



Quick Start Guide

for more information visit www.theheartcheck.com/partner

Getting Started

Step 1 Install the AAA batteries

Slide open the battery compartment on the back of the PEN device and install the two AAA batteries contained in the package.

Step 2 Turn the device on and set the date and time

Press the POWER button to turn the device on and use the black UP and DOWN arrow to scroll through the DAY, MONTH, and YEAR. Select the correct number by pressing the OK button.

Step 3 Capture and store ECG readings

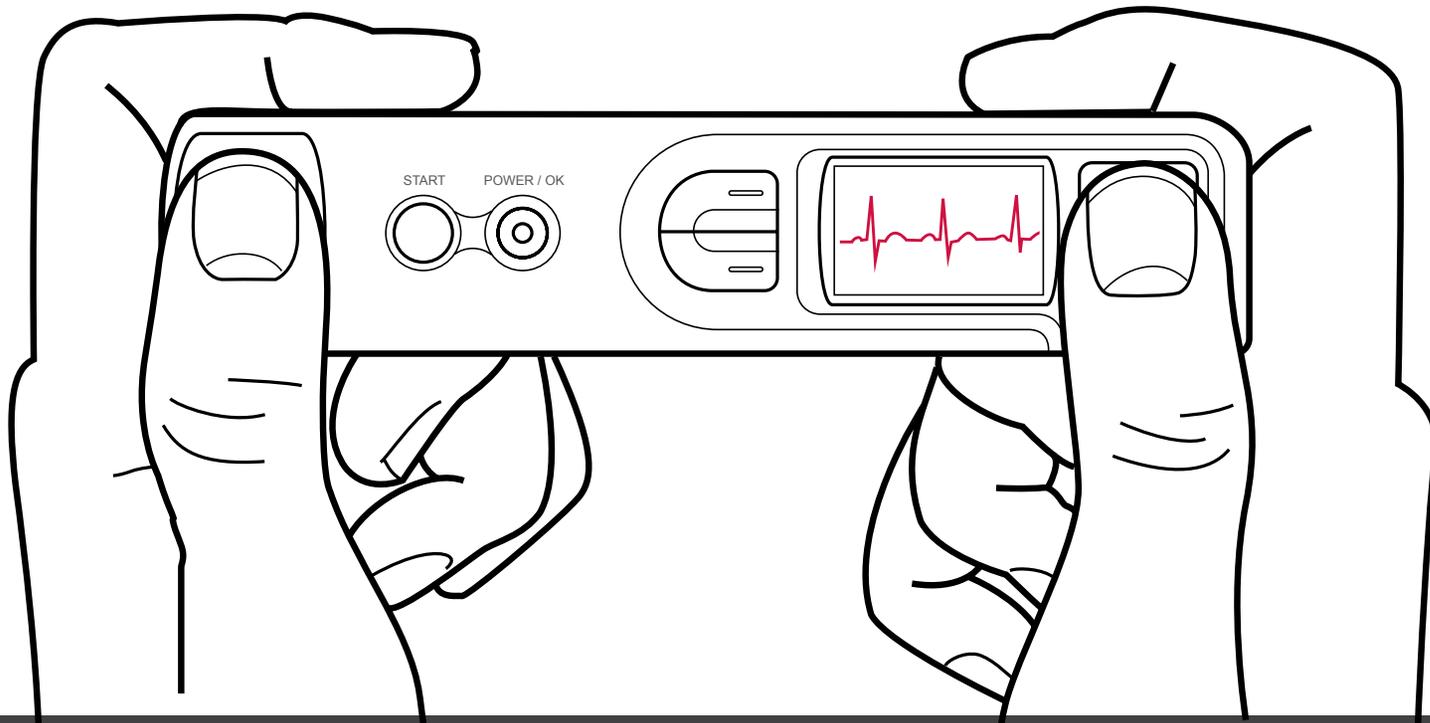
Visit page 2 or www.theheartcheck.com/how to learn how to take hand and chest measurements

Take hand measurements by holding the device ensuring the metal electrodes are in direct contact with your skin. (See image below)

Press the START button when ready.



When the 30 second reading is complete, select the OK (POWER) button to save the reading.

