

Document Number: 3657

## INTRODUCTION

Please read this guide prior to device use. Failure to follow the guide may cause measurment 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. No part of this guide may be copied, reproduced or translated into another language without prior written consent of the Company. The Company reserves the right to revise this guide at any time without prior notice. All rights reserved. Issue Date: May 1, 2014

### Intended Use

The HeartCheck™ PEN Handheld device with GEMS™ Home software is an over-the-counter device intended to record, store and transfer single channel Heart Rhythm signals and, under a physician’s care, display Heart Rhythm waveforms. The HeartCheck™ PEN Handheld device along with GEMS™ Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user’s Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS™ Home is a simple software user interface for managing Heart Rhythm recordings and associated data.

### Using GEMS™ Home And Your PEN

The HeartCheck™ PEN records and displays heart rate data, and with GEMS™ Home software, will transfer the Heart Rhythm (“HR”) recording to your computer for storage. GEMS™ Home manages the HeartCheck™ PEN HR recordings and associated user data, and can be used to send HR recording to a physician for review. With approved physician review, the HeartCheck™ PEN, with GEMS™ Home software, can be unlocked to display the recorded HR waveform as an electrocardiogram (“ECG”). Refer to “Enable Heart Rhythm Display” below.

### Notes on Safety

Users may view ECG waveforms once a physician-patient relationship has been established (see ”Enable Heart Rhythm Display” below). This device is not designed or intended for self-diagnosis.

The heart rate and HR results are for monitoring purposes only and should not be used as a basis for starting or modifying medical treatment. Always consult your physician if you have any questions or if you believe you have abnormal measurements.

The values displayed by the device are the ones derived at the time of measurement. Medical conditions can change suddenly. If you notice any change in your condition, consult your physician, regardless of the measured results. No alterations to the HeartCheck™ PEN device may be made. The device is sold as a finished product and any disassembly or modifications will render the warranty null and void.

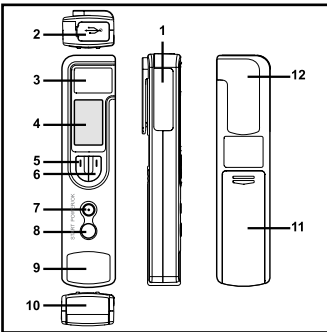
### CAUTION

- Do not expose the device to strong shocks or vibrations.
- Do not take measurements with overly wet skin.
- Avoid use near strong electromagnetic forces.
- Do not expose the device to static electricity.
- Ensure the device is powered off before replacing the batteries.
- Ensure the polarity of the batteries is correct.
- Do not use new and used batteries together.
- Remove the batteries when the device is not used regularly.
- When replacing batteries, you will need to reset the date and time.

## BATTERY REPLACEMENT

Low batteries may affect the accuracy of HR measurements. Monitor the Battery Life icon on the display screen. Change batteries when the battery icon indicates low battery life, or the screen displays “Change Batteries”. The device will turn off when batteries are too low for normal operation. When replacing batteries you will need to reset the date and time.

## DEVICE DESCRIPTION



### Display Screen

The display screen shows the date and time, and battery icon. There are five menus to navigate through use of the LEFT and RIGHT buttons as described below.

### Menu Items

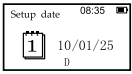
	HR Measure: Select this screen, and press the START button to start a recording.		HR Recordings: Select this screen to view recorded measurements. Use the LEFT and RIGHT buttons to navigate through recordings. Press POWER to replay them (unlocked devices only). Refer to “Enable Heart Rhythm Display” below.
	Sys Setup: This menu allows you to set date, time, and other settings.		Delete Data: This screen allows you to delete recorded measurements. Use the LEFT and RIGHT buttons to select a recording, and then press the POWER button to delete it.
	About: This screen provides device information such as version and serial number.		

## SETUP DATE AND TIME

Ensure the device’s date and time are correctly set as these are recorded when a HR measurement is taken. The date format is “Day/Month/Year”, and the 24-hour clock is “Hour:Minute”. The device will display “SETUP DATE AND TIME” when running the device for the first time, or after the batteries have been changed. Note: time and date may not be maintained correctly with low batteries. After changing the batteries, make sure to set the date and time again.

### Setup the Date

- Turn on the Device with the POWER button.
- Press the RIGHT button and select “Sys Setup.”
- Press the POWER button to enter the “Sys Setup” screen.
- Select the Date Setup item (Calendar icon) and press the POWER button to enter the date setting screen.
- Press the POWER button to select the item you want to change: D is Day, M is Month, and Y is Year. Use the LEFT and RIGHT buttons to change the selected item.
- Once the date is set, press and hold the POWER button to return to the previous screen.



