

You are being given this Fact Sheet because your healthcare provider needs to monitor your vital signs (including, but not limited to, heart rate, electrocardiography (ECG or EKG), respiratory rate, and the presence of particular non-lethal arrhythmia events) while you are in the hospital undergoing treatment for COVID-19. Use of the VitalPatch Biosensor will assist in remote monitoring of your vital signs, including detecting changes in the QT interval measurement on your ECG, because you are being treated 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). Monitoring your vital signs remotely will allow healthcare providers to monitor you for the duration of your treatment, while reducing 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 VitalPatch Biosensor for the remote monitoring and detection of changes in vital signs while you are in the hospital for treatment for COVID-19, which may reduce healthcare exposure to SARS-CoV-2. 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. There is limited information available about the different types of illness that one may show if infected with the virus. The virus most likely spreads from one person to another when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

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.

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 monitoring and is then disposed of at the end of the monitoring session. The VitalPatch Biosensor measures and then transmits your vital signs to a secure cloud network, allowing your healthcare provider to view your vital signs remotely. The VitalPatch Biosensor also analyzes events that may occur in your ECG data. These events may indicate arrhythmias (abnormal heart rhythms). When the VitalPatch Biosensor detects an arrhythmia event, your healthcare provider will be notified of the event.

Why will this VitalPatch Biosensor be used on me?

The medical community is rapidly coming to realize that there may be a need to remotely monitor patients being treated for COVID-19 because some medications that are being evaluated and/or used for the treatment of COVID-19 may increase the risk for developing abnormal heart rhythms in certain patients. Remote monitoring of your vital signs and ECG may allow for healthcare providers to identify problems before they occur, and can reduce healthcare provider exposure to SARS-CoV-2.

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

Known and potential benefits of the VitalPatch Biosensor include:

- Your doctor can use the VitalPatch Biosensor to remotely monitor and detect ECG changes to assess your risk for heart rhythm problems associated with drugs that are being used to treat COVID-19 (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin), without being exposed to SARS-CoV-2, the virus that causes COVID-19.
- Through remote monitoring, the VitalPatch Biosensor can also be used to monitor heart rate, heart rhythm, respiratory rate, and other measures, without repeatedly exposing healthcare workers to SARS-CoV-2.

The VitalPatch Biosensor is not likely to cause injury. However, harms may occur due to:

- Inaccurate measurement or failure to detect certain abnormal heart rhythms.
- Failure to adhere to the skin for the expected duration.
- Skin irritation related to the medical adhesive. You should seek medical attention if either of the following occurs: a severe reaction or an allergic reaction persisting beyond 2-3 days.

Based on these factors, the potential benefits from the use of the VitalPatch Biosensor are expected to outweigh the risks during the COVID-19 pandemic.

You have the option to refuse this product. While this product is expected to be low risk, you may consider these risks to be unacceptable in the context of your present condition and anticipated outcome.

How is the VitalPatch Biosensor Used?

The VitalPatch Biosensor may be self-applied or applied by your healthcare provider. The VitalPatch is removed from its pouch and then powered on. The skin where the VitalPatch Biosensor is to be applied must be prepared by removing body hair at the application site (if necessary) and then cleaning the skin with an alcohol wipe. The VitalPatch Biosensor is then positioned on the upper left of the chest in the location described in the *Instructions for Use*. Once positioned, the adhesive backings are removed and the VitalPatch Biosensor is adhered to the skin. Optionally, an adhesive overlay may be applied over the VitalPatch Biosensor to help keep the product adhered to the skin. Use only the recommended overlay product. Do not use adhesive tapes or bandages over the VitalPatch Biosensor.

After the VitalPatch Biosensor is applied, it is paired with a compatible software application on a relay device. It is then calibrated for body position and location on the chest. You may be asked whether you have a pacemaker or other implanted medical device.

Following the instructions in the software application, body temperature needs to be calibrated by measuring temperature with a clinical-grade thermometer. The temperature calibration should be repeated after 30 minutes to ensure a steady reading, and then calibration is to be repeated once each day the VitalPatch Biosensor is used.

Before using the VitalPatch Biosensor to monitor for and detect ECG changes, a standard 12-lead ECG will need to be acquired and interpreted by your healthcare provider. If the VitalPatch detects any significant ECG changes, a 12-lead ECG recording may be repeated to confirm the finding.

Before you start using the VitalPatch Biosensor, you should discuss with your healthcare provider the correct protocol for using the VitalPatch Biosensor, the relay device, and the software application. 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 VitalPatch Biosensor, contact technical assistance at support@vitalconnect.com or call 955-757-9086.

How Long Will Monitoring be Required?

Your healthcare provider will determine the remote monitoring period. Each VitalPatch Biosensor can be used for up to seven (7) days. 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 should only be used according to the *Instructions for Use*. Using the VitalPatch to measure vital signs has only been tested with the recommended patch placement, and the accuracy of vital sign measurement with nonstandard patch placement is unknown. Real-time monitoring requires uninterrupted wireless connection. When the wireless connection is lost, data will be stored on the VitalPatch Biosensor for transfer after connectivity is reestablished.

The VitalPatch Biosensor is designed to detect abnormal heart rhythms and ECG changes. However, no machine interpretation is completely reliable. Your healthcare provider will review the data before

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deciding on a treatment strategy. Measurements with the product may be unreliable in cases of motion or changes to heart rate. Your healthcare provider may take measurements when you are at rest. To confirm any significant ECG changes, you may need to have a standard 12-lead ECG taken for review.

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. You may wear the VitalPatch Biosensor while showering. However, you should 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.

The VitalPatch Biosensor is not intended to detect life threatening abnormal heart rhythms. The VitalPatch Biosensor is intended to detect changes in the QT interval measurement of your ECG. Changes in the QT interval of your ECG can potentially lead to life-threatening abnormal heart rhythms.

This VitalPatch Biosensor is not intended to be used in the critical care setting and is not intended for use as a stand-alone diagnostic monitor and detect changes in vital signs.

Is the VitalPatch Biosensor FDA-approved or cleared?

The VitalPatch Biosensor is FDA-cleared. However, the particular authorized use of the VitalPatch Biosensor described in this document (remote monitoring of vital signs and detection of abnormal heart rhythms and ECG changes in patients receiving drugs that may cause life-threatening arrhythmias for the treatment of COVID-19 in a hospital setting) is **not cleared** by the FDA. The FDA has authorized this use of the VitalPatch Biosensor through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic. The particular use of the VitalPatch Biosensor 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 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 vital signs, including detecting changes in the QT interval measurement on an ECG, in patients who are 18 years of age or older who 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 virus that causes COVID-19.

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>

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

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