July 10, 2020

Coronavirus  
Disease 2019  
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the gammaCore Sapphire CV during the Coronavirus Disease 2019 (COVID-19) pandemic. Early reports of COVID-19 infections demonstrate a high level of aggressive, prolonged inflammation in the airways which may result in significant worsening of asthma-related symptoms in the large adult asthmatic population. 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 (VNS) on either side of the patient's neck during the (COVID-19) pandemic.

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**All patients who are treated with the gammaCore Sapphire CV should receive the Fact Sheet for Patients: Emergency Use of gammaCore Sapphire CV During the COVID-19 Pandemic**

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## What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). Early reports of COVID-19 infections demonstrate a high level of aggressive, prolonged inflammation in the airways which may result in significant worsening of asthma symptoms in the large asthmatic population. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please

check the CDC webpage (link provided below) for the most up to date information.

## What is the gammaCore Sapphire CV?

The gammaCore Sapphire CV is a multiuse, handheld, rechargeable, portable, non-invasive vagus nerve stimulator consisting of a rechargeable battery, signal-generating and amplifying electronics, with a slide control switch for user/operator control of the signal amplitude (relative range, 0-40 continuous), an LED screen and auditory signal (to indicate device status), and a pair of stainless steel skin contact surfaces (referred to as the "stimulation surfaces").

The gammaCore Sapphire CV produces a low-voltage electrical signal consisting of five 5000-Hz pulses that are repeated at a rate of 25 Hz. The waveform of the electric pulses approximates a sine wave with peak voltage limited to +/-30 Volts (24 Volts when against the skin of the neck) and a maximum output current of 60mA. The signal is transmitted through the skin of the neck to the vagus nerve.

## What do I need to know about the emergency use of the gammaCore Sapphire CV?

- The gammaCore Sapphire CV has been authorized 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 (VNS) on either side of the patient's neck.
- The gammaCore Sapphire CV is a prescription device for use at home or in healthcare settings.
- Healthcare providers should review the applicable gammaCore Sapphire CV Instructions for Use and ensure patients are adequately trained on the proper use of the device.
- The device has not been studied in COVID-19 patients.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as

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outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

## Who should be prescribed this medical device?

Adult patients at home or in healthcare settings with known or suspected COVID-19 infection who are experiencing acute 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 VNS on either side of the patient's neck.

## What are the known and potential benefits and risks of the gammaCore Sapphire CV?

Potential benefits of gammaCore Sapphire CV:

- Improvement in airflow restriction secondary to asthma
- Improvement in dyspnea

Known and potential risks include:

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

## What are the contraindications or warnings?

The gammaCore Sapphire SV is contraindicated for:

- Patients with 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 their neck.
- Patients with an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on their neck at the treatment location

Warnings/precautions for the gammaCore Sapphire CV:

- The gammaCore Sapphire CV has not been cleared or approved 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 (VNS) on either side of the patient's neck.

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;
- Near microwave machines, magnetic resonance imaging, radio frequency surgical, or computer-aided tomography machines;
- Near wireless communications equipment, as these can affect its use. Patients should keep the gammaCore Sapphire CV at least 3.3 m / 10.8 feet away from items such as these while in use:
  - Wireless home network devices,
  - Mobile phones,
  - Walkie-talkies,
  - Cordless telephones and their base stations;
- In an explosive atmosphere or in the presence of flammable gas mixtures;

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- If the patient has wet skin, is in water, or just stepped out of the water (e.g. shower, bath, pool); or
- If the patient is using another device at the same time (e.g. TENS Unit, muscle stimulator) or any portable electronic device.
- More than 24 stimulations in a 24-hour period. The use of more than 24 stimulations per day has not been evaluated in controlled clinical trials.
- With other conductive gels. Patients should only use an electroCore-approved gel with gammaCore Sapphire CV
- Applied across or through the head, directly on the eye, covering the mouth, on the chest or the upper back, or over the heart

In addition, patients should not share the gammaCore Sapphire CV with another person.

## What are the alternatives to gammaCore Sapphire CV and the known and potential benefits and risks of such products?

While there are drug treatments available, the gammaCore Sapphire CV may provide benefits to some patients for whom standard drug therapy is unable to meet their needs. This therapy could also potentially be an alternative for those who cannot tolerate beta agonists or those whose exacerbations cannot be controlled with the limited use associated with standard inhaled treatments

There are no FDA approved or cleared devices for the acute use 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 (VNS) on either side of the patient's neck.

Non-device alternatives to gammaCore Sapphire CV for managing asthma in patients with known or suspected COVID-19 infection include beta agonists (bronchodilators).

Benefits of these medications include:

- Proven safety and effectiveness in managing asthma
- Clinician familiarity with use, dosing, and side effects

Risks of these medications include:

- Tachycardia
- Tremors
- Headache
- Mood changes
- Weight gain
- Thrush
- Cough
- Sore Throat

## What is an EUA?

The United States FDA has authorized use of the gammaCore Sapphire CV device 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 (VNS) on either side of the patient's neck, available under an emergency access mechanism called an EUA.

The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

This device has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the device meets certain criteria for safety, performance, and labeling, and that it may be effective in treating patients with COVID-19.

The EUA for the gammaCore Sapphire CV device is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless

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terminated or revoked (after which the products may no longer be used). An FDA approved or cleared device should be used instead of the gammaCore Sapphire CV under EUA, when applicable and available.

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## Where can I go for updates and more information?

### **CDC webpages:**

**General:** <https://www.cdc.gov/COVID19>

**Healthcare Professionals:**

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

**Infection Prevention and Control Recommendations in Healthcare Settings:**

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

**Infection Control:** <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

### **FDA webpages:**

**General:** [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

**EUAs:** (includes links to patient fact sheet and manufacturer's instructions) <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

### **Manufacturer contact info:**

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