

Shimmer Receives CE Certification for ECGmd Holter Monitor Electrocardiograph

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ECGmd is now recognized as a medical device in Europe, capable of providing medical-grade ECG output from Shimmer's wearable sensor



Shimmer Research, a global leader in wearable technology for research applications, on 4 Nov 2019, announced that ECGmd – its five-wire, four-lead holter monitor electrocardiograph (ECG) – is now a CE certified, Class IIa medical device under the Medical Device Directive (93/42/EEC).

“We are delighted to report that we can now deliver robust ECG data wirelessly from a CE-certified wearable medical device,” said Geoffrey Gill, president of Shimmer Americas.

“Shimmer has more than a decade of experience developing ECG sensors and it’s evident in this device. We developed a five-wire, four-lead ECG system to ensure that it would produce the very detailed, low noise signal required by healthcare professionals and medical researchers. Patients will also benefit from its lighter, low-profile form,” Mr Gill added.

Shimmer’s ECGmd weighs only about 40 percent as much as an average Holter monitor (39.32 grams versus 99 grams) and it presents a slimmer format, measuring just 100 mm x 33 mm x 8 mm.

The ECGmd was developed for Shimmer’s original equipment manufacturer (OEM) business as a small, high-quality ECG for system integrators to incorporate into their products. As a result, it is supplied in kit form with only the hardware and firmware included so that clients can develop their own display software. The shimmer is also prepared to submit a 510(k) application to the FDA for the ECGmd if needed by OEM customers.

Shimmer’s ECGmd is not intended for use as an unattended critical care monitor.