

User Manual

ECG-Check - OTC

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Version	Date	Name	Description
01	1/16/2013	C. Pillar	Initial Document
02	1/18/2013	M. Jandes	Added screen shots of progress bar



ECG Check Wireless
1-Lead Cardiac Monitor

OTC Use



Dear ECG Check Owner:

Thank you for selecting the ECG Check cardiac monitor.

This user guide includes information and instructions about your new ECG Check and will help familiarize you with the basic skills of using your ECG Check, so please take a moment to read it carefully before you begin testing.

We have included a warranty registration card.

Please complete and return it promptly to enable us to provide you the full benefits regarding your ECG Check product.

For the most up-to-date list of compatible devices, please refer to the supported list at <http://www.cardiacdesigns.com>.

We care about what you think and want to keep you informed about its use and care.

If you have any questions about your new ECG Check, please contact:

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Copyright Declaration

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Declaration of Conformity

Conformance to Standards – non-clinical testing demonstrated conformance to voluntary safety IEC60601-1 and to IEC60601-1-2:2001 Class B

Warning: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are

designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- ☐ Reorient or relocate the receiving antenna.
- ☐ Increase the separation between the equipment and receiver.
- ☐ Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- ☐ Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Cardiac Design, LLC's Quality System conforms to 21 CFR 820 and ISO 13485:2003

Danger

Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

Graphic Symbols on ECG Check



This symbol is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the appliance.

This symbol indicates type BF equipment classified in accordance with IEC Publication 601-1 Safety of medical electrical equipment.

Intended Use

The ECG Check is intended for use whenever you are interested in your cardiac activity. It can be used any time, including during or after strenuous activity (i.e., during or after exercise) or if you experience the following symptoms that are suggestive of abnormal heart rhythms:

- Skipped Beats
- Pounding Heart (Palpitations) Heart Racing or Irregular Pulse
- Lightheadedness or Faintness
- History of Arrhythmias

The ECG Check is not intended for diagnostic use and does not provide diagnostic quality ECG data.

Contraindications

There are no potential adverse effects of the ECG Check on health.

Who Should NOT Use the ECG Check

In order to use this device, you must be able to perform all of the following:

- Understand principle of operation described in this manual
- Speak and understand English
- Place the ECG Check in your hands or on your chest and hold it for at least 30 seconds
- Operate a ECG Check and the Web Center application
- Operate simple push-buttons

Due to the possible seriousness of the abnormal heart rhythms that can be associated with these conditions, persons with the following conditions should consult their physician before using this device:

- Coronary heart disease
- Valvular heart disease
- Heart transplant
- Heart failure

Warning

The ECG Check is not a diagnostic device.

This non-standard 1 - lead electrocardiogram (ECG), which is measured using the ECG Check, should not be used for diagnostics in comparison to the standard 12 lead ECG obtained with standard electrode placement.

This device should not be used with pacemakers or implanted defibrillators and cannot predict or diagnose a heart attack or be used for chest pain monitoring.

The ECG Check is not a defibrillation-proof device.

To prevent fire or shock hazard, do not expose the unit to rain or moisture. Refer servicing to qualified personnel only.

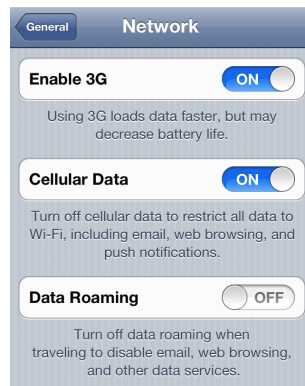
When used as an Over-the-Counter device, the display function for actual ECG waveforms and ECG reports is disabled. To access the display feature for viewing your ECG data, contact your physician and obtain a prescription. Only patients under the care of a physician with a prescription for this service may view ECG data and ECG reports.

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Quick Start Guide

1. Install the ECG Check Application on the iPhone via the iPhone App Store or visit <http://ecgcheck.com> from your iPhone for a direct link (first time use).
2. Ensure data and Bluetooth communications are enabled.
 - a. Configure the outgoing communication to the ECG Check Web Center by enabling either cellular data or Wifi (or both -- See your iPhone documentation for more information).



