FACT SHEET FOR HEALTHCARE PROVIDERS

VitalPatch Biosensor **April 26, 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 VitalPatch Biosensor when used in the hospital setting for remote monitoring and detection of changes in the QT interval of an electrocardiogram (ECG) in general care (not in the intensive care unit) patients who are 18 years of age or older and are undergoing treatment for COVID-19 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 (HCP) exposure to SARS-CoV-2, the virus that causes COVID-19.

All patients who use the VitalPatch Biosensor should receive the Fact Sheet for Patients: VitalPatch Biosensor

What do I need to know about COVID-19 treatment?

Current information on COVID-19 infection for HCPs, 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 (a) those with serious heart conditions may be at greater risk for severe illness with COVID-19 and (b) there may be a need to remotely monitor those diagnosed with COVID-19**.** Additionally, some medications that are being evaluated and/or used for the treatment of COVID-19, can prolong QT intervals (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin) and may cause life threatening arrhythmias (such as torsade de pointes (TdP)) in certain susceptible patients. These patients can be identified by monitoring QT prolongation during drug treatment. 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 pandemic, 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., bedside monitors, ECG telemetry units) or personal protective equipment (PPE). As a result, continuous and remote monitoring of vital signs and ECG using disposable patches may provide a mechanism for QT monitoring of patients at risk of developing drug-induced arrhythmias due to COVID-19 treatment, and reduce HCP exposure to SARS-CoV-2.

What is the VitalPatch Biosensor?

The VitalPatch Biosensor is a wireless, battery-operated, wearable biosensor, worn on the torso. It can be used on one (1) patient and lasts for up to seven (7) days of continuous vital sign monitoring and is then disposed of at the end of the monitoring session. The VitalPatch measures and then transmits vital signs to a secure cloud network, allowing an HCP to view a patient's vital signs remotely. The VitalPatch Biosensor also analyzes events that may occur in a patient's ECG data, including QT prolongation and cardiac arrhythmias. When the VitalPatch detects events such as a QT measurement over a certain threshold or an arrhythmia, notification of the event will be transmitted through the secure network.

What are the known and potential risks and benefits of the VitalPatch Biosensor?

Known and potential benefits of the VitalPatch Biosensor include:

- Remote monitoring of QT measurement, vital signs, and arrhythmia detection for patients, while minimizing exposure of HCPs to SARS-CoV-2.
- Alleviate the COVID-19 burden to the healthcare system by providing an additional option for remote monitoring of hospitalized patients to minimize in-person interactions.

The VitalPatch has been designed to minimize the risk of misuse with guidelines provided in its *Instructions for Use*. However, should misuse occur, they may present the following risks to patients:

- Inaccurate measurement of vital signs (including QT measurement).
- Failure to adhere to the skin for the expected duration.
- Skin irritation due to the medical adhesive. The patient should seek medical attention if either of the following occurs: a severe adverse event or an allergic reaction persisting beyond 2-3 days.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

If arrhythmia detection is employed, the following additional risk applies:

- Misdiagnosis and misclassification of arrhythmias.

Based on these factors, the potential benefits from the use of the VitalPatch Biosensor are expected to outweigh the risks.

What are the Alternatives to Remote Monitoring with VitalPatch Biosensor?

FDA consulted with subject matter experts within HHS on the public health needs for vital sign and ECG monitoring to monitor for complications related to COVID-19 or its treatment (such as QT prolongation).

While alternate FDA-approved, cleared, or authorized devices for remote monitoring exist, those may not measure QT and/or may not be adequately available during the COVID-19 pandemic. Additionally, alternate FDA-approved, cleared, or authorized devices for recording ECGs and arrythmia detection (including QT prolongation) may not offer remote monitoring capabilities to reduce HCP exposure to SARS-CoV-2 or may not be adequately available during the COVID-19 emergency.

Healthcare workers are at particular risk of COVID-19 transmission, especially when conducting procedures that require direct patient contact, such as taking vital signs. Remote monitoring practices can reduce the risk of transmission.

How Long Will Monitoring be Required?

