



User Manual

Ver 08.01.2019

NOTICE:

It is required that you read this instruction manual before trying to operate the HeartCheck™ CardiBeat.

It is not recommended that you start using the device before reading the whole manual.

Failure to follow this instruction manual may result in measurement abnormalities and equipment damage. CardioComm Solutions, Inc. (the “Company”) assumes no responsibility for personal injury or device damage sustained by or through the use of this product.

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Warnings and Cautions

Precautions

- Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.
- This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.
- The equipment must be used per the requirements of this manual. Failure to properly use the equipment may result in degraded performance or loss of functionality.
- Use of the equipment near mobile and portable RF communications equipment or other electronic devices may affect the equipment.
- Other devices may emit harmful radiation or interference that could affect equipment performance.
- Use of accessories and cables other than those provided with the equipment could result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2007.
- The received signal may be interfered/disrupted by other equipment operating in this frequency band (i.e. Bluetooth, other non-associated access points, microwave ovens, ISM devices, etc.) even if the other equipment complies with its applicable regulations such as CISPR 11.

Warnings

- Changes or modifications to this unit not expressly approved by the party responsible for compliance will void the user's authority to operate the equipment and any applicable manufacturer's warranty.
- The HeartCheck™ CardiBeat is not a diagnostic device. This single lead ECG device should not be used for diagnostic purposes in comparison to the standard 12 lead ECG recorder obtained with typical electrode placement.
- This device cannot predict or diagnose a heart attack and should not be used for chest pain monitoring.
- The HeartCheck™ CardiBeat 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.

Contraindications










- This device should not be used with active pacemakers or implanted defibrillators.

Intended User

- Should be able to hold the device steady in both hands for at least 30 seconds.
- Should be able to read and understand the content in the user manual.
- Should understand principle of operation described in this manual.
- Should be able to operate a phone/tablet.

Technical Specifications & Declarations

Key Symbols

Symbol	Description	Symbol	Description
	Type BF applied part		“CAUTION, CONSULT ACCOMPANYING DOCUMENTS”
	Complies with the Medical Device Directive of the European Union.		“AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY”
	Waste Electrical and Electronic Equipment (WEEE) It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.	IP22	Protected against access to hazardous parts with a finger and against vertically falling water drops when enclosure tilted up to 15°
	Year of Manufacture	SN	Serial Number
	Symbol for “MANUFACTURER”		Refer to instruction manual / booklet
	Trademark		

Classification

Type of Protection:	Class II / Internally powered equipment
Degree of Protection:	BF Type
Safety:	IEC 60601-1
Ingress Protection (IPXX):	IP22

Technical

Characteristic	Value
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 durations	30 seconds to 300 seconds, single-lead ECG
Sample rate	200 Hz
Transmission mode	Bluetooth Low Energy

Characteristic	Value
Battery type	3V 1x1 Lithium ion 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 +60 ^o C (-4 to 149 ^o F)
Relative humidity	30 to 85%
Dimensions	118 x 62 x 17mm
Net weight	40 (grams)

Electromagnetic Compatibility

The device meets the requirements of IEC 60601-1-2. All the accessories also meet the requirements of IEC 60601-1-2 when in use with this device.



Warnings

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.
- Other device that have RF transmitters or sources may affect this device.
- This device is Magnetic Resonance (MR) unsafe.

Guidance and Manufacture's Declaration – Electromagnetic Emissions

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

Emission Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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 emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emission IEC 61000-3-3	Complies	

Guidance and Manufacture's Declaration – Electromagnetic Immunity


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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic Discharge IEC 61000-4-2	±2kV, ±4kV ±6kV, ±8kV, ±15kV	Contact: ±8kV Air: ±15kV	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 IEC 61000-4-4	±1kV ±2kV	Power supply lines ±2kV	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV, ±2kV	±1kV line to line	Main power quality should be that of a typical commercial or hospital environment.
Voltage Dips & Interruption IEC 61000-4-11	0% 40% 70% 0% of U_T	0% for 0.5 cycles 40% for 5 cycles 70% for 25 cycles 0% for 250 cycles	Main power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m	30 A/m, 60 Hz	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 equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Radiated Immunity IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	10 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 230 MHz 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). 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: 

Conducted Immunity IEC 61000-4-6	3Vrms 150KHz to 80MHz	3Vrms 150KHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
	6Vrms ISM/Amateur Radio bands inside 150KHz to 80MHz	6Vrms ISM/Amateur Radio bands inside 150KHz to 80MHz	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetics are 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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

Guidance and Manufacture's Declaration – Electromagnetic Immunity

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
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 metres (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.