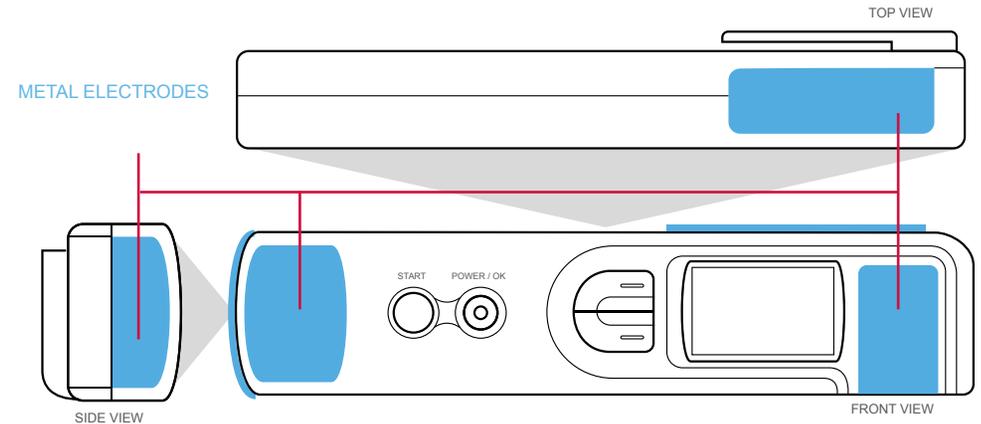


Taking Hand Readings

Step 1 Hold the PEN device with both hands

To take a hand reading turn the device on by pressing the POWER button and hold the device ensuring the metal electrodes are in direct contact with your skin.

Your right and left index fingers should make full contact with the **metal electrodes** located on the top and side of the device, and your left and right thumbs should make full contact with the 2 metal electrodes located on the front of the device.



Step 2 Press the Start button

When ready, press the START button to enter the preparation stage and begin the 30 second reading.

While the device is on, you can take a measurement at any time by pressing the START button located on the front of the device.



To better ensure you're getting a high quality ECG reading, be seated while resting your elbows on a sturdy surface (such as a table) while taking the reading.

This helps keep your arms steady during the reading period, which will more likely produce a cleaner reading.

Step 3 Remain still for 30 seconds

After the 6 second preparation stage is complete, the device will begin the ECG reading.

During this period, try to remain still, and do not flex or move your fingers or arms until the reading is complete.

Step 4 Save the reading

Once the measurement is complete, the device will provide the heart rate and a basic analysis of the ECG reading.

Select the OK button to save the results within the device.

Tips and Hints

Some readings may produce an ECG waveform that is not clear enough for a health care professional or physician to make an accurate diagnosis.

A common indicator that the ECG reading may be unclear is that after the reading is complete, the monitor displays an Unexpected Heart Rate message.



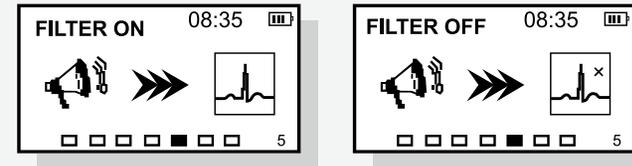
CLEAR ECG READING



UNCLEAR ECG READING

Using the PENs Filter

Activating the PENs Filter (ON) will filter out unwanted electric noise making the waveform more clear. You would use this when you notice the signal is being affected by electronic interference and is not clear; such as in an environment containing a substantial amount of florescent lighting or other devices that may cause electromagnetic interference, such as computers or televisions.



In the SYS SETUP screen, press the LEFT or RIGHT button to move the selection box to the Filter ON(OFF) item and press the POWER button to select Filter ON or OFF

- ✓ Keep still and DO NOT move or speak until the reading is complete
- ✓ Make sure the electrodes are directly touching your skin
- ✓ If your hands are dry, wipe them with a damp cloth so that they are slightly moist
- ✓ Ensure your fingers, hands, and arms are in a relaxed position
- ✓ Sit comfortably with with your back straight
- ✓ Rest your elbows on a sturdy surface (such as a table)
- ✓ If this is the first time using the device or if you haven't used the device in a while, try repeating the reading process up to 3 times to allow the device to adjust to your body type
- ✓ If after repeating the reading process with your hands, the device continues to display the Unexpected Heart Rate message, try taking a chest measurement.
- ✓ If the monitor continues to display the Unexpected Heart Rate message after taking the chest measurement, consider consulting a physician or using the SMART Monitoring Service to upload your ECGs through GEMS Home for analysis.

Registering a User

Step 1 Download GEMS Home onto your computer

visit www.theheartcheck.com/GEMS and select the DOWNLOAD GEMS HOME button to begin the installation process.

Step 2 Connect the PEN to your computer

Launch the GEMS Home application and, using the USB cable provided, connect the PEN to your computer.

