FACT SHEET FOR PATIENTS

G Medical VSMS ECG Patch **May 14, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider needs to remotely monitor the "QT interval" on your electrocardiogram (ECG or EKG) using the G Medical VSMS ECG Patch ("VSMS Patch") while you are in the hospital undergoing treatment for COVID-19. The QT interval is a measurement used to evaluate some of the electrical properties of your heart.

Use of the VSMS Patch will assist in remote monitoring of the QT interval on your ECG because you are being treated for COVID-19 with drugs that can prolong the QT interval and may cause life-threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Monitoring your heart rhythm remotely will allow healthcare providers to monitor you for the duration of your treatment in the hospital, while reducing their exposure to SARS-CoV-2, the virus that causes COVID-19.

This Fact Sheet contains information to help you understand the risks and benefits of using the VSMS Patch to monitor the QT interval on your ECG. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

For the most up to date information on COVID-19, please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?

COVID-19 is a disease caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat, or new loss of taste or smell.

What is the VSMS Patch?

The VSMS Patch consists of an adhesive patch device with a reusable recorder and a smartphone, which will be provided to you. The VSMS Patch and recorder are worn on your chest for up to 14 days. The patch records your ECG data and transmits the data to the smartphone. The data are saved and wirelessly transmitted to a call center for analysis. A certified cardiographic technician at the call center will compile the clinical findings and send the report to your healthcare provider at the hospital.

Why will this VSMS Patch be used on me?

The medical community is rapidly coming to realize that there may be a need to monitor patients being treated in the hospital for COVID-19 because some drugs (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin) that are being evaluated and/or used for the treatment of COVID-19 can prolong the QT interval in an ECG and may cause life-threatening arrhythmias in certain patients.

The VSMS Patch is specifically used to remotely monitor the QT interval measurement on your ECG. Monitoring your QT interval remotely will allow healthcare providers to monitor you for the duration of your treatment, which may allow for healthcare providers to identify problems before they occur, while reducing their exposure to SARS-CoV-2, the virus that causes COVID-19.

What are the known and potential risks and benefits of the VSMS Patch?

Known and potential benefits of the VSMS Patch include:

- Your healthcare provider can use the VSMS Patch to remotely monitor, throughout your hospital stay, the QT interval on your ECG to assess your risk for heart rhythm problems associated with some of the drugs that are being used to treat you for COVID-19 (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin).

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General Webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

- Through remote monitoring, the VSMS Patch may reduce repeated exposure of healthcare workers to SARS-CoV-2, the virus that causes COVID-19.

The VSMS Patch is not likely to cause injury. However, harms may occur due to:

- Inaccurate measurement of or failure to measure the QT prolongation on your ECG.
- Skin irritation related to the medical adhesive. You should seek medical attention if a severe reaction or an allergic reaction lasts beyond 2-3 days.

Based on these factors, the potential benefits from the use of the VSMS Patch are expected to outweigh the potential risks during the COVID-19 outbreak.

You have the option to refuse this product. If you choose to decline use of this device, you should discuss any alternative options with your healthcare provider. This product is expected to be low risk, and reduces healthcare provider exposure to SARS-CoV-2, the virus that causes COVID-19.

How is the VSMS Patch used?

The VSMS Patch is applied on your upper left chest by your healthcare provider. Then, it is connected with the smartphone. The smartphone will automatically send the data to the call center for analysis at a fixed time interval set up by your healthcare provider.

If you feel a symptom (such as dizziness, faint, chest pain, pounding heart, short of breath, and light headed), you may quickly press the blue button on the patch twice (i.e., two quick clicks). This will send the event data to the call center for analysis immediately.

You may take a shower with the VSMS Patch attached to your chest; splashing water over the device is allowed. However, you should minimize exposure directly under the shower head, excessive contact with soap, or scrubbing. Gently dry the VSMS patch after showering.

The VSMS Patch must be replaced after 14 days.

Before using the VSMS Patch, a standard 12-lead ECG will need to be acquired and interpreted by your healthcare provider. If the VSMS Patch records any significant QT interval prolongation on your ECG, a standard 12-lead ECG recording may be repeated to confirm the finding.

Before you start using the VSMS Patch, you should discuss with your healthcare provider the correct protocol for using the VSMS patch and the smartphone. You should also discuss additional actions to take during the monitoring period, and the possibility of adverse events. For assistance and for reporting adverse reactions with the VSMS Patch, contact technical assistance at 1-800-747-4455 or Support.Us@gmedinnovations.com.

How long will monitoring be required?

Your healthcare provider will determine the monitoring period. Each VSMS Patch can be used for up to 14 days. If the monitoring period exceeds 14 days, the VSMS Patch will need to be replaced by your healthcare provider.

Limitations of the VSMS Patch

The VSMS Patch must be used in accordance with the G Medical Innovations VSMS ECG Patch Professional User Guide and VSMS ECG Patch Quick Start Guide.

Using the VSMS Patch to measure QT intervals has only been tested with the recommended patch placement. The accuracy of QT measurement with nonstandard patch placement is unknown.

Transmitting the data to the call center with a smartphone requires wireless connection. When the wireless connection is lost, data will be stored on the VSMS Patch for transfer after connectivity is reestablished.

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Measurements with the VSMS Patch may be unreliable in cases of motion or changes to heart rate, or in the presence of noise or artifacts. To confirm any significant QT interval prolongations on your ECG, you may need to have a standard 12-lead ECG taken for review.

Do not use the VSMS Patch during a magnetic resonance imaging (MRI) scan or in a location where it will be exposed to strong electromagnetic forces. Your doctor should remove the VSMS Patch during external defibrillation procedures. Do not use the VSMS Patch if you have unhealed surgical incisions/dressings on the thoracic region, or if you have skin or soft tissue damage in the area where the VSMS Patch is placed (such as burns, irritation, infections, wounds, etc.).

The VSMS Patch is not intended to automatically detect life-threatening abnormal heart rhythms and alert your healthcare provider immediately. It is intended to record the QT interval measurement on your ECG for later analysis. Prolongations in the QT interval on your ECG can potentially lead to life-threatening abnormal heart rhythms.

The VSMS Patch does not provide continuous monitoring of your ECG. This VSMS patch is not intended to be used in the critical care setting and is not intended for use as a stand-alone diagnostic monitor.

Is the VSMS Patch FDA-approved or cleared?

No. The VSMS Patch is not approved or cleared by the FDA. FDA has authorized the use of the VSMS Patch through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

This 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, including alternative devices used as medical devices, due to shortages during the COVID-19 outbreak. The VSMS Patch available under this EUA 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 demonstrating that it is reasonable to believe that when used in a hospital setting, the VSMS Patch may be effective for remotely monitoring the heart rhythm for the QT interval measurement on an ECG for general care (i.e., not in the intensive care unit) patients who are 18 years of age or older and are undergoing treatment for COVID-19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce healthcare provider exposure to SARS-CoV-2, the virus that causes COVID-19.

The EUA for the VSMS Patch is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless terminated or revoked (after which the product may no longer be used).

How can I learn more?

CDC websites:
General: https://www.cdc.gov/COVID19

FDA websites:
General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Manufacturer: G Medical Innovations Ltd Israel
5 Oppenheimer Str.
Rehovot 7670105 Israel
Call center: G Medical Diagnostic Services
12708 Riata Vista Circle, Suite A-103, Austin, TX 78727
For Technical Assistance:
Email: Support.Us@gmedinnovations.com
Phone: 1-800-747-4455

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