



PhysiolGuard ECG-QT Analysis System

PhysiolGuard ECG-QT Analysis Platform User Manual

Rx Only

(Prescribed by healthcare provider for home use or for in-hospital telemetry, patients with minor symptoms in negative pressure isolation room)

Ver. 1.0

For use under Emergency Use Authorization (EUA) Only



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I. System

PhysiolGuard ECG-QT Analysis System

II. Website

<https://autocloud.ibsalab.com/>

III. Device Description

The PhysiolGuard ECG-QT Analysis System is composed by a cloud-based ECG analysis software (PhysiolGuard ECG-QT Analysis Platform) used in conjunction with the MiCor A100 Wearable ECG Recorder.

The PhysiolGuard ECG-QT Analysis Platform is a software application that runs on Google Cloud Platform (GCP) and is intended to do the interval analysis of ECG data uploaded from FDA-cleared MiCor A100 Wearable ECG Recorder (K162665).

The MiCor A100 is a wearable ECG recorder, with watch-like form factor. It includes a pair of electrodes on the opposite surfaces, allowing the recording of a single ECG lead. The “internal” electrode is in contact with the left wrist/hand, while the “external” electrode is touched against the left leg (to record lead II) or against the chest (to record lead V5), as instructed by the healthcare provider. ECG recorded by the MiCor A100 are transmitted via a cellphone/tablet/PC app to a cloud server, where the data is analyzed by the PhysiolGuard ECG-QT Analysis Platform.

PhysiolGuard ECG-QT Analysis Platform analyzes the ECG recorded by the MiCor A100 and provides single-lead measurements of ECG intervals (RR, QT, and QTc) and automated detection of non-life threatening cardiac rhythms (Normal Sinus Rhythm, Atrial Fibrillation, Ventricular Premature Contraction, Atrial Premature Contraction, Bradycardia, Pause/LongPause, and Bundle branch block).

A 12-lead ECG QT measurement should be used as a baseline for comparison, as QT intervals from PhysiolGuard ECG-QT Analysis System are calculated from a single-lead and therefore likely to underestimate the global QT measurement.

The platform can generate pre-screening reports for physicians' reference. The users shall install Chrome browsers on their own devices such as PC, Mac or iPad. The PhysiolGuard ECG-QT Analysis Platform provides two user-friendly interfaces that allow the users to upload the measured ECG data.

End users (Patients) can upload their ECG data through the HCQ. QTc apps installed on an Android or iOS device via Wi-Fi or internet connection. The ECG data can be uploaded by Healthcare professional using USB-WIFI adaptor if internet connection is unavailable.

The PhysiolGuard ECG-QT Analysis System provides a user account and data management system and allows the users to download ECG pre-screening reports. The PhysiolGuard ECG-QT Analysis Platform software is not intended to provide treatment decision, and is not to be used as a substitute for healthcare professionals' care. All medical diagnostics and treatment



plans are to be performed by licensed healthcare professionals.

IV. Intended Use of the Product

The PhysiolGuard ECG-QT Analysis System is composed by an electrocardiogram (ECG) analysis software (PhysiolGuard ECG-QT Analysis Platform) used in conjunction with the MiCor A100 Wearable ECG Recorder. The PhysiolGuard ECG-QT Analysis Platform is a software which analyzes ambulatory ECG waveform and rhythms to remotely monitor the QT prolonging condition in the treatment of COVID-19 patients on multiple QT prolonging medications or with known congenital long QT. The PhysiolGuard ECG-QT Analysis Platform can process the uploaded ECG data, automatically detect certain cardiac rhythms (Normal Sinus Rhythm, Atrial Fibrillation, Ventricular Premature Contraction, Atrial Premature Contraction, Bradycardia, Pause/LongPause, and Bundle branch block), provide interval analyses (RR, QT, and QTc), and generate the pre-screening reports for both healthcare professionals and end users. The interpretation results on the pre-screening reports are not intended to be the sole means of diagnosis.

It is offered to healthcare professionals on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

The PhysiolGuard ECG-QT Analysis System is not for use in life supporting or sustaining systems or ECG monitor and alarm devices.

