FACT SHEET FOR HEALTHCARE PROVIDERS

G Medical VSMS ECG Patch May 14, 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 G Medical VSMS ECG Patch ("VSMS Patch" in this Fact Sheet). The VSMS Patch is authorized for emergency use in the hospital setting for remote monitoring of the QT interval of an electrocardiogram (ECG) in 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 using drugs that can prolong the 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 providers' exposure to SARS-CoV-2, the virus that causes COVID-19.

All patients who are monitored with the VSMS Patch should receive the Fact Sheet for Patients: G Medical VSMS ECG Patch, regarding this product.

What do I need to know about COVID-19 treatment and drug-induced arrhythmias?

Current information on COVID-19 infection for healthcare providers, including case definitions and information about clinical signs and symptoms and/or epidemiological criteria, is available on the CDC website listed below.

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 intervals and may cause life-threatening arrhythmias (such as torsade de pointes (TdP)) in certain susceptible patients.

In general, a 12-lead ECG is used to monitor QT prolongation during treatment (e.g., by acquiring and measuring a 12-lead ECG at certain timepoints). During the COVID-19 outbreak, the need to sanitize equipment and personnel between patients can be extremely burdensome. Some hospitals face a shortage of other FDA-cleared ECG monitoring solutions for QT prolongation (e.g., ECG telemetry units) or personal protective equipment (PPE). As a result, remote monitoring using disposable patches may provide a mechanism for QT prolongation monitoring of patients at risk of developing drug-induced arrhythmias due to COVID-19 treatment, and reduce healthcare providers' exposure to SARS-CoV-2.

What is the VSMS Patch?

The VSMS Patch is a 2-lead ECG event monitor with an additional calculated lead. The system comprises an adhesive patch with a reusable recorder attached to it and a smartphone. The VSMS Patch is applied to the patient's upper left chest. It records and transmits the ECG data to the smartphone. The length of event recording and the frequency of data transmission are set by the healthcare provider. The default is to record and transmit 10 minutes of ECG data every 1 hour. The data are saved and wirelessly transmitted by the smartphone to the G Medical Diagnostics Call Center for QT analysis. A call center certified cardiographic technician will compile the clinical findings and send the report to the prescribing physician at the hospital.

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

Known and potential benefits of the VSMS Patch include:

- Remote monitoring of QT interval prolongation in hospitalized patients undergoing treatment for COVID-19 patients may allow for healthcare providers to identify problems associated with drug-induced arrhythmias early.
- Remote monitoring of QT interval prolongation may reduce in-person interactions and reduce healthcare provider exposure to SARS-CoV-2.

The VSMS Patch has been designed to minimize risk when used in accordance with the G Medical Innovations VSMS ECG Patch Professional User Guide.

However, known and potential risks of the VSMS Patch include:

- Inaccurate measurement of or failure to measure the QT prolongation on the ECG.
- Skin irritation related to the medical adhesive. The patient should be provided medical attention if a severe reaction or an allergic reaction persists 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.

What are the alternatives to remote monitoring of QT prolongation with the VSMS Patch?

FDA consulted with subject matter experts within HHS on the public health needs for remote monitoring of QT prolongation for complications related to COVID-19 or its treatment.

While alternative FDA-approved or cleared devices for remote ECG monitoring exist, those alternatives may not measure the QT interval and/or may not be adequately available during the COVID-19 outbreak. Additionally, alternative FDA-approved or cleared devices for recording the QT interval may not offer remote monitoring capabilities to reduce healthcare provider exposure to SARS-CoV-2, or may not be adequately available during the COVID-19 emergency.

How long will monitoring be required?

Healthcare providers will determine the duration of monitoring for each patient undergoing treatment for COVID-19. Each VSMS Patch lasts for up to 14 days of monitoring. If the monitoring session exceeds 14 days, the patch will require replacement.

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.

- The VSMS Patch does not provide continuous monitoring of the QT interval of an ECG.
- 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. In case of a communication problem, the data are saved on the smartphone and then sent to the call center once communication is restored.
- The VSMS Patch is not intended to automatically detect life-threatening arrhythmias associated with QT prolongation and alert the healthcare providers immediately. It is intended to record changes in the QT interval measurement for later analysis.
- 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.
- The VSMS Patch is intended to provide multiple leads of data when used properly. However, a qualified physician should review the interpretations before deciding on a treatment strategy for any patient. Prior to using VSMS patch, a standard 12-lead ECG QT measurement should be obtained to screen for QT prolongation and establish the baseline difference before initiation of corrected QT (QTc)-prolonging drug therapy for treatment of COVID-19. This standard 12-lead ECG should be used as a baseline to track changes to the QT interval. The VSMS Patch QT measurements are likely to underestimate the global QT measurement obtained from a 12-lead ECG. The user should consider this when interpreting the VSMS Patch QT measurements and setting the threshold notification. The VSMS Patch QT measurements should be corrected by comparison with a 12-lead ECG-derived global QT measurement performed at baseline.
- QT measurements with the VSMS Patch may be unreliable in cases of motion or changes to the heart rate, or in the presence of noise or artifacts. Significant changes in T wave morphology or QTc measurement should be further investigated using a standard 12-lead ECG.
- 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.

- Do not use the VSMS Patch during external defibrillation procedures (such use may cause the defibrillator's discharge pulse to be ineffective for the patient).
- Do not use the VSMS Patch on patients with unhealed surgical incisions/dressings on the thoracic region, or patients with skin or soft tissue damage in the area where the VSMS Patch is placed (such as burns, irritation, infections, wounds, etc.).
- While showering is permitted, the patient should minimize exposure directly under the shower head, excessive contact with soap, or scrubbing, and gently dry the patch after showering.

What is an Emergency Use Authorization (EUA)?

The United States (U.S.) FDA issued an Emergency Use Authorization (EUA) for the VSMS Patch in a hospital setting for remote monitoring of the QT interval of ECG in patients undergoing treatment for COVID-19 using 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). The EUA is supported by a 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 use of the VSMS Patch under this EUA has not undergone the same type of review as an FDA-approved or cleared device. However, 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 when used in the hospital setting, the VSMS Patch may be effective in remotely monitoring the QT interval of an ECG in general care patients who are 18 years of age or older and are undergoing treatment 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). Such remote monitoring may reduce healthcare provider exposure to SARS-CoV-2.

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 website:
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

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