Declaration of Conformance

Conformance to Standards – non-clinical testing demonstrated conformance to voluntary safety IEC 60601-1 and to IEC 60601-1-2-2014 Class II.

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

RF Conformance

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.



Any changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Some electronic devices are susceptible to electromagnetic interference sent by this equipment if inadequately shielded. Please use this equipment at least 20cm or as far as you can from TV set, radio and other automated office equipment so as to avoid interference.

This device is a radio transmitter and receiver. It is designed and manufactured not to exceed limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission (FCC) of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age or health.

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.



A minimum separation distance of at least 0.2 m between this equipment and all person shall be guaranteed to satisfy the RF exposure compliance.

Quality of Service and Security

Use of this device assures timely, reliable, accurate, and secure data and wireless data transfer when used in accordance with this manual.

- When you want to establish a wireless connection with the portable ECG monitor, you must input the correct communication instructions so that unauthorized access to the ECG data is prevented.
- The HeartCheck™ CardiBeat does not store or transmit personal data.
- The HeartCheck™ CardiBeat connects to a phone/tablet using Bluetooth 4.0 LE secure connection.
- CardioComm Solutions, Inc. recommends securing the phone/tablet to avoid unauthorized access to personal data by:
 - Avoid connecting to unsecured Wi-Fi networks
 - Set automatic keypad locks to prevent unauthorized use
 - Set a personal device PIN or password to unlock the keypad
 - Only download apps from trusted sources
- GEMS™ Mobile ECG app is only distributed through the Google Play Store and Apple iTunes. If a user downloads software updates from other unauthorized channels, it will increase the risks associated with cybersecurity breaches. CardioComm Solutions, Inc. will not take responsibility for the consequences this may cause.

Overview

Indications for Use

The HeartCheck™ CardiBeat device with the GEMS™ Mobile ECG software is an over-the-counter device to be used by patients 21 years of age or older. It is intended to record, store and transfer single channel ECG signals and display ECG waveforms. GEMS™ Mobile ECG works with this 1-lead cardiac monitor to allow users to display and transmit their recorded ECG data to medical professionals via a compatible Smart phone or tablet to a remote server.

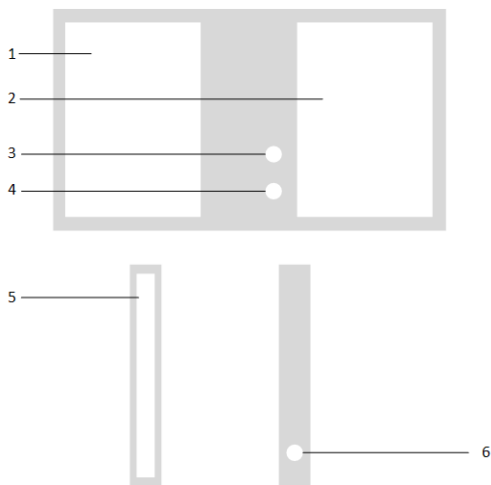
The HeartCheck™ CardiBeat combined with GEMS™ Mobile ECG software is indicated for users who are concerned about their heart rhythm and may have experienced symptoms suggestive of irregular or abnormal heart rhythms. Symptoms may include:

- Skipped beats
- Palpitations
- Racing heart
- Fainting and lightheadedness
- Irregular rate
- History of any related heart abnormalities

The HeartCheck™ CardiBeat along with the GEMS™ Mobile ECG software is not intended to substitute for use of a hospital diagnostic ECG device. Users with an implanted pacemaker are not recommended to use this device while the implanted device is active. Users where their pacemaker is actively pacing the heart will not be able to record their ECG under normal sinus rhythm with the pacemaker on. Not recommended for users with a defibrillator.