### Setup the Time

- From the “Sys Setup” screen, press the RIGHT button to move to “Setup Time” (Clock icon).
- Press the POWER button to enter the time setup screen.
- Press the POWER button to select the item you want to change: H is Hour, M is Minute, S is Second.
- Press the LEFT or RIGHT button to change the selected item.
- Once the time is set, press and hold the POWER button to return to the previous screen.



## MEASURE YOUR HEART RHYTHM

Follow these six steps to properly measure and record your heart rhythm.

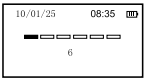
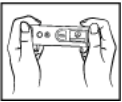
### Step 1 - Preparation

- If your skin is very dry, use a moisturizer.
- After each use, carefully disinfect the contact electrodes only with a disinfectant swab or equivalent.

### Step 2 - Take a Measurement

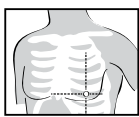
#### Hand Measurement

- Press the POWER button to turn on the device.
- Sit in a comfortable position, your back straight and keep your fingers and arms in a relaxed position for full duration of the measurement.
- Ensure the electrodes are in direct contact with your skin (fingers) as shown with your left and right index fingers on the top electrodes, and your left and right thumbs on the side electrodes.
- Press the START button to begin a measurement.
- The device will display a 6 second countdown, and then it will start the recording.
- During the 30 second recording, a heart will flash on the screen (HCEKGPEN30 Model Only) and a chime will sound for each detected heart beat. A flashing clock icon indicates time remaining in the recording. The screen will display a HR waveform if the device is unlocked (refer to “Enable Heart Rhythm Display” below).
- Remain still, and do not flex or move your fingers or arms until the 30 second recording is complete. If the device senses poor contact or the measurement is interrupted by a hand adjustment, you will need to repeat the recording.



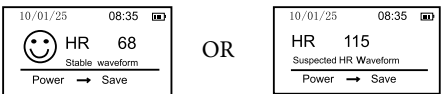
#### Chest Measurement

- If a hand measurement is not ideal, use the device to take a chest measurement. Hold the device with your right hand and place the other electrode against the left side of your chest on bare skin about 5 cm (2 in) below the left nipple.
- CHEST MEASUREMENT FOR WOMEN  
Position the device at the lower end of the breastbone and move horizontally to the middle of the left part of the chest. If necessary, lift the breast and place the left end electrode under the left breast.



When complete, the result is displayed on the screen.

### Step 3 - View the Measurement Analysis



After the measurement is complete, the device will display the heart rate, and a finding of ‘Stable Waveform’ or ‘Unexpected HR’. To save the measurement in the device’s memory, press the POWER button.

If you see Unexpected HR, repeat the preparation and measurement steps above. If you have followed all measurement instructions in this guide, and continue to receive “Unexpected HR” messages, consider consulting a physician or uploading the recording through GEMS™ Home for an on-line medical review. The cause for an Unexpected HR may be a poor quality recording or the presence of a fast or slow heart rate.

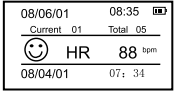
CAUTION! The HeartCheck™ PEN device is not designed for medical diagnosis. Always consult your physician if you notice any change in your health, regardless of the measurement results. If you feel your medical condition has changed, consult a physician even if “Stable Waveform” is displayed as the measurement result, especially if you have been diagnosed with a prior heart condition.

### Step 4 - Save the Measurement

After a measurement is complete, press the POWER button to save the recording. Once saved the display will return to the Main Menu. The device will save up to 20 recordings, and will replace the oldest recordings with the newest if more than 20 records are attempted to be saved.

### Step 5 - Review the Measurement Recordings

- Select “HR Recordings” in the main menu screen, and press the POWER button to enter.
- Scroll through the records using the LEFT or RIGHT Button.
- Press the POWER button to display the selected recording data.



Each recording contains the following information:

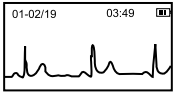
<b>Current 01</b>	The recording number.
<b>Total 05</b>	Number of recordings on the device.
😊	Indicates a stable waveform recording.
<b>88 bpm</b>	Measured heart rate.
<b>08/04/01 07:34</b>	(bottom of display) Date and time of the recording.

### Step 6 - Replay your Measurement Recordings \*Unlocked devices only\*

NOTE: Only unlocked HeartCheck™ PEN devices can replay Heart Rhythm waveforms (ECGs). If your device is locked, refer to “Enable Heart Rhythm Display” below.

If your device is unlocked, follow these steps to replay the Heart Rhythm.