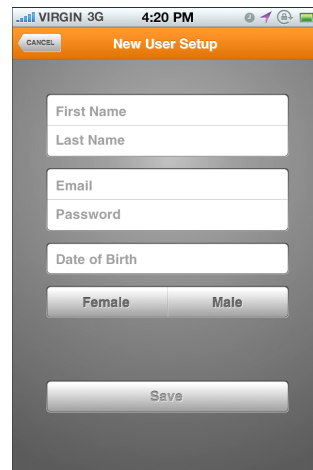
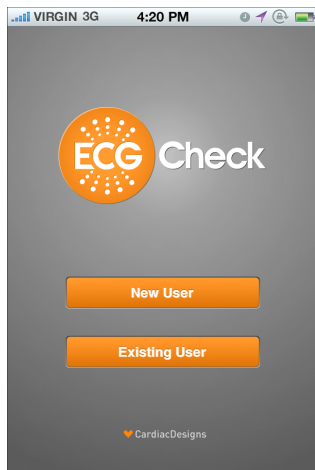
- b. Configure the ECG communication to the ECG Check device by ensuring your Bluetooth radio is enabled.



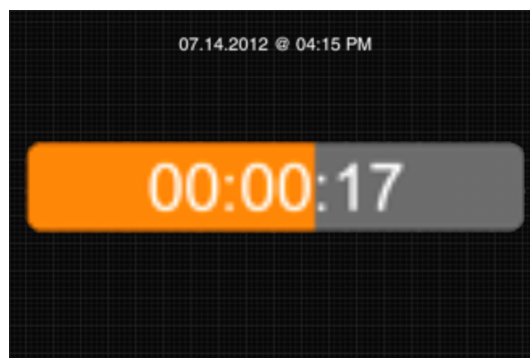
3. Start the ECG Check Application on the iPhone by pressing the ECG Check icon.



4. Set up the user profile (first time use or when necessary).



5. Place your fingers on the silver pads of the ECG Check device to start the ECG recording.
6. Once the progress bar is full, the recording will be automatically stored and sent for analysis. Upon completion, you will see the screen below.



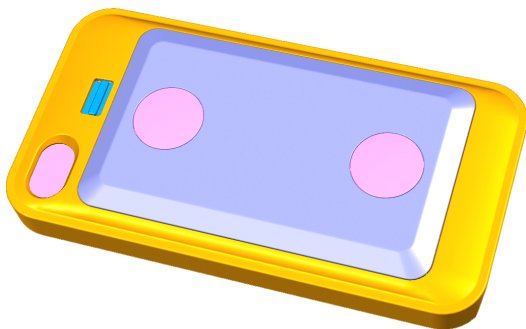
ECG Check Introduction

General Description

The ECG Check is a medical device that allows recording and sending of an ECG recording (using Bluetooth technology). The recording is sent to a device (ECG Check Application compatible iPhone). This allows you and your physician to monitor your health information (ECG) from anywhere any time you wish.