Description of the Device

The HeartCheck™ CardiBeat is a small card sized ECG monitor measuring 87 x 49 x 7 mm and weighing 33 g. The device is made of PC plastic and silver plated electrodes.



1. Left index finger electrode
2. Right index finger electrode
3. Bluetooth connection indicator
4. Charge indicator
5. Left palm electrode
6. Battery recharging port

Environmental Conditions

Temperature: 10°C to 40°C

Humidity: 15% to 93% RH

Pressure altitude: 700 hPa to 1060 hPa

Getting Started

Package Content

- 1 HeartCheck™ CardiBeat ECG Monitor
- 1 HeartCheck™ CardiBeat ECG Monitor USB charging cable
- 1 Carrying Case
- 1 Quick Start Instruction Card

Device Setup Instructions

The HeartCheck™ CardiBeat ECG monitor comes with a partially charged lithium ion battery so you can start using your device straight away.

The HeartCheck™ CardiBeat ECG monitor connects to a compatible smart device via Bluetooth. In order for the device to communicate with the GEMS™ Mobile ECG application, make sure Bluetooth is enabled on the smart device under Settings.

Software Installation

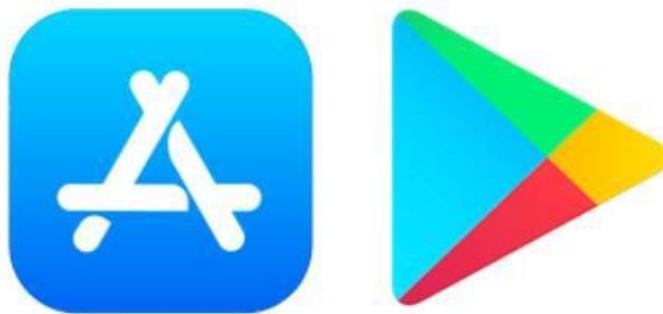
On your smart device, download the GEMS™ Mobile ECG software to use with your HeartCheck™ CardiBeat ECG monitor.

For Apple iOS Systems:

1. Go to the Apple App Store.
2. Search for GEMS™ Mobile ECG.
3. Download and Install the GEMS™ Mobile ECG app.

For Android Systems:

1. Go to the Google Play store.
2. Search for GEMS™ Mobile ECG.
3. Download and Install the GEMS™ Mobile ECG app.



Operating Instructions

Create a User and Verify your Email Address

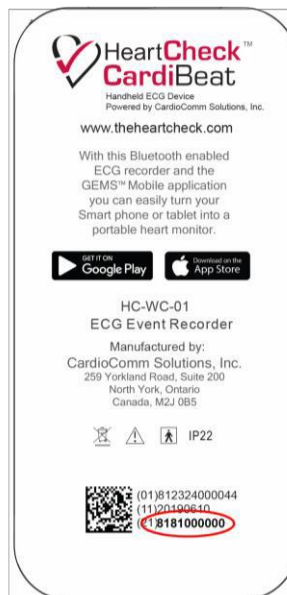
On your mobile device, start the application:

1. Upon running the app for the first time, you will be prompted to enter user information. Fill in all the fields.
2. In the GEMS™ Mobile ECG app, on the top menu bar, tap on Settings.
3. On the Settings page, tap Verify to request email verification.
4. A verification email will be sent to your email address. Click on the link in that email to verify your email address.
5. Once the email is verified, on the Settings page, tap Check for Verified Email to complete the verification process. A green checkmark will appear next to your email address if verification is successful.
6. Tap the first 'Connect' navigation button on the bottom left of the screen to take you to the device welcome and connection screen.