GEMS Home will take a moment to authenticate your PEN device.

Step 3 Register yourself in GEMS Home

Select the MANAGE USERS section and enter your contact information into the fields. Select the VERIFY button at the bottom of the form when completed.



A verification email will be sent you within a few moments completing the form. Click the link in the email to complete the verification process.

Return to the MANAGE USERS section in GEMS Home and select the CHECK FOR VERIFIED EMAIL button at the bottom of the form.



You will need to verify a user within GEMS Home in order to send ECGs for analysis

First Name:	<input type="text" value="Paul"/> *	Birth Date:	<input type="text" value="13/05/2013"/>
Last Name:	<input type="text" value="Mastroianni"/> *	Gender:	<input type="text" value="Male"/>
		Ethnicity:	<input type="text" value="Caucasian"/>

Email Address:	<input type="text" value="pmastroianni@cardiocommsolutions.com"/>	* A verified email is required in order to request a SMART Monitoring Review.
	<input checked="" type="checkbox"/> <input type="button" value="Verify"/> <input type="button" value="Check for Verified Email"/>	
Verify Status:	Verified on 10/04/2013 12:09:29 PM	
	<input checked="" type="checkbox"/> Receive Email Notification	
	<input checked="" type="checkbox"/> Attach Report To Email Notification	

Sending ECG Readings for Analysis

Step 1 Launch GEMS Home

Launch GEMS Home by double-clicking the GEMS Home icon located on your desktop or find and click the GEMS Home link within your program files.

Step 2 Connect the PEN to your computer

Using the USB cable provided, connect the PEN to your computer. GEMS Home will take a moment to detect your PEN device.

Step 3 Upload ECG readings

Select the MANAGE YOUR DATA section of GEMS Home and select the UPLOAD HRS button on the left.

The import process may take a few moments depending on how many heart rhythm files are stored on your device.

Step 4 Select and send ECG readings for analysis

In the SMART Monitoring Review section of GEMS Home, select the REQUEST SMART MONITORING REVIEW button.



Check the heart rhythm file or files you would like to have reviewed and select the UPLOAD SELECTED HRs button to begin uploading the selected heart rhythm files.

It will take 30 min to receive your ECG Analysis Report from the time you upload your ECG files.

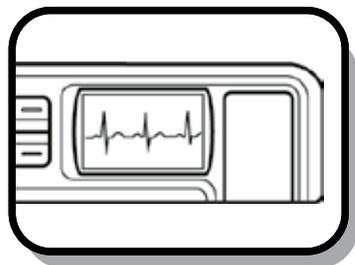


A notification email will be sent to you when a report is ready. Alternatively, you can also check for reports though GEMS Home in the SMART MONITORING REVIEW section. Simply click the CHECK FOR REPORTS button, or the NOTIFICATIONS button to have GEMS Home search for any available reports.

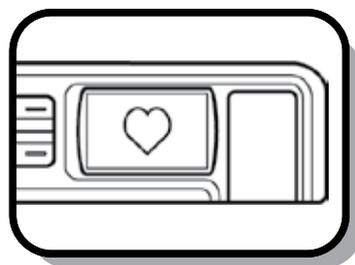
Your first SMART Monitoring review is free of charge.

Selected	User Name	Recording Date	Import Date	Heart Rate	Last Uploaded Date
<input type="checkbox"/>	Paul Mastroianni	03/03/2013 10:23:45 PM	14/05/2013 4:36:21 PM	63	14/05/2013 4:41:53 PM

Unlocking your HeartCheck PEN



UNLOCKED PEN DISPLAY



LOCKED PEN DISPLAY

When you first receive your HeartCheck™ PEN device, it will be in locked mode. While in this mode, you will not be able to view or print ECG waveforms.

While the PEN is locked, the device's monitor will display a heart icon during the reading period. It is only when the PEN has been unlocked through GEMS Home, will you be able to view and print your ECG waveforms within the GEMS Home software. Once unlocked the device's monitor will also display your actual ECG waveform during recording.

Step 1 Connect the device

Turn the PEN device on and connect it to your computer using the USB cable provided.

Your HeartCheck PEN can only be unlocked after you have submitted and received your first ECG analysis report. If you have NOT done so already, submit an ECG for analysis

Visit page 3 for details on how to send ECGs for analysis

Step 2 Select the Unlock PEN Display button

From the MANAGE DATA section of GEMS Home, select the UNLOCK PEN DISPLAY button.