The ECG Check Kit

1. ECG Check Monitor



2. (1) CR2032 Battery

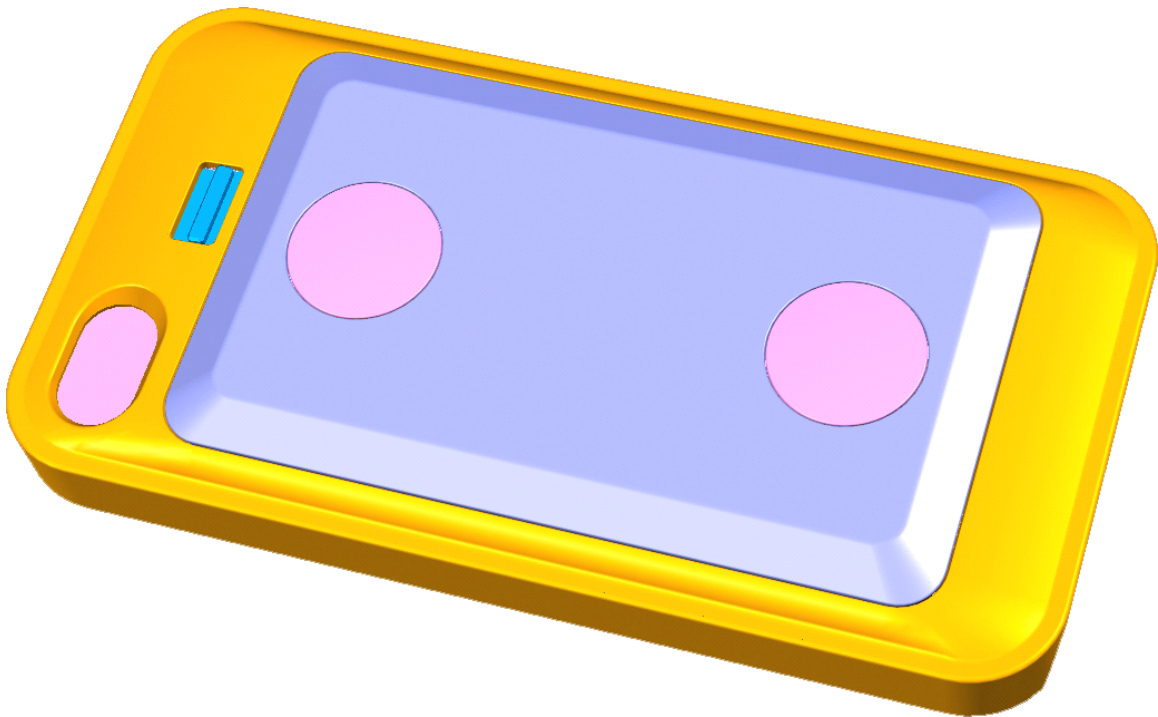


3. Quick User Guide (this document)

Using the ECG Check

General

The ECG-Check is a single lead ECG recording device that uses the 2 built-in electrodes (silver pads) on the underside of the device to record and transmit your ECG to an application via Bluetooth for display and analysis.



Place your fingers on the electrodes or place the device on your chest to start the recording.

Device Functions

1. On/Record
 - If the device is off, pressing your fingers to the electrodes will turn the device on and begin recording once the device has initiated communication with the iOS application.

- If the iOS application is not loaded, please start the iOS application prior to initiating a recording on the device. The device will not begin recording data until the iOS application has been started.
2. Standby / Power Off
- The device will turn off automatically after the device has detected no skin contact for 4 seconds. If there was an on-going test, the test will be invalidated and need to be restarted

Note: The devices starts recording when there is electrode contact with the skin AND the iOS has communicated with the device via Bluetooth to begin recording

Before Testing

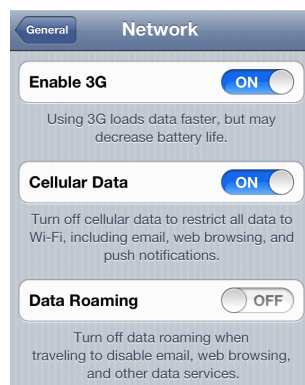
Read the testing instructions before attempting a test. Pay careful attention to the electrode positions as instructed.

Make sure you have all items needed to test:

- ECG Check
- ECG Check Application compatible iPhone (with application installed)

Recording

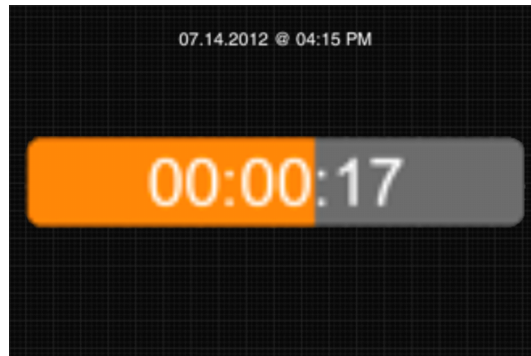
1. Verify that Bluetooth is on and cellular data is enabled on the iPhone.



2. Start the ECG Check application by tapping the ECG Check icon.



3. Log into your user account.
4. Press your fingers to the electrodes to initiate a recording.
5. Wait for the progress bar to fill up while the system records your ECG. You will see the screen shown below as it is recording.



6. The system will automatically send the ECG for analysis.

Medical Records

To examine a list of previous recordings stored on the device, tap the medical history icon to open the medical history screen; here you will see a list of the previous tests stored on your device.

VIRGIN 3G 4:20 PM		
RECORD	HISTORY	REPORTS SETTINGS
	06.21.2012 4:45 AM	EVENT
	06.21.2012 4:45 AM	PENDING
	06.21.2012 4:45 AM	NORMAL
	06.21.2012 4:45 AM	EVENT
	06.21.2012 4:45 AM	PENDING
	06.21.2012 4:45 AM	NORMAL
	06.21.2012 4:45 AM	NORMAL
	06.21.2012 4:45 AM	NORMAL
	06.21.2012 4:45 AM	NORMAL
	06.21.2012 4:45 AM	NORMAL
	06.21.2012 4:45 AM	PENDING
	06.21.2012 4:45 AM	EVENT
	06.21.2012 4:45 AM	NORMAL
	06.21.2012 4:45 AM	NORMAL

Maintenance

Battery Replacement

Caution: Use only CR2032 lithium ion batteries.

