

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the PhysiolGuard ECG-QT Analysis System when used in the hospital setting for remote monitoring and detection of changes in 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 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.

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### All patients who use the PhysiolGuard ECG-QT Analysis System should receive the Fact Sheet for Patients: PhysiolGuard QT Analysis System

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#### 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, remote monitoring of ECG using wearable devices 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 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. To collect an ECG, the user places the ECG electrodes of the MiCor A100 Wearable ECG Recorder against their body for the duration of the recording. The PhysiolGuard ECG-QT Analysis Platform is a software application that runs on Google Cloud Platform (GCP) and performs analysis of ECG data uploaded from the MiCor A100 Wearable ECG Recorder. The PhysiolGuard ECG-QT Analysis Platform analyzes single lead ECG to detect certain cardiac rhythms (Normal Sinus Rhythm, Atrial Fibrillation, Ventricular Premature Contraction, Atrial Premature Contraction, Bradycardia, Pause/Long Pause, and Bundle branch block), and provide interval analyses (RR, QT, and QTc). The software can generate pre-screening reports for HCPs to reference and alarm the HCP when abnormal QT or QTc intervals are detected.

The ECG data can be uploaded through the HCQ.QTc mobile application installed on a smartphone with Android or iOS, or using USB-WIFI adaptor if an internet connection is unavailable.

The PhysiolGuard ECG-QT Analysis Platform is not intended to process ECG data acquired by products other than the MiCor A100 Wearable ECG Recorder. The PhysiolGuard ECG-QT Analysis System does not provide continuous monitoring of the QT interval of an ECG.

#### 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:

- Remote monitoring of ECG, including QT measurement and arrhythmia detection for patients, while reducing exposure of HCPs to SARS-CoV-2.

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- Alleviate the COVID-19 burden to the healthcare system by providing an additional option for remote monitoring of hospitalized patients to reduce in-person interactions.

The PhysiolGuard ECG-QT Analysis System 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 ECG (including QT measurement).
- Skin irritation due to the use of the MiCor A100 Wearable ECG Recorder. 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.
- Misdiagnosis and misclassification of arrhythmias.

Based on these factors, the potential benefits from the use of the PhysiolGuard ECG-QT Analysis System are expected to outweigh the risks.

### What are the Alternatives to Remote Monitoring with PhysiolGuard ECG-QT Analysis System?

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

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

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While alternate FDA-approved, cleared, or authorized devices for remote ECG 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 arrhythmia 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.

### How Long Will Monitoring be Required?

Each PhysiolGuard ECG-QT Analysis System lasts for up to fifteen (15) days of monitoring. If the monitoring period exceeds fifteen (15) days, the PhysiolGuard ECG-QT Analysis System (specifically, the MiCor A100 Wearable ECG Recorder) can be recharged.

### Limitations of the PhysiolGuard ECG-QT Analysis System

The PhysiolGuard ECG-QT Analysis System must be used in accordance with the *Instructions for Use*.

Using the PhysiolGuard ECG-QT Analysis System to measure QT intervals has only been tested for leads II and V5. The accuracy of QT measurement with other leads is unknown.

The PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System, 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. PhysiolGuard ECG-QT Analysis System QT measurements are likely to underestimate the global QT measurement obtained from a 12-lead ECG. The user should consider this when interpreting the PhysiolGuard ECG-QT Analysis System QT measurements and setting the threshold notification. PhysiolGuard ECG-QT Analysis System QT measurements should be corrected

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by comparison with a 12-lead ECG-derived global QT measurement performed at baseline.

QT measurements with the PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System QT measurements was evaluated in a small sample of healthy volunteers, by comparing with the same lead simultaneously recorded by a 12-lead ECG. QT measurements resulted in an error (mean  $\pm$  standard deviation) of  $-6.7 \pm 15.8$  ms (lead II) and  $15.2 \pm 13.4$  ms (lead V5); corrected QTc (Bazett's formula) resulted in error of  $-0.3 \pm 17.1$  ms (lead II) and  $14.0 \pm 13.8$  ms (lead V5). PhysiolGuard ECG-QT Analysis System QT measurement was not evaluated (a) during drug treatment, (b) in non-healthy subjects.

The PhysiolGuard ECG-QT Analysis System can optionally detect the following type of cardiac rhythms: Normal Sinus Rhythm, Atrial Fibrillation, Ventricular Premature Contraction, Atrial Premature Contraction, Bradycardia, Pause/Long Pause, and Bundle branch block.

Automated measurements (e.g., QT measurement) or analysis (e.g., rhythm detection) are not cleared by FDA.

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. The PhysiolGuard ECG-QT Analysis System is not intended to be worn while swimming or submerged under more than three (3) feet of water, or used in a sauna.

PhysiolGuard ECG-QT Analysis System does not detect life threatening arrhythmias (e.g., ventricular fibrillation, ventricular tachycardia, torsade de pointes);

PhysiolGuard ECG-QT Analysis System detects changes in the QT interval that may lead to such life threatening arrhythmias. The PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System 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 PhysiolGuard ECG-QT Analysis System may be effective in remotely monitoring and detecting changes in 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 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 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).

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# FACT SHEET FOR HEALTHCARE PROVIDERS

PhysiolGuard ECG-QT Analysis System

May 5, 2020

Coronavirus  
Disease 2019  
(COVID-19)

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## 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](http://www.fda.gov/novelcoronavirus)

**EUAs:** <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

### **Manufacturer: PhysiolGuard Corporation Ltd.**

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### **For Technical Assistance:**

Product Support website: <https://autocloud.ibsalab.com/>

Email: [Tech.support@PhysiolGuard.com](mailto:Tech.support@PhysiolGuard.com)

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