The PhysiolGuard ECG-QT Analysis Platform is not intended to process ECG data acquired by devices other than the MiCor A100 Wearable ECG Recorder.

V. Warning and caution

**** sponsor needs to include appropriate warning and caution consistent with authorization letter ****

VI. System Requirements

The PhysiolGuard ECG-QT Analysis System, for both end users and health professionals, needs to be accessed through Chrome browsers.

The version of Chrome browsers should be 77 above and the HCQ.QTc Apps are require



running on the version 7 or above of Android systems or version 12 or above of iOS systems.

VII. Operation Steps for the End-Users

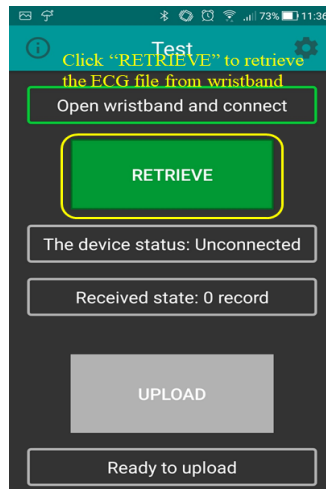
An end-user obtains a wearable ECG Recorder MiCor A100 (with up-to-date User Manual of MiCor A100) and a smartphone (with HCQ.QTc App) from healthcare professionals. After measuring the ECG signals by the wearable ECG Recorder, the end-user needs to use the HCQ.QTc App to receive and upload the ECG data to the PhysiolGuard ECG-QT Analysis System. After successfully uploaded, the end-user can log in to the PhysiolGuard ECG-QT Analysis System to download the ECG pre-screening reports via a Chrome browser. End-users can follow the steps of MiCor A100 user manual to complete ECG measurements. They can then upload ECG data and download ECG pre-screening reports by following steps stated below.

1. Click the icon to launch the HCQ.QTc App.

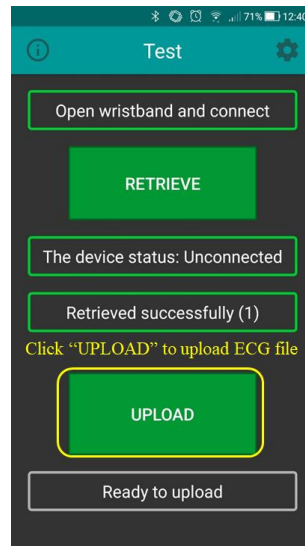




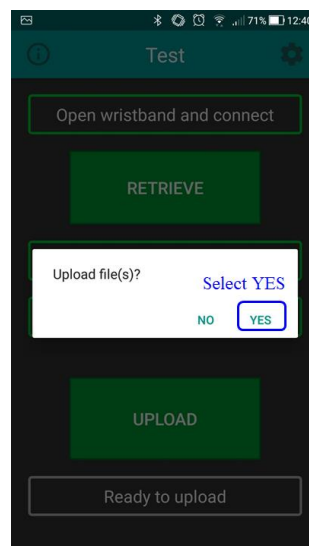
2. Press the button on the side of the wristband to turn on the BLE connection and click “RETRIEVE” push button to retrieve the ECG data from wristband.