Each VitalPatch Biosensor lasts for up to seven (7) days of continuous monitoring. If the monitoring period exceeds seven (7) days, the VitalPatch Biosensor will require replacement during the monitoring period.

Limitations of the VitalPatch Biosensor

The VitalPatch Biosensor must be used in accordance with the *Instructions for Use Vital Patch Biosensor*. Using the VitalPatch to measure QT intervals has only been tested with the recommended patch placement. The accuracy of QT measurement with nonstandard patch placement is unknown.

Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact continuous or real-time monitoring. Data will be stored on the VitalPatch Biosensor for transfer to the relay device once connectivity is reestablished. The patient must remain in range of the relay device, and the relay device must remain operational.

The VitalPatch Biosensor is intended to provide automated interpretation of arrhythmias when used properly. However, no automated interpretation is completely reliable, and a qualified physician should review the interpretations before deciding on a treatment strategy for any patient. Prior to using VitalPatch Biosensor, 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. VitalPatch Biosensor QT measurements are likely to underestimate the global QT measurement obtained from a 12-lead ECG. The user should consider this when interpreting the VitalPatch Biosensor QT measurements and setting the threshold notification. VitalPatch Biosensor QT measurements should be corrected by comparison with a 12-lead ECG-derived global QT measurement performed at baseline.

QT measurements with the VitalPatch Biosensor may be unreliable in cases of motion or changes to heart rate. Consider taking QT measurements when the patient is at rest.

QT measurement is unreliable 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.

Performance of 1-minute average VitalPatch Biosensor QT measurements was evaluated in a small sample of healthy volunteers; it resulted in an error of -5.94 ± 9.51 ms (QTcb: mean ± standard deviation) compared to a manually adjudicated Lead-I ECG from a 10-lead Holter monitor. VitalPatch Biosensor QT measurement was not evaluated (a) during drug treatment, (b) in non-healthy subjects, and (c) for average periods of different lengths (e.g., 2, 5, or 10 minutes).

There are options to disable additional types of arrhythmia detection that are available, but not FDA

cleared. The specific types of arrhythmia detection that are not FDA cleared are:

- ventricular ectopic beats,
- pause,
- atrial fibrillation or flutter,
- sinus rhythms (normal sinus rhythm, sinus bradycardia, sinus tachycardia),
- second degree AV block,
- supraventricular tachycardia,
- idioventricular rhythm,
- ventricular bigeminy, and
- ventricular trigeminy; as well as
- measurement of heart rate, PR interval, and QRS duration for each rhythm listed above.

Do not use the VitalPatch during a magnetic resonance imaging (MRI) scan or in a location where it will be exposed to strong electromagnetic forces.

The VitalPatch Biosensor may be used while showering. Minimize exposure directly under the shower head, excessive contact with soap, or scrubbing. Gently dry the VitalPatch Biosensor after showering. Do not submerge the VitalPatch Biosensor or use in a sauna.

VitalPatch does not detect life threatening arrhythmias (e.g., ventricular fibrillation, ventricular catchycardia, torsade de pointes), VitalPatch detects changes in the QT interval that may lead to such life threatening arrhythmias. The VitalPatch Biosensor is not intended for use on critical care patients and is not intended for use as a stand-alone diagnostic monitor for vital signs.

What is an EUA?

The United States (U.S.) FDA issued an Emergency Use Authorization (EUA) for VitalPatch Biosensor when used for remote monitoring and detection of changes in the QT interval of ECG in hospitalized, COVID-19 patients as described above. 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 authorized use of VitalPatch Biosensor under this EUA has not undergone the same type of review as for the FDA-approved or cleared uses of the 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 when used in the hospital setting, the VitalPatch Biosensor may be effective in remotely monitoring and detecting changes in the QT interval of an electrocardiogram (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 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 HCP exposure to SARS-CoV-2. The EUA for the VitalPatch Biosensor 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
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html

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

Manufacturer: VitalConnect
224 Airport Parkway Suite 300
Phone: 408-963-4600
For Technical Assistance:
Email: support@vitalconnect.com
Phone: 955-757-9086

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**