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:

Cardiac Designs, LLC
1104 S. Mays
Suite 219
Round Rock, TX 78664
Tel: 512-582-2453
Fax: 713.589.7964
Email: info@cardiacdesigns.com
Website: www.cardiacdesigns.com
Copyright Declaration

Copyright © 2012 Cardiac Designs, LLC
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iPhone, iPad, iPod, iOS and the Apple logo are either registered trademarks or trademarks of Apple Corporation in the United States and/or other countries.

Cardiac Designs, LLC, Cardiac Designs logo, and ECG Check and ECG Web Center are trademarks or registered trademarks of Cardiac Designs, LLC.

All other brand names and product names used in this document are trade names, service marks, trademarks, or registered trademarks of their respective owners.

The information and screens provided in this manual are subject to change without notice.

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Authorized Representatives:
USA
Cardiac Designs, LLC
1104 S. Mays
Suite 219
Round Rock, TX 78664
512-582-2453

Declaration of Conformity

Conformance to Standards – non-clinical testing demonstrated conformance to voluntary safety IEC 60601-1 and to IEC 60601-1-2-2001 Class B

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
Caution: Federal law restricts this device to sale by or on the order of a physician.

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.

In order to receive and view your ECG waveform and ECG reports, you must be under the care of a physician and have a prescription for this service. Cardiac Designs, LLC (or affiliate) will contact your physician to verify in writing that you are their patient and that they are willing to be contacted in cases where there are clinically significant events involving your care.

If a valid physician prescription is not received from your physician within 35 days of activation of this device, you will not be able to utilize any aspects of Cardiac Designs, LLC (or affiliate) service until such verification is received by Cardiac Designs, LLC (or affiliate).

Your agreement certifies you understand that this service is not a substitute for physician care and that it is only a screening service.
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1. Install the ECG Check Application on the iPhone via the iPhone App Store or visit [http://ecgcheck.com](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).
   ![Network Configuration](image1)
   b. Configure the ECG communication to the ECG Check device by ensuring your Bluetooth radio is enabled.
   ![Bluetooth Configuration](image2)
3. Start the ECG Check Application on the iPhone by pressing the ECG Check icon.

4. The first time you open the application you will see the welcome screen. Place your fingers on the silver pads to activate the ECG-Check device and establish communication with the iPhone.

5. Set up the user profile (first time use or when necessary).
6. Place your fingers on the silver pads of the ECG Check device to start the ECG recording. You will see your ECG flow across the screen as the ECG Check iPhone application is recording your heart information.

7. Once the progress bar is full, the recording will be automatically stored and sent for analysis. The view will change to the recorded ECG and the analysis results.

8. Upon completion, you will see the report of the ECG along with the analysis of the recording.
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 device 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 in to 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 your ECG displayed as it is recording as shown below.

![Progress bar filling up](image)

6. The system will automatically send the ECG for analysis and display the results.

![Analysis Findings](image)
Medical Records

To examine previous tests stored on the device:

1. Tap the recordings button to open the previous recordings screen; here you will see a list of the previous tests stored on your device.

2. Tap anywhere on the test results open the ECG view and analysis results screen.
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 insofar 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, water spray, 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 abrasives such as wire wool or metal polish.

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

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause(s)</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device does not send ECG to application</strong></td>
<td>The battery is very low or depleted</td>
<td>Replace battery</td>
</tr>
<tr>
<td></td>
<td>The Bluetooth radio is not enabled on the host device</td>
<td>Turn on the Bluetooth radio in the iPhone</td>
</tr>
<tr>
<td></td>
<td>The user has not touched both electrodes.</td>
<td>Ensure both electrode pads are in contact with the user’s skin</td>
</tr>
<tr>
<td><strong>ECG Data is not being analyzed</strong></td>
<td>There is no connection to the internet</td>
<td>Turn on your cellular data or connect to a wifi access point</td>
</tr>
<tr>
<td><strong>ECG analysis comes back with a bad recording</strong></td>
<td>Too much noise or movement in the recording</td>
<td>Do not move &amp; remain still while the device is recording</td>
</tr>
<tr>
<td></td>
<td>Not enough ECG data was collected</td>
<td>Keep the device in contact with the skin for 30 seconds</td>
</tr>
<tr>
<td><strong>iPhone is running slowly</strong></td>
<td>Too many applications open</td>
<td>Manually close the iOS applications or restart your phone.</td>
</tr>
<tr>
<td><strong>ECG Check application does not launch</strong></td>
<td>Too many applications open</td>
<td>Manually close the iOS applications not in use or restart your phone.</td>
</tr>
<tr>
<td><strong>Glossary</strong></td>
<td></td>
<td></td>
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<tr>
<td>--------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ECG</strong></td>
<td></td>
<td></td>
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<tr>
<td>Electrocardiogram; a representation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of the heart's electrical activity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>recorded from electrodes on the body</td>
<td></td>
<td></td>
</tr>
<tr>
<td>surface.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heart Rate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of beats per minute, measured</td>
<td></td>
<td></td>
</tr>
<tr>
<td>as bpm.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bluetooth (BT)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wireless communication protocol.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ECG Check</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG Check wireless ECG monitor.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal computer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ECG Check Application</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Designs LLC proprietary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iPhone program for measuring, storing,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>displaying, and transmitting data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>gathered from the ECG Check medical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>device.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ECG Check Homepage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG Check Application main page.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ECG Check Web Center</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Designs, LLC proprietary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>internet-enabled program for storing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>and retrieval of patient records.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For use by physicians and medical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>professionals.</td>
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</tbody>
</table>
## Technical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Input Impedance</td>
<td>1.1 mohm</td>
</tr>
<tr>
<td>Input dynamic range</td>
<td>+/- 3.5mV</td>
</tr>
<tr>
<td>Maximum Current consumption</td>
<td>55mA</td>
</tr>
<tr>
<td>CMRR</td>
<td>75db</td>
</tr>
<tr>
<td>DC offset correction</td>
<td>+/- 200mV</td>
</tr>
<tr>
<td>Bandwidth</td>
<td>0.5Hz – 25Hz</td>
</tr>
<tr>
<td>Recording</td>
<td>30 seconds, single-lead ECG</td>
</tr>
<tr>
<td>Sample Rate</td>
<td>200 Hz</td>
</tr>
<tr>
<td>Transmission Period</td>
<td>Instant, dependent on iPhone</td>
</tr>
<tr>
<td>Transmission mode</td>
<td>Bluetooth Low Energy</td>
</tr>
<tr>
<td>Battery Type</td>
<td>3V CR 2032 Lithium ion battery</td>
</tr>
<tr>
<td>Battery Life</td>
<td>8 hours (approximately 480 recordings)</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>+10 to +40°C (50 to 104°F)</td>
</tr>
<tr>
<td>Transport &amp; storage temperature</td>
<td>-20 to +65°C (-4 to 149°F)</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>30 to 85%</td>
</tr>
<tr>
<td>Dimensions</td>
<td>118 x 62 x 17mm</td>
</tr>
<tr>
<td>Net Weight</td>
<td>40 (grams)</td>
</tr>
</tbody>
</table>
Additional Information

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

Manufactured By:

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Round Rock, TX 78664
Tel: 512-582-2453
Fax: 713.589.7964
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