- Select the recording you wish to view, and press the POWER button.
- The animated replay will pause after a moment. Scroll through the remainder of the recording using the RIGHT and LEFT buttons. The measurement contains 19 windows to scroll through, and the top left of the display shows the window in view (eg: 01-02/19 is the first window).
- To exit, press and hold the POWER button.
- To adjust the speed of the replay; refer to “Other Settings”.



## OTHER SETTINGS

Select and enter the “Sys Setup” screen to adjust other device settings. To exit this menu, press the RIGHT button to select the exit icon (a door with arrow), and press POWER. You can also exit any menu at any time by holding the POWER button for two seconds.

### Date and Time Settings

For more information on the date setting, please refer to section “Date and Time Settings” above.

### Sound Settings

	This setting controls the chimes during heartbeat measurements. Use the RIGHT button to highlight the sound icon (a speaker icon), and press the POWER button to turn the heartbeat chime on or off.
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### HR Replay Speed Settings

	Unlocked devices are able to replay heart rhythm recordings. The current replay speed is indicated by the icon (> slow, >> normal, >>> fast). To change the speed, use the RIGHT button to highlight the speed icon, and press the POWER button to change it to the desired speed.
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### Filter Settings

	To change Filter settings, enter the “Sys Setup” menu, and press the RIGHT button to highlight the Filter icon (a wave). Press the POWER button to change the Filter settings to ON or OFF.
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### Power-Off Timer Settings

	The device automatically powers itself off after several seconds. To change this setting, enter the “Sys Setup” screen, and press the RIGHT button to highlight the Power-Off Timer (C* icon). Use the RIGHT button change the value, and the POWER button to save your setting.
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## DELETE RECORDINGS

From the Main Menu, press the RIGHT button to move to the “Delete Data” screen, and then press the POWER button. Use the LEFT or RIGHT button to select the measurement recording to delete. When selected, press the POWER button to delete the recording. Press POWER again to confirm. If the device has no records, the screen displays “Warning! Record is empty”.

## ENABLE HEART RHYTHM DISPLAY (HCEKGPEN30 Model Only)











Regulations require that the Heart Rhythm waveform display is locked for over-the-counter devices. To unlock this display for your device, visit [www.theheartcheck.com](http://www.theheartcheck.com) and download GEMS™ Home software. Follow the instructions with GEMS™ Home to unlock your device, and receive a free ECG Analysis report from a physician. GEMS™ Home is optional software, and is not required for proper operation of the device.

## MAINTANENCE AND STORAGE

- Clean the device electrodes using a medial disinfectant swab only. Do not use water, or substances such as benzene, gasoline, paint thinner, concentrated alcohol, or detergents. Do not clean other parts of the device with any liquid.
- Do not sterilize this device in an autoclave, ultraviolet sterilizer or gas sterilizer (EOG, formaldehyde, high density ozone, etc.).
- This device does not require calibration during the expected life cycle.
- The environment temperature for transport or storage of the packaged device is (-20°C (-4°F)~55°C(131°F)), and the humidity is ≤93%, no condensation.
- Avoid extreme changes in temperature and humidity. Do not use this device in locations subject to high or low temperatures or humidity. Use at a temperature within 5°C (41°F) to 40 °C (104°F) and below 80% RH.
- Do not store the device in ambient conditions: exposed to direct sunlight, with high temperatures and/or high humidity, that are wet or damp or where water may get on the device, that are dusty near fires or open flames or exposed to strong vibration, or strong electromagnetic fields.
- This device is designed to be compliant with the rules and regulations in locations which it is sold and will be labeled as required.
- Any changes or modifications to this device, not expressly approved by the manufacturer, will void the user's authority to operate the equipment.

## TECHNICAL SPECIFICATIONS

### Key Symbols

Symbol	Meaning	Symbol	Meaning
	Type CF applied part		POWER/return button
	Consult ACCOMPANYING DOCUMENTS.		USB interface
	Heart rate: Unit: bpm (beat per minute)		Low battery voltage
<b>SN</b>	Serial Number		European union approval
	Manufacturer's information		Date of Manufacture
	Authorized representative in the European community		

#### Classification

According to the tip-and-run protection, it can be classified into the internal power; its application type is CF and it is the movable common facility with no defibrillator or protection.

#### Heart rate Measurement

**Lead Position:** Lead I Hand Held

**Sampling Rate:** 250Hz

**Heart Rate Measurement Range:** 30bpm~240bpm

**ECG Bandwidth:** 1HZ~40HZ

**Accuracy of Heart Rate Measurement:** 30 bpm~100 bpm; ±2bpm  
101 bpm~240 bpm; ±4bpm

#### Display

**Type:** OLED

**Parameters:** Heart Rate

#### Storage

Data and heart rate strips storage

Heart rate Strips: Can store up to 20 measurements

#### Accessories:

Refer to included Packing Slip.

