ECG Check Universal Wireless
1-Lead Cardiac Monitor

Rx Use
Dear ECG Check Owner:

Thank you for selecting the ECG Check Universal 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, Inc.
25510 Interstate 45
Suite 202
Spring, TX 77386
Tel: 844-324-2432
Fax: 713.589.7964
Email: info@cardiacdesigns.com
Website: www.cardiacdesigns.com
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Authorized Representatives:
USA
Cardiac Designs, Inc.
25510 Interstate 45
Suite 202
Spring, TX 77386
Tel: 844-324-2432

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


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

Caution: Rx only.

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, Inc. (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, Inc. (or affiliate) service until such verification is received by Cardiac Designs, Inc. (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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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 on or 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. After prescription is approved, you will see your ECG flow across the screen as the ECG Check iPhone application is recording your heart information.

6. 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.
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

![ECG Check Monitor]

2. Battery charger chord

![Battery charger chord]

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). You will place your fingers on the electrodes to record and transmit your ECG to an application via Bluetooth for display and analysis.

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

2. Log in to your user account or choose ‘Keep me signed in’.
3.
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.

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

To examine previous tests stored on the device:

1. Tap the recording date to open and view the previously recorded results.

2. ‘Tap for archive recordings’ for previous records not shown.
**Maintenance**

**Re-Chargeable Battery**

Caution: Use only the chord provided in the kit for re-charging the device as illustrated on page 3, section 2 of the ECG CHECK KIT.

**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 device using alcohol wipe or isopropyl alcohol and a lint-free 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>Re-charge 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>
</tbody>
</table>
## Glossary

<table>
<thead>
<tr>
<th><strong>ECG</strong></th>
<th>Electrocardiogram; a representation of the heart's electrical activity recorded from electrodes on the body surface.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Heart Rate</strong></td>
<td>Number of beats per minute, measured as bpm.</td>
</tr>
<tr>
<td><strong>Bluetooth (BT)</strong></td>
<td>Wireless communication protocol.</td>
</tr>
<tr>
<td><strong>ECG Check</strong></td>
<td>ECG Check wireless ECG monitor.</td>
</tr>
<tr>
<td><strong>PC</strong></td>
<td>Personal computer.</td>
</tr>
<tr>
<td><strong>ECG Check Application</strong></td>
<td>Cardiac Designs INC. proprietary iPhone program for measuring, storing, displaying, and transmitting data gathered from the ECG Check medical device.</td>
</tr>
<tr>
<td><strong>ECG Check Homepage</strong></td>
<td>ECG Check Application main page.</td>
</tr>
<tr>
<td><strong>ECG Check Web Center</strong></td>
<td>Cardiac Designs, INC. proprietary internet-enabled program for storing and retrieval of patient records. For use by physicians and medical professionals.</td>
</tr>
<tr>
<td>Specification</td>
<td>Value</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>--------------------------------------------</td>
</tr>
<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, 40, 60 and 120 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>Average QRS Sensitivity</td>
<td>99.04%</td>
</tr>
<tr>
<td>Average QRS Predictivity</td>
<td>95.14%</td>
</tr>
<tr>
<td>Average VEB Sensitivity</td>
<td>90.97%</td>
</tr>
<tr>
<td>Average VEB Predictivity</td>
<td>83.99%</td>
</tr>
<tr>
<td>Battery Type</td>
<td>3V 1xl 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>
# EMC Information

## Guidance and manufacturer’s declaration – electromagnetic emissions

The ECG Check is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG Check should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>EMISSIONS test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>ECG Check uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The ECG Check is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
</tbody>
</table>
| Voltage fluctuations/ Flicker emissions IEC 61000-3-3 | Complies | **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ECG Check or shielding the location.

## Guidance and manufacturer’s declaration – electromagnetic immunity

The ECG Check is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG Check should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>IMMUNITY test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


### Guidance and manufacturer's declaration – electromagnetic immunity

The ECG Check is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG Check should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td>[E1] V/m</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the ECG Check, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ 800 MHz to 2.5 GHz Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a) should be less than the compliance level in each frequency range b) Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>
Note 1: At 80 MHz and 2500 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM & FM radio and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. ECG Check Mobile is used to exceed the applicable RF compliance level above, the ECG Check should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ECG Check device.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

<table>
<thead>
<tr>
<th>Recommended separation distances between Portable and mobile RF communications equipment and ECG Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>The ECG Check is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of ECG Check can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ECG Check as recommended below, according to the maximum output power of the communications equipment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.2</td>
</tr>
<tr>
<td>0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>4.0</td>
</tr>
<tr>
<td>100</td>
<td>12.0</td>
</tr>
</tbody>
</table>
Additional Information

See the ECG Check Application Installation Guide available at the Cardiac Designs, Inc. website.