

ECG Check Universal

Wireless 1-Lead Cardiac Monitor for Home Use in Prescription and Over the Counter Modes

Welcome. 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. **For your safety, please take a moment to read it carefully and in its entirety before you begin testing.**

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

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

FOR ASSISTANCE

If you have any questions about your new ECG Check, its setup, or its use, please contact:

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Symbols Glossary

	Caution (0434A) Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Follow Instructions for Use.
	RoHS Compliant
	Date of Manufacture (2497) Indicates the date when the medical device was manufactured.
	Type CF Applied Part
	Non-ionizing Radiation
	Authorized representative in the European Community Indicates the Authorized representative in the European Community.
	European Conformity
	Serial Number (2498) Indicates the manufacturer's serial number so that a specific device can be identified.
	Dispose of rechargeable batteries only in accordance with all applicable local laws and regulations.
	Keep Dry (0626) Indicates that ECG Check needs to be protected from moisture
	Temperature limit (0632) Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation (2620) Indicates the range of humidity to which the medical device can be safely exposed.

Copyright Declaration

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

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Declaration of Conformity

Conformance to Standards – non-clinical testing demonstrated conformance to voluntary safety IEC 60601-1, and IEC 60601-1-2-2007 Class B.
Type CF Applied Part. Complies with Part 15C of FCC Rules for Class B Digital Devices.

Cardiac Design, Inc.'s Quality System conforms to 21 CFR 820 and ISO 13485:2016

Warnings

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

WARNING: The ECG Check is not a diagnostic device.

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

WARNING: This device should not be used with pacemakers or implanted cardiac defibrillators (or other implanted electronic devices) and cannot predict or diagnose a heart attack or be used for chest pain monitoring.

WARNING: The ECG Check is not a defibrillation-proof device.

WARNING: The ECG Check is not intended for use during magnetic resonance imaging (MRI), cautery, and external defibrillation procedures.

WARNING: The ECG Check device must not be exposed to strong electromagnetic fields.

WARNING: Do not allow conductive parts of electrodes to come into contact with other conductive parts including earth.

WARNING: Do not use the ECG Check if the electrodes appear to be damaged or compromised.

WARNING: To prevent fire or shock hazard, do not expose the unit to rain or moisture. Do not immerse the ECG Check device in any liquid. Do not attempt to open or repair your ECG Check.

WARNING: The ECG Check device is not intended for use for infants weighing less than 10kg.

WARNING: Exposure of the wireless communications features of the device may be interfered with by other devices that operate on the same frequencies even if they comply with applicable regulations and standards.

WARNING: For proper operation, radios in the devices should be unadulterated, turned on, and the ECG Check device within sufficient distance of the cellular device for a consistent connection (within 10 meters).

Cautions

CAUTION: Do not open or attempt to repair your ECG Check. Contact us at 844-324-2432 or at www.ecgcheck.com if you require assistance with your ECG Check.

CAUTION: 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.

CAUTION: The ECG Check is not a waterproof or water resistant device. Do not immerse the ECG Check in any liquid.

Precautions

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

This device is available in the USA in both over the counter mode (OTC) and prescription mode (Rx).

Prescription Mode:

This device must only be used for the person for whom it has been prescribed and only for the use for which it is intended.

Until a valid physician prescription is received from your physician, you will only have access to the OTC mode of the system, described below.

Your agreement certifies you understand that this service is not a substitute for physician care and that it is only a screening service.

Over-the-Counter Mode:

In the Over-the Counter Mode you will know that the 30-second recording occurs as the 'Progress Bar' fills up while the system records your ECG. If you chose Prescription

Mode, after your prescription has been approved you will see your ECG displayed in real time as it is recording. If you are in Over-the Counter mode you will see the 30-second recording "Progress Bar" fill up while the system records your ECG after which the result will be displayed as Green (Normal), Red (Irregular) or Yellow (Unable to read).

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.

Indications for Use

The ECG Check Universal family of devices is intended for self-testing at home. These 1-lead cardiac monitors allow remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server.

Specifically, the ECG Check Universal models are indicated for patients who are concerned about their heart rhythm and have experienced 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

Description

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 cellular device). This allows you and your physician to monitor your health information (ECG) from anywhere any time you wish.

