

ECG Check Universal

Wireless 1-Lead Cardiac Monitor for Home Rx Use

Cardiac Designs Inc., 695 Minnesota Street, San Francisco, CA 94107. USA

Welcome. Thank you for selecting the ECG Check Universal cardiac monitor. ECG Check is USFDA 510 (k) cleared (K17506) and CE Marked (0086).

General Information

The ECG-Check is a single lead ECG recording device that uses the 2 built-in electrodes. Place your fingers on the electrode pads to record and transmit your ECG to an iOS or Android App via Bluetooth for display and analysis as shown.



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

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

Due to the possible seriousness of the abnormal heart rhythms that can be associated with these conditions, persons with Coronary heart disease, Valvular heart disease, Heart transplant and Heart failure should consult their physician before using this device.

To use this device, your patient must be able to download an iOS or Android app on a mobile phone, place the ECG Check in their hands or on their chest or leg and hold it for at least 30 seconds,

This device is available in over-the-counter ('OTC') mode and prescription ('Rx') mode. Until a valid prescription is received by us, your patient will only have access to the OTC mode of the system (described below). 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.

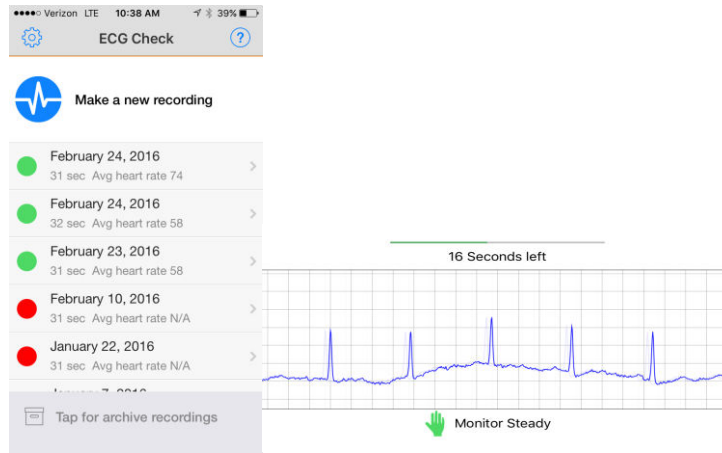
The ECG Check is not intended for diagnostic use and does not provide diagnostic quality ECG data.

Setup and Use of the ECG Check

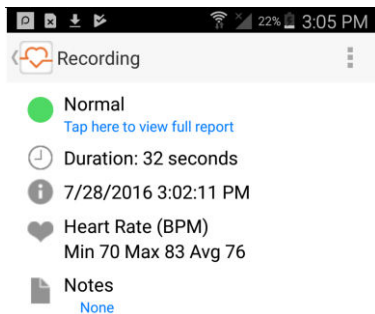
ECG Check comes fully assembled. You will need to fully charge your ECG Check prior to first use and download the ECG Check Application from the AppStore (iPhone) or Play Store (Android).

Create your user profile and account by following the prompts in the App and send us a copy of your prescription (Rx) if you have one.

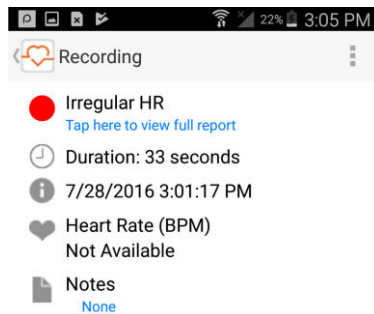
Now the ECG Check is ready for use and the following screen will be displayed:



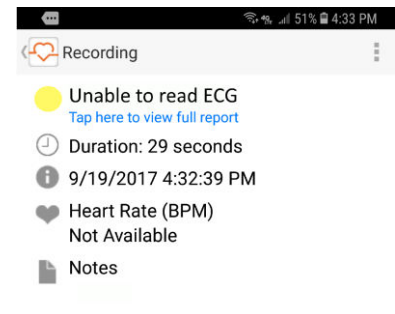
1. Press the BLUE CIRCLE icon at the top of the App to be prompted on how to start recording.
2. If you are in Prescription Mode, you will see your ECG displayed as it is recording as shown above.
3. If you are in Over-the-Counter (OTC) Mode, you will only see a 'progress bar' as the recording progresses and not the actual waveform.
4. Results will be returned to the App with one of the following:



Normal Heart Rate



Irregular Heart Rate



Unable to Read ECG Data

Medical Records

Each ECG recording made will be stored within the smartphone App for future viewing at no charge to the patient or to you. ECG recordings can be sent by email to you, or can be connected to your portal, and can be uploaded to EMRs to become part of your medical record if needed.

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.

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.

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 ^o C (50 to 104 ^o F)
Transport & storage temperature	-20 to +65 ^o C (-4 to 149 ^o 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

Manufactured By:

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