Once the unlocking process is complete, you can view your ECG waveforms both while taking a recording and within GEMS Home.

In the MANAGE DATA section, check the heart rhythm file of your choice and select VIEW HR REPORT to view the corresponding analysis report for that ECG waveform.

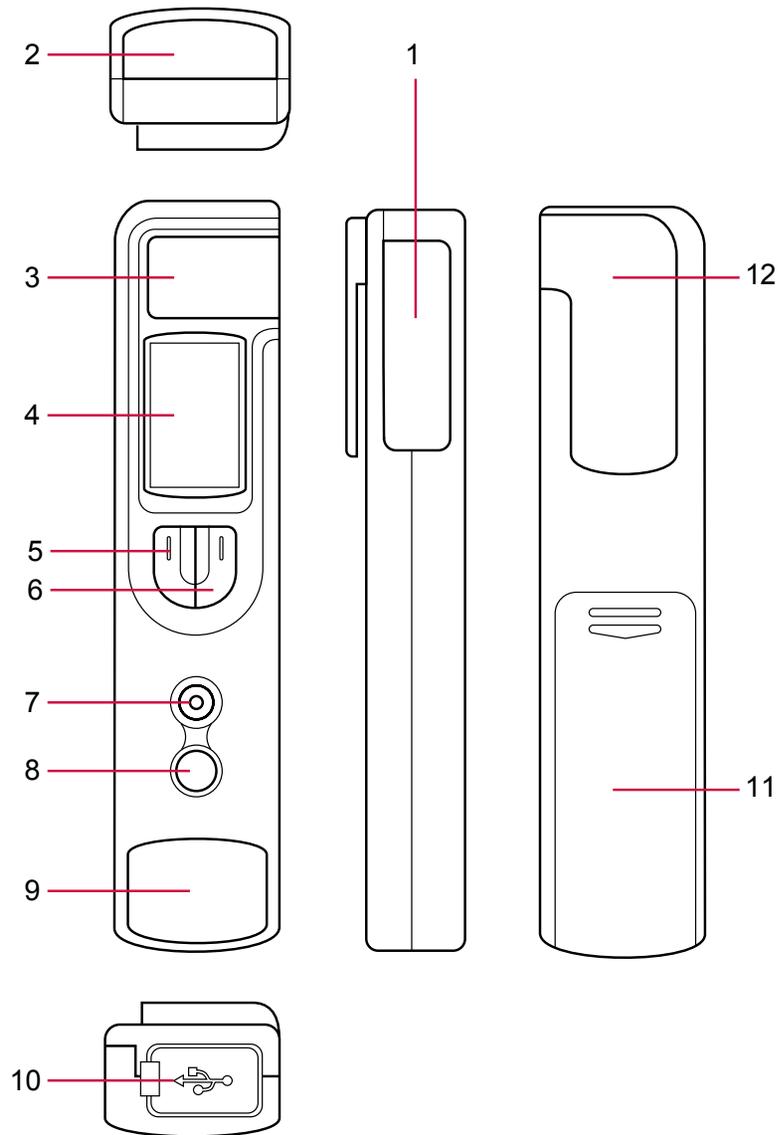
Selected	Recording Date	Import Date
<input type="checkbox"/>	27-Sep-2012 11:52:02 AM	27-Sep-2012 4:...
<input type="checkbox"/>	27-Sep-2012 11:50:04 AM	27-Sep-2012 4:...
<input type="checkbox"/>	27-Sep-2012 11:48:21 AM	27-Sep-2012 4:...
<input type="checkbox"/>	27-Sep-2012 11:47:30 AM	27-Sep-2012 4:...
<input type="checkbox"/>	27-Sep-2012 11:46:45 AM	27-Sep-2012 4:...

why

The HeartCheck PEN is the only device of its kind cleared by the FDA for consumer use. One of the conditions of the FDA clearance is that the device itself prevents people from seeing their ECG waveform until they have interacted with a physician.

Self Diagnosis can be dangerous. Its important that the user excercise caution when viewing ECG waveforms.

HeartCheck PEN Specifications



1. Right index finger electrode
2. Left index finger electrode
3. Right thumb electrode
4. Display screen
5. Scroll right button
6. Scroll left button
7. Power / Select button: Use this button to power on the device and/or select a menu item from the display screen
8. Start button: Use this button to start taking a heart measurement
9. Left thumb electrode
10. USB Port: Plug USB cable into this port to connect device to PC
11. Battery cover
12. Clip