Your ECG Check comes with the following:

ECG Check Device



ECG Check USB Charging Cord



Device Functions



1. On/Record

- If the device is off, pressing your fingers to the electrodes will turn the device on and begin initiating a connection with the open application. NOTE: The ECG Check device must be within 10 meters of the cellular device.
- If the ECG Check application is not open, please start the application prior to initiating a recording on the device. The device will not begin recording data until the ECG Check application has been started and the blue 'Make a New Recording' icon has been pressed.

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 cellular device application has connected with the ECG Check device via Bluetooth to begin recording.



The ECG Check is not waterproof. Do not allow it to get wet. Remove before bathing or swimming.



Do not use or store the ECG Check in extreme heat or cold.



Do not use or store the ECG Check outside of stated humidity levels.

Setup and Use of the ECG Check

Setup the ECG Check Device

Your ECG Check comes fully assembled. You will need to fully charge your ECG Check prior to first use by following these steps:

1. Unpack the USB cord that is provided with the ECG Check.
2. Connect the USB cord to the charging port of the ECG Check, which is located on the side of the device.
3. Connect the USB end of the device to your computer, or to a wall adapter.
4. Allow to charge for a full 8 hours before first use. When charging is complete, remove the USB cord from the ECG Check and the computer and store in an easy to find location so you will have it easily accessible for recharging when necessary.

Download the ECG Check Application and Create your Account

1. Download the ECG Check Application from the AppStore (iPhone) or Play Store (Android).
2. Ensure the Bluetooth setting is turned ON for the cellular device (i.e. iPhone) you are using. If the Bluetooth setting is not on, refer to the instructions for use of the cellular device to determine how to turn the Bluetooth on. NOTE: Bluetooth must be ON for the ECG Check to connect to the ECG Check application on the cellular device.
3. Once downloaded, tap the ECG Check icon to open the application on the smartphone.



ECG Check Application Icon

4. Create your user profile and account by following the prompts.
5. Keep the application open while making your ECG Recording with the ECG Check device.

Now the ECG Check is ready for use.

General Information

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

Before Recording

For your safety, read this instruction manual in its entirety before attempting a recording. Pay careful attention to the electrode positions as instructed.

Recording

1. Start the ECG Check application by tapping the ECG Check icon (see below).



ECG Check Application Icon

2. Log in to your user account or choose 'Keep me signed in'.

ECG Check Application Log-in Screen

3. After you are signed in, the following screen will be displayed:



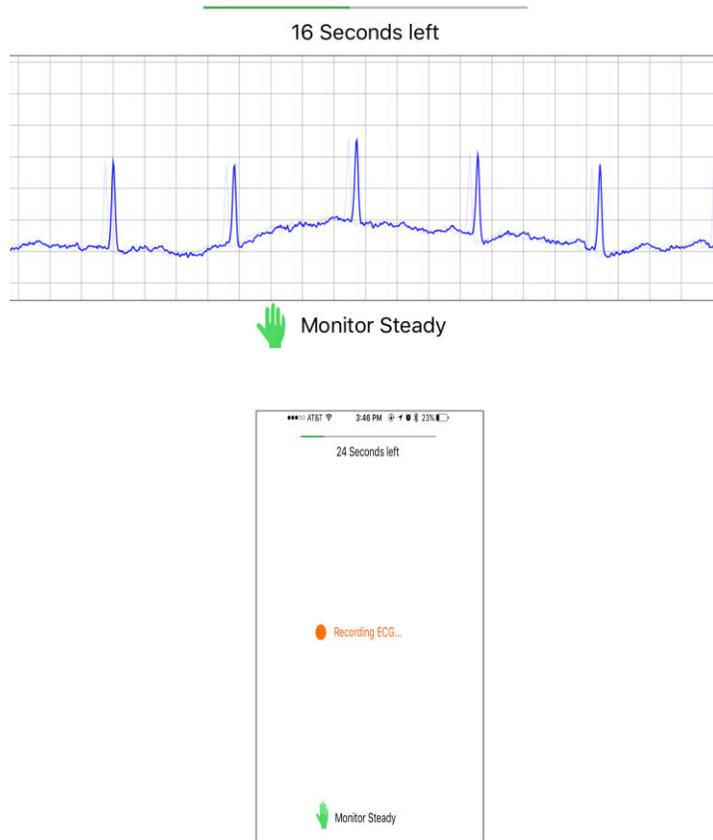
4. Press the BLUE CIRCLE icon at the top of the application to be prompted on how to start recording.
5. The following screen will appear once you have established a connection and the ECG Check device begins recording.



ECG Check Application Recording in Progress Screen

6. The application will present the screen below. Wait for the progress bar to fill up while the system records your ECG. The countdown feature tells you how long until the recording is complete.