3. Click “UPLOAD” push button to upload the ECG files to PhysiolGuard ECG-QT Analysis System.

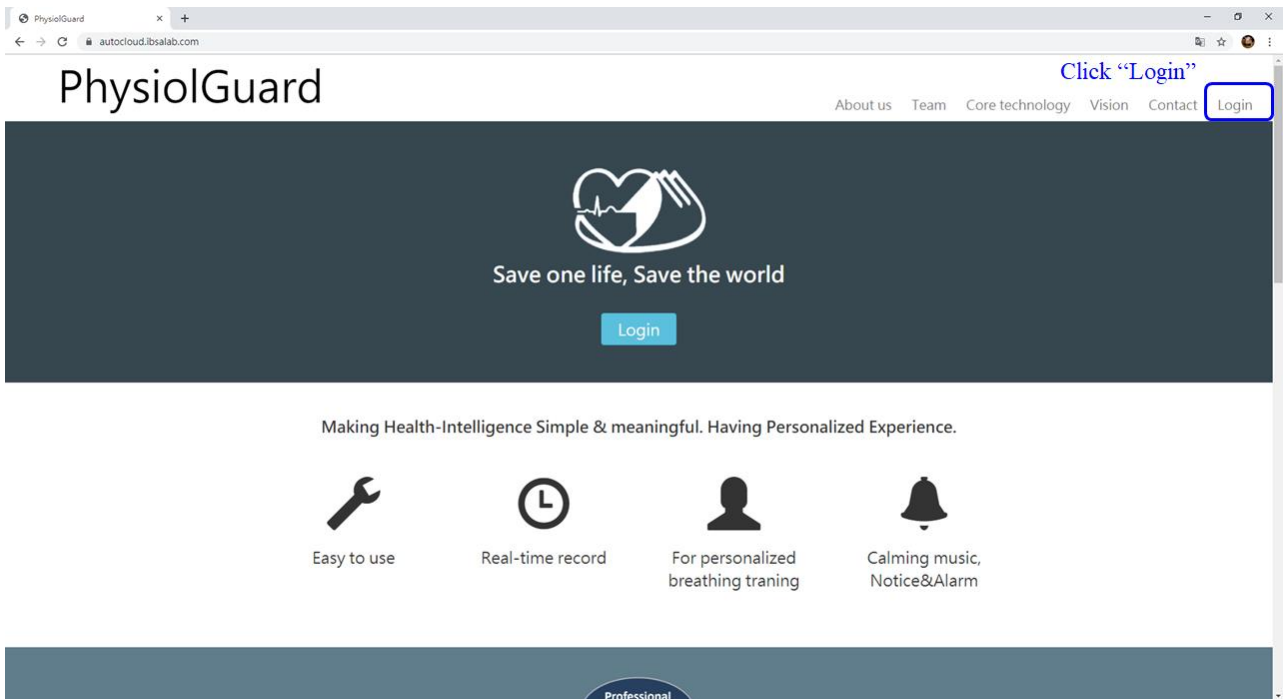


4. Select YES to upload the ECG data to PhysiolGuard ECG-QT Analysis System.

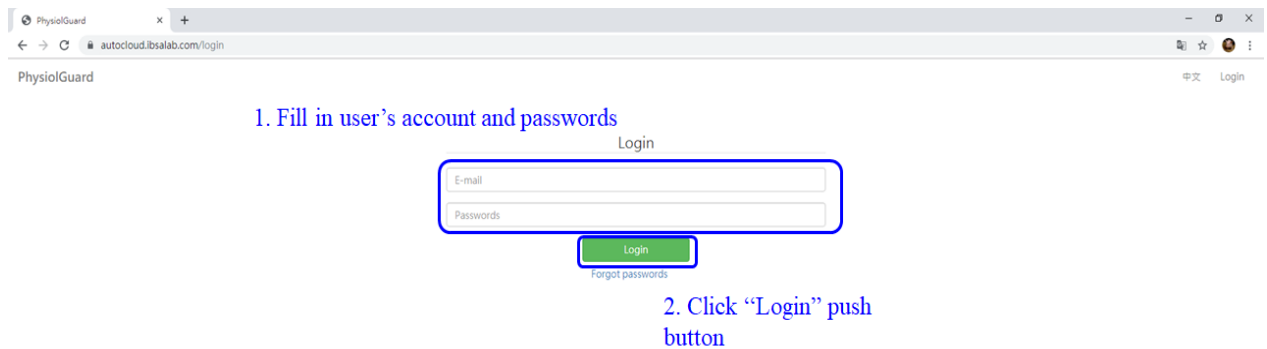




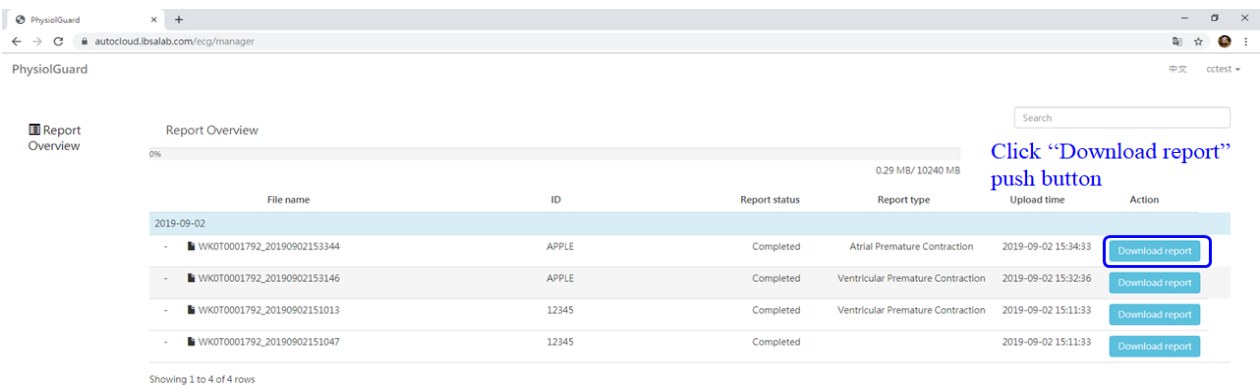
5. After successfully upload, the end-user can open Chrome browser to link to the PhysiolGuard ECG-QT Analysis System (<https://autocloud.ibsalab.com/>) and then click “Login” to login in.



6. Fill in the user’s account and passwords, and then click “Login” push button.



7. Click “Download report” push button to the download ECG pre-screening report.



8. Print the report or show the report on the smartphone to the healthcare professionals.



VIII. Steps for the Healthcare Professionals

Healthcare professionals can view the ECG pre-screening reports of patients who are under management of the healthcare professional’s master account, by following steps bellow:

1. Create New Patient Account: Click “Account Management” to link to “Patient Management” page to create the new patient’s account after login to PhysiolGuard ECG-QT Analysis System. If the targeting end-user already has an account, please go to step 10.

Click “Account management”

	E-mail	Name	Total files for last 3 days	Action
<input type="checkbox"/>	ncutest@lbsalab.com	ncutest	0	<input type="button" value="Check"/>
<input type="checkbox"/>	tainan@lbsalab.com	tainan	0	<input type="button" value="Check"/>