1. Place the ECG Check device with electrode pads down on a stable surface
2. Using a Phillips head screwdriver, unscrew the screw securing the battery cover.
3. Slide out the used battery
4. Slide in the new CR2032 lithium ion battery
5. Replace the battery cover and secure with the cover screw

Conditions of Use

Your ECG Check conforms to international regulations in so far as it is used under normal conditions and in accordance with the following instructions.

Caring for your ECG Check

Do not open or attempt to repair your ECG Check yourself. Only authorized service personnel may repair the product.

Do not drop your ECG Check or subject it to severe impacts. Bending the body can damage the circuitry. Do not use extreme force when pressing the display or keys.

Do not use solvents to clean your ECG Check. Use only a soft, dry cloth.

Environment

Keep away from extreme heat. Do not leave it on the dashboard of a car or near a heater. Do not leave it in any place that is extremely damp or dusty.

As this product is not waterproof,do not use it or store it where fluids such as water can splash onto it. Raindrops,waterspray,juice,coffee,steam,perspiration,etc.may also cause a malfunction.

Keep accessories that might be swallowed away from children.

Precautions

Warning: Dispose of all used batteries in a proper waste disposal in accordance with local regulation. Used batteries must not be discarded in the normal trash.

Preventive Maintenance

The following simple preventive maintenance tasks should be performed monthly to ensure continued performance of the device at maximum capacity, and to reduce the possibility of a failure.

Mechanical Inspection

Check for splits,cracks,or imperfections in the case.If you have any questions or doubts,call your service provider.

Cleaning

Clean the outside of the device only, using a lint-free dry cloth.

Do not allow any liquid to enter the case,and avoid pouring water or other liquids on the device while cleaning.

Never use a brasives such as wirewool or metal polish.

During cleaning,make sure you do not expose the device to temperatures in excess of 45°C(113°F).

Troubleshooting

Problem	Possible Cause(s)	Solution
Device does not send ECG to application	The battery is very low or depleted	Replace battery
	The Bluetooth radio is not enabled on the host device	Turn on the Bluetooth radio in the iPhone
	The user has not touched both electrodes.	Ensure both electrode pads are in contact with the user's skin
ECG Data is not being analyzed	There is no connection to the internet	Turn on your cellular data or connect to a wifi access point
ECG analysis comes back with a bad recording	Too much noise or movement in the recording	Do not move & remain still while the device is recording
	Not enough ECG data was collected	Keep the device in contact with the skin for 30 seconds
iPhone is running slowly	Too many applications open	Manually close the iOS applications or restart your phone.
ECG Check application does not launch	Too many applications open	Manually close the iOS applications not in use or restart your phone.

Glossary

ECG	Electrocardiogram;are presentation of the heart's electrical activity recorded from electrodes on the body surface.
Heart Rate	Number of beats per minute, measured as bpm.
Bluetooth (BT)	Wireless communication protocol.
ECG Check	ECG Check wireless ECG monitor.
PC	Personal computer.
ECG Check Application	Cardiac Designs LLC proprietary iPhone program for measuring, storing, displaying, and transmitting data gathered from the ECG Check medical device.
ECG Check Homepage	ECG Check Application main page.
ECG Check Web Center	Cardiac Designs, LLC proprietary internet-enabled program for storing and retrieval of patient records. Foruse by physicians and medical professionals.

Technical Specifications

Input Impedance	1.1 mohm
Input dynamic range	+/- 3.5mV
Maximum Current consumption	55mA
CMRR	75db
DC offset correction	+/- 200mV
Bandwidth	0.5Hz – 25Hz
Recording	30 seconds, single-lead ECG
Sample Rate	200 Hz
Transmission Period	Instant, dependent on iPhone
Transmission mode	Bluetooth Low Energy
Battery Type	3V CR 2032 Lithium ion battery
Battery Life	8 hours (approximately 480 recordings)
Operating Temperature	+10to+40 ⁰ C(50to104 ⁰ F)
Transport & storage temperature	-20to+65 ⁰ C(-4to149 ⁰ F)
Relative humidity	30 to 85%
Dimensions	118 x 62 x 17mm
Net Weight	40 (grams)

Additional Information

See the ECG Check Application Installation Guide available at the Cardiac Designs, LLC web site.

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