

# ECGmd Frequently Asked Questions

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## 1. What is ECGmd?

ECGmd is a very small form factor, 5-wire, four-lead holter monitor electrocardiograph. ECGmd is different from our standard ECG sensor because it contains further circuitry for defibrillation protection. This leads to increased dimensions on the sensor and the ability to use it for medical applications.

## 2. What is ECG?

ECG (electrocardiogram) is the measure of a subject's heart rate. This is measured by recording the pathway of electrical impulses through the heart muscle; ECG can be recorded on resting and ambulatory subjects, or during exercise to provide information on the heart's response to physical exertion.

## 3. Where is ECGmd data stored?

Unlike our standard ECG sensor, the data collected by our ECGmd sensor is not stored on the unit via an SD card. Instead, all data is passed via a Bluetooth link to a host storage and display device.

## 4. Is ECGmd sterile?

This sensor is not sterile. However, this sensor can be reused for many subjects. The electrodes used with ECGmd are disposable and intended for single-use only.

## 5. What is the battery life for the ECGmd sensor?

When fully charged, you can expect up to 10 hours of battery life. Recharging ECGmd from 0% to 100% typically takes about 4.5 hours.

## 6. Can I clean the ECGmd sensor?

The ECGmd Unit should only be cleaned by wiping it with a damp cloth, or an alcohol wipe. Do not immerse or autoclave the ECGmd Unit, or the USB Charging Cable within the safety harness.

## 7. Is ECGmd compliant with medical devices standards?

Yes, ECGmd meets the requirements for Electromagnetic Compatibility for Medical Devices as stated in IEC60601-1-2 4th Edition.

8. Can ECGmd be used in conjunction with a cardiac pacemaker?

Yes, the Bluetooth communications link is very low power, so it is unlikely to interfere with cardiac pacemakers. To remove any possibility, it is recommended that the ECGmd Unit is located away from the immediate vicinity of the heart (like a breast pocket) and instead in a side pocket or a belt clip.

9. What should I do if my ECGmd sensor stops working after a few hours?

The maximum recording duration is 10 hours. If the device repeatedly shuts down after a few hours (less than the max duration), even when fully charged between uses, then the battery should be replaced – contact Shimmer.

10. Are there any cardiac precautions associated with the ECGmd sensor?

One precaution that should be taken is with direct cardiac application. The ECGmd Unit is not suitable for direct cardiac application, as it is a Class BF applied part.

Additionally, in the event of the user requiring defibrillation, it is advisable to remove the ECGmd Unit electrodes/wires from the patient. If, however, the ECGmd Unit remains connected to the user during defibrillation, the ECGmd Unit has defibrillation protection. The ECGmd Unit is designed to continue to operate after defibrillation. There may be an offset to the ECG trace for a few seconds after the defibrillation pulse(s) have been applied. In the unlikely event the ECGmd Unit stops streaming data and/or disconnects for the host device, it will be undamaged and automatically restart itself, but reconnection of the data link might need to be forced. Please refer to the software user manual to check how to reestablish the data link connection.

11. Who is ECGmd intended for?

ECGmd is intended for system integrators, medical researchers, or qualified medical professionals. If you think you have a potential application for ECGmd, we would be happy to discuss further with you.

12. Is ECGmd FDA approved?

ECGmd is not FDA approved. However, ECGmd is designed and manufactured in conformity with the essential requirements and provisions of the European Medical Device Directive (MDD) and European Council Directive 93/42/EEC.

13. Is supporting software sold with ECGmd?

Because all data collected with ECGmd is sent directly to host storage, no supporting software is needed. We do provide display software that essentially just shows you the output of the signals being collected; however, you can't do anything with the output being shown.

14. Is ECGmd compatible with Consensys?

No, ECGmd is not compatible with Consensys. The only software Shimmer provides in conjunction with ECGmd is the display software that shows the output of the signals being collected.