FACT SHEET FOR PATIENTS

PhysiolGuard ECG-QT Analysis System **May 5, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider needs to monitor your heart rhythm (including, but not limited to, heart rate, electrocardiography (ECG or EKG), and the presence of particular non-lethal, abnormal heart rhythms, called arrhythmia events) while you are in the hospital undergoing treatment for COVID-19. Use of the PhysiolGuard ECG-QT Analysis System will assist in remote monitoring of your heart rhythm, 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 heart rhythm 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 PhysiolGuard ECG-QT Analysis System for the remote monitoring and detection of changes in your heart rhythm 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.).

What is the PhysiolGuard ECG-QT Analysis System?

The PhysiolGuard ECG-QT Analysis System is comprised of the PhysiolGuard ECG-QT Analysis Platform (an ECG analysis software) and the MiCor A100 Wearable ECG Recorder, a battery-operated, wrist-worn ECG recorder. To collect an ECG, you will need to place the ECG electrodes of the MiCor A100 Wearable ECG Recorder against your body for the duration of the recording (see *Instructions for Use* for details). The PhysiolGuard ECG-QT Analysis Platform includes a software application that runs on Google Cloud Platform (GCP) that analyzes ECG data to remotely monitor events that may indicate arrhythmias. The software is used with the MiCor A100 Wearable ECG Recorder and the HCQ.Qtc mobile application ("app") on your smartphone, which transfers data to be analyzed by the PhysiolGuard ECG-QT Analysis Platform. This system will automatically notify your healthcare provider of any arrhythmia events. The PhysiolGuard ECG-QT Analysis System does not provide continuous monitoring of arrhythmia events.

Why will this PhysiolGuard ECG-QT Analysis System 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 heart rhythm 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 PhysiolGuard ECG-QT Analysis System?

Known and potential benefits of the PhysiolGuard ECG-QT Analysis System include:

- Your doctor can use the PhysiolGuard ECG-QT Analysis System 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), to reduce your doctor's exposure to SARS-CoV-2, the virus that causes COVID-19.

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 PhysiolGuard QT Analysis System can also be used to monitor heart rate, heart rhythm, and other measures, to reduce repeated exposure of healthcare workers to SARS-CoV-2.

The PhysiolGuard ECG-QT Analysis System is not likely to cause injury. However, harms may occur due to:

- Inaccurate measurement or failure to detect certain abnormal heart rhythms.
- Skin irritation related to the use of the MiCor A100 Wearable ECG Recorder. 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 PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System Used?

The PhysiolGuard ECG-QT Analysis System includes an ECG sensor (MiCor A100 Wearable ECG Recorder) shaped like a watch. Your healthcare provider will explain how to use the ECG sensor to record signals by pressing the sensor against your body.

Your healthcare provider will help you in configuring a smartphone or other electronic platform to automatically transmit your recordings.

Your healthcare provider will instruct you when and how often you need to record a signal.

You may be asked whether you have a pacemaker or other implanted medical device.

Before using the PhysiolGuard ECG-QT Analysis System 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 the PhysiolGuard ECG-QT Analysis System detects any significant ECG changes, a 12-lead ECG recording may be repeated to confirm the finding.

Before you start using the PhysiolGuard ECG-QT Analysis System, you should discuss with your healthcare provider the correct protocol for using the PhysiolGuard ECG-QT Analysis System, including the MiCor A100 Wearable ECG Recorder, and the mobile app on your smartphone or tablet. 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 PhysiolGuard ECG-QT Analysis System, contact technical assistance at Tech.support@PhysiolGuard.com or 1-909-394-5000.

How Long Will Monitoring be Required?

Your healthcare provider will determine the remote monitoring period. Each PhysiolGuard ECG-QT Analysis System can be used for up to fifteen (15) days. If the monitoring period exceeds fifteen (15) days or the battery is otherwise depleted, the PhysiolGuard ECG-QT Analysis System (MiCor A100 Wearable ECG Recorder) can be recharged.

Limitations of the PhysiolGuard ECG-QT Analysis System

The PhysiolGuard ECG-QT Analysis System should only be used according to the *Instructions for Use*. Using the PhysiolGuard ECG-QT Analysis System to measure your heart rhythm has only been tested with the MiCor A100 Wearable ECG Recorder when used as shown in the *Instructions for Use*. The accuracy of the system has not been tested when taking recordings from other parts of the body.

The PhysiolGuard ECG-QT Analysis System 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 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.

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.

Do not use the PhysiolGuard ECG-QT Analysis System during a magnetic resonance imaging (MRI) scan or in a location where it will be exposed to strong electromagnetic forces. You may wear the PhysiolGuard ECG-QT Analysis System while showering. Gently dry the PhysiolGuard ECG-QT Analysis System after showering. Do not submerge the PhysiolGuard ECG-QT Analysis System under more than 3 ft of water or use in a sauna.

The PhysiolGuard ECG-QT Analysis System is not intended to detect life threatening abnormal heart rhythms. The PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System is not intended to be used in the critical care setting and is not intended for use as a stand-alone diagnostic monitor to detect changes in your heart rhythm.

Is the PhysiolGuard ECG-QT Analysis System FDA-approved or cleared?

The PhysiolGuard ECG-QT Analysis System is not FDA-cleared. The FDA has authorized this use of the PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System may be effective in remotely monitoring and detecting changes in your heart rhythm, 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 PhysiolGuard ECG-QT Analysis System 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

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