Recording Your ECG

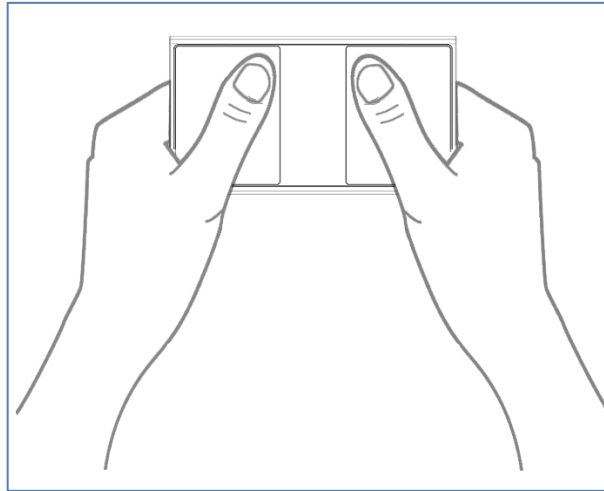
The waveform display is locked until after one ECG has been uploaded for a SMART Monitoring ECG physician interpretation and the returned ECG report has been viewed in the GEMS Mobile app.

1. The device connection page can be accessed by tapping the 'Connect' icon at the bottom left of the screen.
2. Select the HeartCheck™ CardiBeat device and click the Connect button.
 - a. The first time connecting to your HeartCheck™ CardiBeat to the GEMS™ Mobile app, you will be prompted to enter the device's serial number. This step will only be required the first time the device is used with the app. The serial number is listed on the label on the back of the device as well as on the back of the box packaging. It is the 10 digit number after the bracketed number twenty one (21).



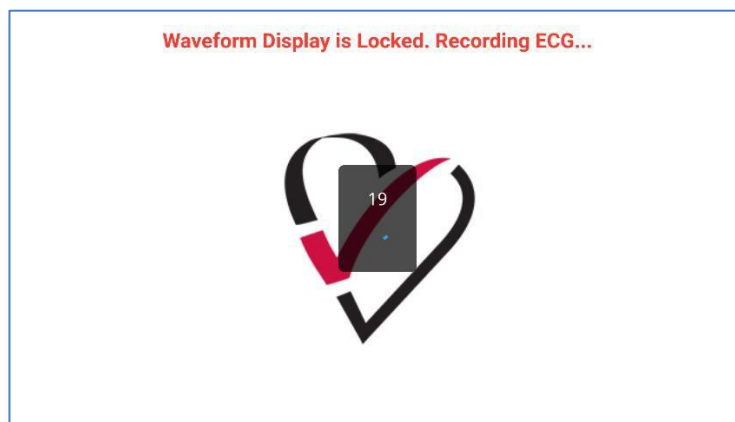
Note: For Android 6.0+ users, you will be asked to “Allow HeartCheck™ CardiBeat to access this device’s location?”. Tap ‘Allow’—your HeartCheck™ CardiBeat will not be recognized if access to your device’s location is not allowed.

- Use your thumbs and index fingers of both hands to gently grip the metal sheet, leaning hands on a desktop or the thigh. Maintain a relaxed state and do not apply a lot of pressure when holding the HeartCheck™ CardiBeat.



- As soon as it is held, the HeartCheck™ CardiBeat device will automatically connect to the GEMS™ Mobile ECG app on your smart phone. It will show a six second countdown before the ECG recording begins.
- You will be able to see the ECG waveform on the screen of your Smart phone as it is being recorded after the GEMS™ Mobile ECG application has been unlocked*. Initially you will only see a locked screen with a countdown recording timer backwards from 30 seconds to zero seconds.

** the GEMS™ Mobile ECG App display will be unlocked after submitting and receiving back one free included review through the CardioComm Solutions, Inc. SMART Monitoring service – see section 'Upload your ECG to Smart Monitoring' below.*