- One Quick Operation Guide
- One User Guide
- One Service Policy
- One Certificate of Quality
- One USB Cable
- One Packing Slip
- Two AAA Battery
- One Instruction Card (HCEKGPEN30 Model Only)

#### Classification:

**Type of protection:** Internally powered equipment

**Degree of protection:** CF type

**Safety:** IEC 60601-1

- Notes:**
- Specifications may be changed without prior notice.
  - Disposal of this product and used batteries should be carried out in accordance with the local regulations for the disposal of electronic products.

## DECLARATIONS

#### Electrostatic Discharge Precaution

When using USB devices do not touch the USB ports. Contacting the ports may create electrostatic discharge which may cause the system to freeze and prevent the USB peripherals from functioning properly. Before restarting the computer, attempt to restore functionality by unplugging the USB device and re-plugging it back into the port. Wait approximately 10 seconds to determine if functionality has been restored. If not, restart the computer.

#### Precautions

- 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.
- Mobile and portable RF communications equipment may affect the equipment.
- If the system is installed near or on other electronic devices, please observe to verify normal operation.
- 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 quipment complies with its applicable regulations such as CISPR 11.

#### IEC 60601-1-2:2007(Ed 2.1) Table 202 Requirements

Guidance and manufacturer’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 (ESD)  IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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	N/A	Main power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Main 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 % UT (>95% dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles < 5 % UT (>95% dip in UT) for 5 sec	N/A	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 (50/60 Hz) magnetic field  IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U <sub>T</sub> is the a. c. mains voltage prior to application of the test level.			


#### IEC 60601-1-2:2007(Ed 2.1) Table 201 Requirements

1	Guidance and manufacturer’s declaration – electromagnetic emission		
2	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.		
3	Emissions test	Compliance	Electromagnetic environment – guidance
4	RF emissions CISPR 11	Group 1	The equipment 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.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 610000-3-2	N/A	
7	Voltage fluctuation / flicker emissions IEC610000-3-3	N/A	

#### IEC 60601-1-2:2007(Ed 2.1) Table 206 Requirements:

Recommended separation distances between portable and mobile RF communications equipment and the equipment			
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	Separation distance according to frequency of transmitter M		
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	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.			

#### IEC 60601-1-2:2007(Ed 2.1) Table 204 Requirements

Guidance and manufacturer'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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A  3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		where <i>p</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.  <sup>a</sup> 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.  <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

#### TROUBLING SHOOTING

PROBLEM	CAUSE	SOLUTION
The unit can NOT be turned on.	1. The batteries are worn out. 2. The batteries are inserted incorrectly. 3.The unit might be damaged.	1. Replace batteries with new ones. 2. Reinstall batteries with their polarities correct. 3. Please contact the local service center.
The unit is failing to measure a heart rate.	1. The electrodes are not making good contact with your skin. 2. You have not kept still during measurement. 3. Electromagnetic interference. 4. The signal is too weak.	1. Place the electrodes correctly. 2. Keep motionless and avoid moving when measuring. 3. Keep away from electromagnetic interference 4. Attempt to take another measurement.
Others		Please contact the local service centre.

#### APPENDIX

##### General information about the Heart Rate Measurements

The heart is a muscular pump controlled by electrical impulses generated by the body.

The electrical impulse that causes the heart to beat spreads across the atria, causing the left and right atrium to contract and pump blood into the left and right ventricles respectively.

The HeartCheck™ device is able to measure the electrical impulse as it passes across and through the heart, causing the heart to beat. The measurements recorded by the HeartCheck™ device, when combined with a medical examination, can help your doctor monitor your heart condition.

##### About the HR waveform

The HR waveform shows the rhythm of your heartbeat during the 30-second measurement and displays the electrical activity causing the heart to beat.

The first peak indicates the spread of the impulse over the atria and the beginning of their contraction. This is known as the P wave. The second peak indicates the spread of impulse over the ventricles and the beginning of their contraction. This is known as the QRS complex. The third peak indicates the activity as the heart relaxes (re-polarization), and is known as the T wave.

##### What is Arrhythmia?

Arrhythmia is a condition where the heartbeat rhythm is abnormal due to flaws in the bio-electrical system that drives the heartbeat. Typical symptoms are skipped heartbeats, premature contraction, an abnormally rapid (tachycardia) or slow (bradycardia) pulse. This can be caused by heart disease, ageing, physical predisposition, stress, lack of sleep, fatigue etc. Arrhythmia can only be diagnosed by a doctor through a special examination.

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