<input type="checkbox"/>	tainan2@lbsalab.com	tainan2	0	<input type="button" value="Check"/>
<input type="checkbox"/>	tainan3@lbsalab.com	tainan3	0	<input type="button" value="Check"/>

2. Click “+New patients” push button to setting the patients’ account and passwords.

Click “+New patients” to create new account

	E-mail	Name	Create time	Status	Action
<input type="checkbox"/>	ncutest@lbsalab.com	ncutest	2018/10/08 14:41:56	Enable	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
<input type="checkbox"/>	tainan@lbsalab.com	tainan	2019/04/29 23:21:10	Enable	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
<input type="checkbox"/>	tainan2@lbsalab.com	tainan2	2019/05/15 18:58:46	Enable	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
<input type="checkbox"/>	tainan3@lbsalab.com	tainan3	2019/05/15 18:59:20	Enable	<input type="button" value="Edit"/> <input type="button" value="Delete"/>

3. After filling in the patient’s information (the “Status” should be indicated “Enable”), click “Create” push button to create a new account.

1. Fill in the information

2. Click “Create” push button



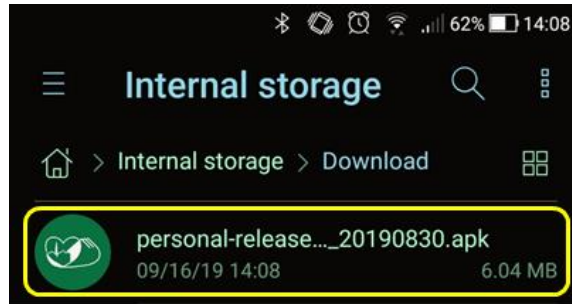
4. After creating new patients account, install HCQ.QTc App on the smartphone, follow the steps below:

a. For Android system

i. Download HCQ.QTc APK from web address

http://autocloud.ibsalab.com/apks/HCQ.QTc_en

ii. Copy the HCQ.QTc APK to smartphone and install on the smartphone.