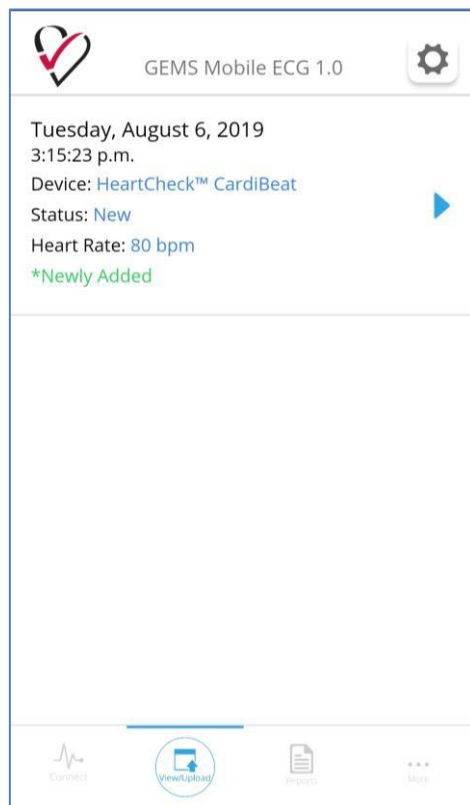


Locked GEMS™ Mobile ECG App display while recording



Unlocked GEMS™ Mobile ECG App display while recording

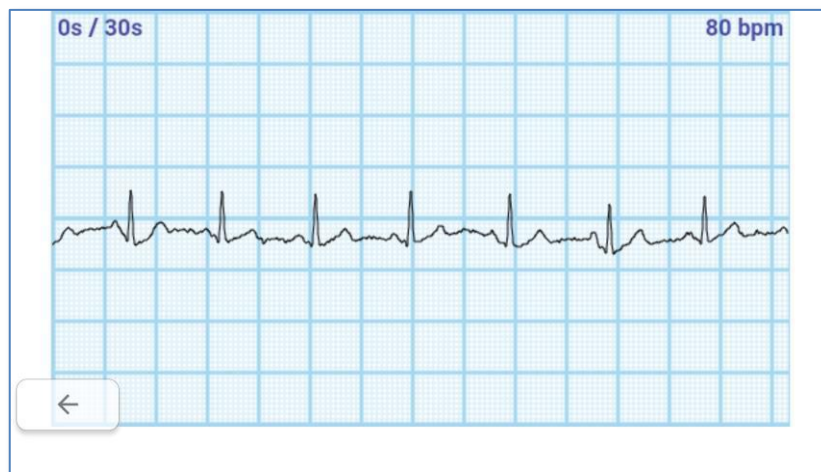
6. Once recording is complete, the GEMS™ Mobile ECG app will indicate the recording was successful and the device will disconnect from the GEMS™ Mobile ECG App.
7. Click the second navigation button from the left along the bottom of the App to go to the View/Upload list where it will show a listing of all saved ECG recordings.



Viewing Your ECG Waveform

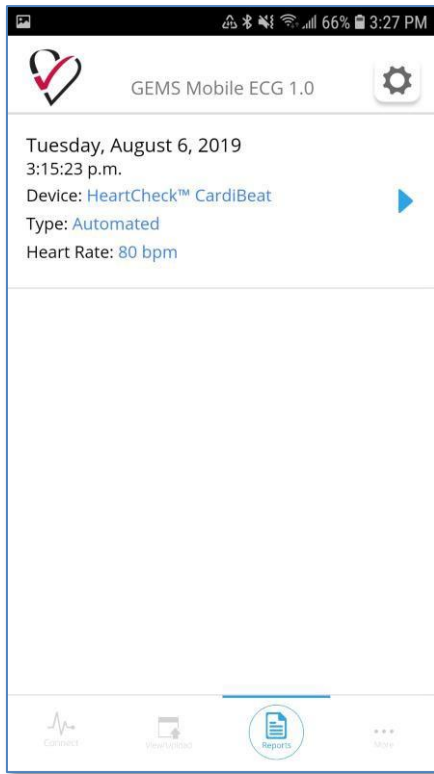
1. In GEMS™ Mobile ECG, tap the second navigation icon from the left, View/Upload.
2. A list of your ECG recordings will be displayed.
3. Select an ECG recording by tapping the record.
4. Scroll down. The ECG details are displayed along with buttons to View, Upload and Delete ECGs under the ECG Actions header.
5. Tap the View button to display the ECG waveform*. Swipe to the left to advance through the recording, swipe to the right to return towards the beginning.
6. To exit the ECG waveform display, click the Back button at the bottom left.