- If you are in Prescription Mode, you will see your ECG displayed as it is recording as shown below. If you are in Over-the-Counter Mode, you will only see a progress bar as the recording progresses.



- The system will automatically send the ECG for analysis by the backend arrhythmia analysis algorithm.

- Results will be returned to the application with one of the following:

Normal Heart Rate

Irregular Heart Rate

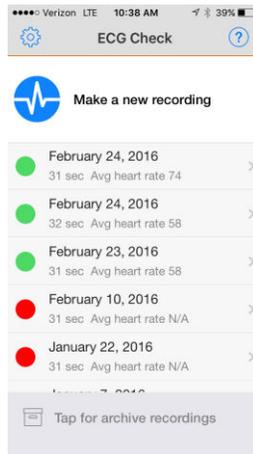
Unable to Read ECG Data

Medical Records

Each ECG recording you make will be stored within the smartphone application for future viewing.

To examine previous tests stored on the device:

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



2. Tap on the 'Tap for archive recordings' to view older recordings than those shown on the screen.

Maintenance & Cleaning

Rechargeable Battery



Warning: Do not dispose of the internal rechargeable battery in the normal trash. Dispose of rechargeable batteries only in accordance with local law and regulations

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

CAUTION: Do not open or attempt to repair your ECG Check. Contact us at 844-324-2432 or at www.ecgcheck.com if you require assistance with your ECG Check.

CAUTION: 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.

CAUTION: The ECG Check is not a waterproof or water-resistant device. Do not immerse the ECG Check in any liquid.

The Cardiac Designs, Inc. ECG Check devices are non-sterile devices for use in non-sterile clinical and home environments. The following manual Cleaning and Disinfection procedure below provides directions for cleaning and disinfecting the device. Failure to follow these procedures may result in substandard recordings or the cross-contamination among patients.

Preventive Maintenance

The following simple preventive maintenance tasks should be performed monthly (at minimum) to ensure continued performance of your ECG Check device at maximum capacity, and to reduce the possibility of a failure. Refer to the cellular device instructions for proper maintenance of your cellular device.

Ensure your ECG Check device battery is charged. We recommend that you fully charge your ECG Check device at least once per month according to the instructions in the 'Set Up Your ECG Check Device for Use' section of this manual.

Mechanical Inspection

Check for splits, cracks, or imperfections in the case. If you have any questions or doubts, contact us at 844-324-2432 or at www.ecgcheck.com.

Do not use the device if it does not appear to be functioning properly or shows signs of damage. Use of an ECG Check for a task other than that for which it is intended may result in damage to the device, or provide unsatisfactory performance.

Cleaning & Disinfection for the ECG Check device

Always clean your ECG Check before disinfection. Clean & disinfect your ECG Check Device each month or immediately after another person handles the device to prevent the spread of germs or infection and to keep your ECG Check in good working order.

Always clean the ECG Check first and then disinfect it according to the instructions provided below.

We recommend use of the Sani-Cloth® HB cleaning & disinfecting wipes (or equivalent) for cleaning and disinfection of the ECG Check device.

The ECG Check is not intended for sterilization.

Cleaning

Wipe all exterior surfaces with a fresh Sani-Cloth® HB cloth to remove any visible soil or residue. Discard the Sani-Cloth® HB cloth immediately.

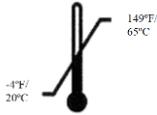


Do not allow any liquid to enter the case, and avoid pouring water or other liquids on the device while cleaning.

Never use abrasives such as wire wool or metal polish.

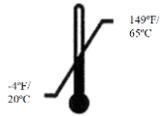
Disinfection

Using a new Sani-Cloth® HB cloth after cleaning, wipe all exterior surfaces of the ECG Check and allow to air dry for 10 minutes. It is crucial that these instructions be followed EXACTLY for the desired effect. See instructions provided with Sani-Cloth® HB for more information.



Never expose the device to temperatures in excess of stated temperature limitations.

Storage



Store the ECG Check in a dry temperate location.



Caution:

Do not store the ECG Check in a damp area, or in areas that experience extreme heat or cold. These conditions can damage the internal components and case of the ECG Check.