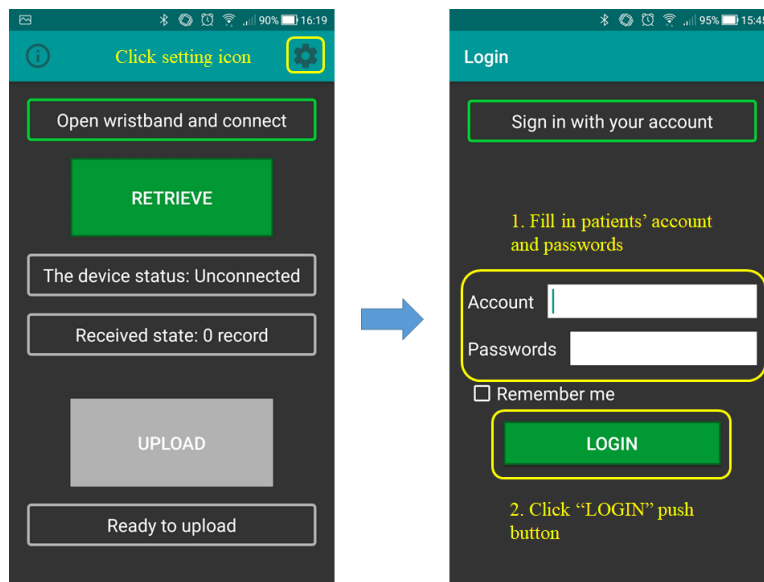


Click this item to install

b. For iOS system

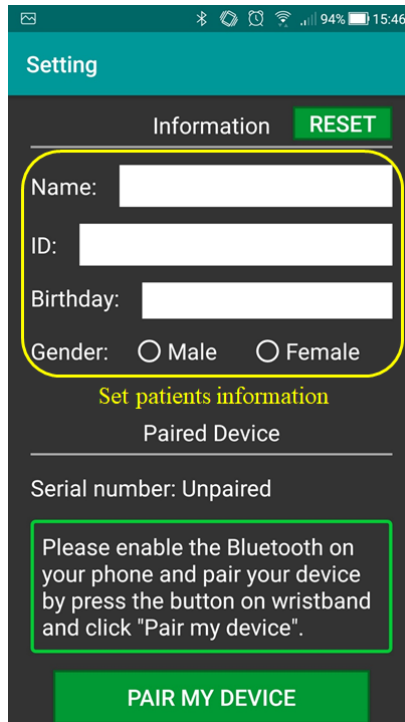
i. Install “HCQ.QTc” App from App Store

5. Log In On App: With a registered patient account, launch the HCQ.QTc App, and then click setting icon to login.



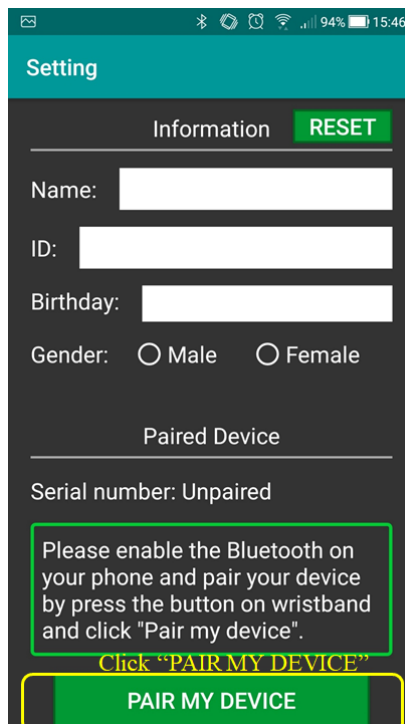


6. Set patients information.



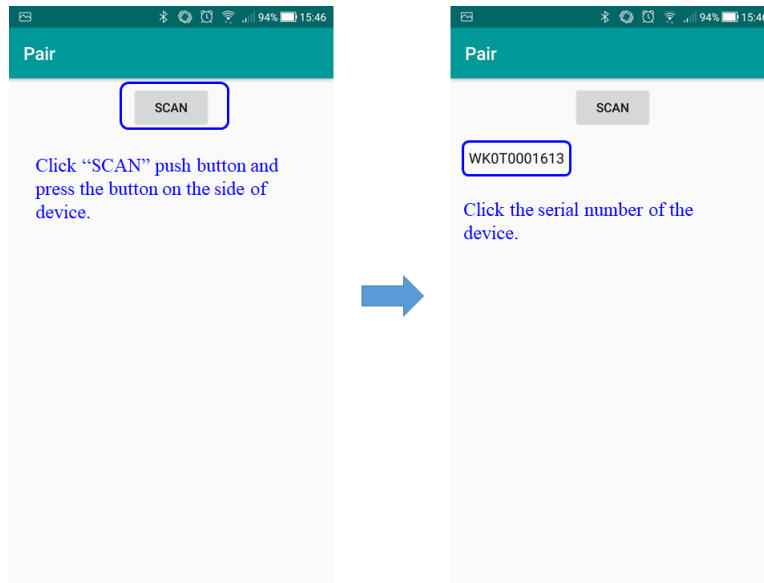
7. Pair the Wearable ECG Recorder MiCor A100 with app.

- a. Check Bluetooth of smartphone or tablet is open.
- b. Click “PAIR MY DEVICE” push button.

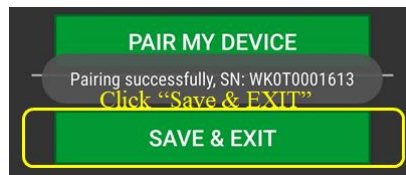




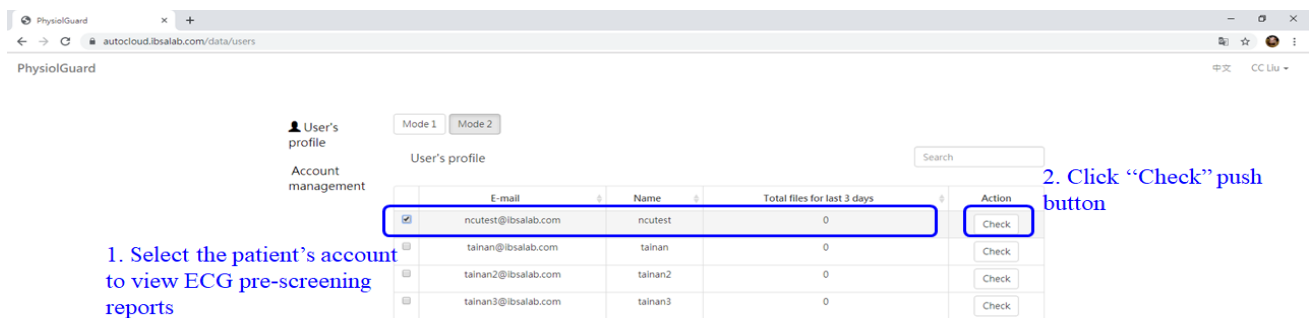
- c. Click “Scan” push button and press button on the side of device, and then click the serial number of device.



- d. Click “SAVE & EXIT”



- 8. Ensure the patients know how to use wearable ECG Recorder MiCor A100 to record ECG signals and use app retrieve ECG files from Wearable ECG Recorder MiCor A100 and upload these files to PhysiolGuard ECG-QT Analysis System by HCQ.QTc App. Provide the patients with user manual of MiCor A100 Wearable if necessary.
- 9. Provide the smartphone with the HCQ.QTc App installed and a wearable ECG Recorder such as MiCor A100 to the patient. The duration of the measurement is prescribed by doctors.
- 10. After ECG files of patients is well-uploaded, the healthcare professional can log in PhysiolGuard ECG-QT Analysis System, select the patients’ account with whom the healthcare professional is targeting to view ECG pre-screening reports.