**The GEMS™ Mobile ECG App display will be unlocked by submitting and receiving back one free included review through the CardioComm Solutions, Inc. SMART Monitoring service – see below.*



Upload Your ECG to Smart Monitoring

1. If you would like your ECG to be reviewed by an ECG technician or a doctor, you can upload your ECG to the CardioComm Solutions, Inc. SMART Monitoring reading service. The first ECG reading is provided at no charge in order to facilitate unlocking the display in the Application. A fee will be applied to all subsequent ECG review requests.
2. In GEMS™ Mobile, click the second View/Upload navigation icon along the bottom.
3. A list of your ECG recordings will be displayed.
4. Select an ECG recording by tapping the record.
5. Fill-in the Symptom and Activity fields. These fields are required.
6. Fill in the free text diary field (250 characters maximum). This is optional.
7. Tap the Upload button.
8. Select the Report option.
9. You may be requested to verify your email address if this is your first time requesting a report – see Verify Email Address for instructions.
10. Complete payment if this is not the first free included review.
11. Your report will be sent back to your smart device via GEMS™ Mobile ECG within the standard reporting period. An email notification informing the report is ready for viewing will be sent to the verified email address.
12. Tap the third navigation icon along the bottom to see a list of completed Reports. Tap any in the list to open it as a PDF.



Cleaning

- Do not open or attempt to repair your HeartCheck™ CardiBeat by yourself. Only authorized service personnel may repair the device.
- Do not drop the device or subject it to severe impacts. Bending the body can damage the circuitry.
- Do not use solvents to clean your device.
- Use only a soft, dry cloth.

Maintenance

1. Please contact us if battery replacement needed.
2. Charge the battery with the certified charging cable provided by CardioComm Solutions, Inc.
3. Charging the device: please charge the device with dedicated charging cable; charging voltage: DC 5V, charging current: $\geq 100\text{mA}$.

Storage

- Keep the device 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 device is not waterproof, do not use it or store it at place where fluids such as water can splash onto it. Raindrops, water spray, juice, coffee, steam, perspiration, etc. may also cause a malfunction.
- Keep the device and accessories away from children as the device or accessories could pose a swallowing hazard.

Troubleshooting

PROBLEM/ERROR MESSAGE	CAUSE	RESOLUTION
"Could not retrieve serial number"	Mobile device is not connected to the internet.	Ensure that the mobile device is connected to the internet.
	Serial number for device is invalid.	Navigate to the GEMS™ Mobile ECG settings page. Under "Serial Number" verify that the number listed is the same as the back of the device/box packaging. Tap on the field and amend if not and save the changes.
"Error sending verification email" "Error retrieving Email Verification Status"	Mobile device is not connected to the internet.	Ensure that the mobile device is connected to the internet.
"Could not authenticate device"	Mobile device is not connected to the internet.	Ensure that the mobile device is connected to the internet.
"Could not find compatible device"	Low battery.	Recharge the HeartCheck™ CardiBeat.
	HeartCheck™ CardiBeat device held incorrectly.	Place fingers firmly against the HeartCheck™ CardiBeat's contacts.
"Upload unsuccessful. Please try again."	Mobile device is not connected to the internet.	Ensure that the mobile device is connected to the internet.
Wireless communication failure	The recording environment has strong electromagnetic noise	Remove the interference source or record in an environment with less electromagnetic noise.
	Unable to send data	Restart the device Check that Bluetooth has been enabled on the phone/tablet
ECG waveform contains noise or heart rate is random	Your skin is too dry	Wipe the skin that is in contact with the electrodes with alcohol or electric salve.
	The recording environment has strong electromagnetic noise	Remove the interference source or record in an environment with less electromagnetic noise.
	There is unwanted movement in the recording process or the device is being held too tightly	While recording an ECG, sit comfortably, with your arms in a resting position while not moving. Apply gentle and steady pressure when holding the device in your hands.

Manufactured By

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Device ID:	812324000044