Troubleshooting

Problem	Possible Cause(s)	Solution
Device does not send ECG to application	The battery is very low or depleted	Re-charge battery
	The Bluetooth radio is not enabled on the cellular device	Turn Bluetooth ON in the cellular device
	The ECG Check is out of range with the cellular device	Move closer to the cellular device – the ECG Check device and the cellular device must be within 10 meters for ECG data transfer.
	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
Cellular device is running slowly	Too many applications open	Manually close the applications or restart your cellular device.
ECG Check application does not launch	Too many applications open	Manually close the applications not in use or restart your cellular device.

Cybersecurity

Cardiac Designs, Inc. takes the protection of personal information very seriously. The ECG Check device system uses data encryption for all points of data transmission and storage from the point of ECG recording, through return of analyzed ECG data back to the ECG Check application.

To be certain your ECG Check data remains secured, we recommend that you do not share your log-in and password information for your ECG Application with anyone. Follow the manufacturer recommendations for security for your cellular device.

If you are concerned that your cellular device may have been compromised, follow the cellular device manufacturer recommendations. Once your cellular device has been re-secured, contact Cardiac Designs, Inc. for any questions or assistance you may need with the ECG Check application. Our contact information is shown below:

Cardiac Designs Inc. Tel: 844-324-2432
Email: info@cardiacdesigns.com Website: www.ecgcheck.com

Wireless Technology

The ECG Check device system uses wireless technology to transmit data from the ECG Check Device to the ECG Check application on the cellular device. The cellular device transmits data to and from the back-end analysis engine using the cellular network.

For proper operation of your ECG Check, do not attempt to open the ECG Check or otherwise tamper with the Bluetooth radio. The Bluetooth on the cellular device must be unadulterated, turned on, and within sufficient distance of the ECG Check device (no more than 10 meters) to allow for a consistent connection. You must have a cellular signal for transmission to and from the back-end analysis engine. If you do not have a cellular signal, the recordings will be saved on the cellular device and transmitted once a cellular signal is detected.

If you experience wireless connection issues, please refer to the Troubleshooting section of this manual.

The ECG Check device system is suitable for use in the U.S. and the EEC (European Economic Community). The ECG Check device system may not function properly in

countries outside of the U.S. and EEC due to possible wireless technology and technical parameter differences.

Glossary

Communication Device	Cellular device.
ECG	Electrocardiogram; a representation 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, Inc. proprietary software 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, Inc. proprietary internet-enabled program for storing and retrieval of patient records. For use 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 second, single-lead ECG
Sample Rate	200 Hz
Transmission Period	Instant, dependent on cellular device
Transmission mode	Bluetooth™ - Low Energy
Modulation	Digital
Radiated RF Power	1W
Frequency Band	2.4 GHz ISM (Industrial, Scientific, and Medical)
Average QRS Sensitivity	99.87%
Average QRS Predictability	99.77%
Average VEB Sensitivity	93.91%
Average VEB Predictability	94.12%
Battery Type	3.7V x1 Lithium ion rechargeable battery
Battery Life	8 hours (approximately 480 recordings)
Operating Temperature	+10 to +40°C (50 to 104°F)
Transport & storage temperature	-20 to +65°C (-4 to 149°F)
Relative humidity	30 to 85%
Device Casing Material	ABS/PC Plastic
Electrode Material	Copper Plating AG/CL
Dimensions	87 x 49 x 7mm
Net Weight	33 (grams)
FCC Identifier	RP4ECGC4S001

Operating Components

PCB	1
Electrode Sensors	2
LED Status Indicators (Bluetooth Connection Status & Charging Status)	2

Heart Rate Calculation

The ECG Check calculates heart rate by excluding the minimum and maximum values from the RR intervals of the recording and using the remaining values to calculate the average heart rate.

EMC Information

Guidance and manufacture's declaration – electromagnetic emission		
The ECG Check is intended for use in the electromagnetic environment specified below. The customer of the user of the ECG Check should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The 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. The ECG Check is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ECG Check requires continued operation during power mains interruptions, it is recommended that the ECG Check be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture'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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p>	<p>3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur radio bands</p> <p>150 kHz to 80 MHz</p>	<p>Not applicable</p>	<p>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.</p> <p>Recommended separation distance</p> $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>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 metres (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Radiated RF IEC 61000-4-3</p>	<p>0 V/m</p> <p>80 MHz to 2.6 GHz</p>	<p>10 V/m</p>	

NOTE 1 At 80 MHz and 800 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.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast 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. If the measured field strength in the location in which the ECG Check is used exceeds 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.

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

Recommended separation distances between portable and mobile RF communications equipment and the ECG Check			
The ECG Check is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 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.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			

Manufactured By:

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