11. Select and click “Report” push button to download ECG pre-screening report.

The screenshot shows the PhysiolGuard web application interface. At the top, there are navigation tabs for 'Mode 1' and 'Mode 2'. Below this, there is a user profile section and a search bar. The main content area displays a table titled 'User's profile / cctest / ECG list'. The table has columns for 'File name', 'ID', 'Report status', 'Report type', 'Upload time', and 'Action'. The first row is selected, and its 'Report' button is highlighted with a blue box. A blue callout box with the text '2. Click “Report” push button to download ECG pre-screening report' points to this button. The table contains the following data:

File name	ID	Report status	Report type	Upload time	Action
2019-09-11 WK0T0001792_20190911182927	12345	Completed	Ventricular Premature Contraction	2019-09-11 18:31:53	Report
2019-09-02 WK0T0001792_20190902153344	APPLE	Completed	Atrial Premature Contraction	2019-09-02 15:34:33	Report
WK0T0001792_20190902153146	APPLE	Completed	Normal	2019-09-02 15:32:36	Report
WK0T0001792_20190902151013	12345	Completed	Ventricular Premature Contraction	2019-09-02 15:11:33	Report
WK0T0001792_20190902151047	12345	Completed		2019-09-02 15:11:33	Report

PhysiolGuard Biotechnology Inc. | Address: 2F, No.275-4, Yuanhua Rd., Zhongli Dist., Taoyuan City 320, Taiwan (R.O.C.) | TEL: +886 3 427 1734
The PhysiolGuard ECG Analysis Platform software is not intended to provide treatment decision, and is not to be used as a substitute for a Healthcare Professional's care.
V1.0. © 2016 PhysiolGuard Biotechnology Inc. All rights reserved.

Warning: The PhysiolGuard ECG-QT Analysis Platform is not intended to process ECG data acquired by devices other than the MiCor A100 Wearable ECG Recorder.



IX. Error and Warning Message

- If the smartphone loses its internet connection while uploading the ECG data through the HCQ.QTc App, the message “Upload failed, please check your internet” will pop-up on the screen. (Note:1)
- If one fails to provide the correct format of his/her email account to log in to the PhysiolGuard ECG-QT Analysis System, a warning message “The email address should contain @ and complete email address.” will pop up.
- If one fails to provide correct account or passwords to log in to the PhysiolGuard ECG-QT Analysis System, the system will display a warning message “Wrong email or password.”
- In Mode 1, if a healthcare professional upload an ECG data not in .xml format, the system will display “Error! Please upload the file again” when.
- In Mode 2, if a healthcare professional fails to provide the correct format for a new user account, the system will display a warning message “The email address should contain @ and complete email address.”
- In Mode 2, if a new user account is created with a password less than 6 characters, the system will display a warning message “The password must be at least 6 characters.”
- If a healthcare professional provides an account in the wrong format to log in to the HCQ.QTc App, a warning message “Wrong email or password. Check your input” will pop up.
- If a healthcare professional provide passwords less than 6 characters or wrong password to log in to the HCQ.QTc App, a warning message “Wrong email or password. Check your input” will pop up.
- If the phone loses its internet connection while logging in to the HCQ.QTc App, a warning message “Didn’t connect to Internet or Server side error. Checking your internet or using the offline mode” will show on the screen.

Note:

1. To enhance the WIFI connectivity for ECG data upload, healthcare professional can use a USB-WIFI adaptor available in the consumer market. You can also call for technical support.



X. Version Information

PhysiolGuard ECG-QT Analysis System, Version: 1.0

HCQ.QTc App, version: 1.0

User Manual Version: Ver. 1.0

Issued date: 2020/04/22

XI. Company Information

Taiwan (Manufacturer)

PhysiolGuard Corporation Ltd

Address: 2F, No.136 Beinei Street, Shulin District, New Taipei City, Taiwan 238

Tel: (+886) 922-426981

U.S. (Technical Support and Customer Service)

MITAC DIGITAL CORP.

21660 E. Copley Drive, Suite 170, Diamond Bar, CA 91765

Email: Tech.support@PhysiolGuard.com

Tel: 1-909-394-5000