



Advanced Monitors Now in the Palm of Your Hand (Part 2): Portable EKG Sensors

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Editor's Note: This article is the second in a series on medical wearable devices. Opinions stated here are solely those of the authors. ASA does not endorse these or any other products. While this is not a scientific product review with objective testing standards, and other studies of product efficacy may be available in addition to the ones mentioned here, we hope you'll enjoy the discussion on this emerging technology.

Electrocardiography (ECG/EKG) allows the visualization of electrical activity of the heart by measuring changes in voltage across two or more contact points on the body. Understanding a patient's heart rhythm preoperatively can be important for anticipating intraoperative cardiac and hemodynamic support requirements during the stress of surgery. Patients traditionally only got EKGs during hospital appointments or admissions, but they can now capture EKG information from portable devices at home or whenever they have symptoms.

While standard medical EKGs use either three, five, or many more electrodes to get a comprehensive perspective of a patient's electrophysiology, even just two electrodes touching different sides of the body are sufficient to capture a 1-lead EKG waveform. FDA-approved devices now available for consumers incorporate 1-lead EKGs in smart watches (requiring the other hand to touch part of the watch) or separate devices the size of credit cards or built into phone cases to allow for easy portability and use at the onset of potential cardiac-related symptoms. There are even versions designed to be held by both hands against a leg to gather a 6-lead EKG. Here are some of these device types and the current evidence regarding their capabilities.

Smart watches (Apple Watch, Withings ScanWatch)

One increasingly popular type of portable EKG device are smartwatches with the capacity to capture 1-lead EKGs, such as the Apple Watch or the Withings ScanWatch. This requires the user to wear the watch on one hand while touching the rim of the watch with the other, thus capturing the electrical potential across the body with two electrodes (standard lead



I). Both devices claim to be able to detect atrial fibrillation. One of the largest studies of smart watch-based arrhythmia detection devices is the Apple Heart Study, funded by Apple, which recruited 419,297 participants over eight months and specifically alerted users if they had an "irregular pulse" concerning for atrial fibrillation. The Apple Watch at the time did not have the ability to capture EKGs and could only use pulse oximetry to detect pulse irregularity. People who received the "irregular pulse" notification were then sent an ECG patch to wear for up to seven days. Study results showed 0.5% of the 400,000-plus participants received an irregular heart rhythm notification. Among participants who received notification of an irregular pulse, 34% had atrial fibrillation on subsequent ECG patch readings, and 84% of notifications were concordant with atrial fibrillation (*NEJM* November 2019).

EKG stethoscopes (Eko DUO)

The Eko DUO is a new type of digital stethoscope that captures both audio and electrical information. This device measures one precordial lead. Eko devices can connect wirelessly to a mobile app to help with identification of murmurs and atrial fibrillation using their built-in algorithm. There have also been studies using this device to see if AI algorithms can be trained to use one precordial lead alone to predict if a patient has an ejection fraction (EF) under 40%. Using data from 1,050 patients undergoing transthoracic echocardiography, this device was used to measure EKG data at multiple different positions on the chest. They found that the pulmonary valve landmark position was optimal for precordial lead EF prediction, and their model was able to predict reduced EF with



a sensitivity of 91.9% and specificity of 80.2% (*The Lancet Digital Health* 2022;4:e117-e125). The downsides of this device are that positioning on the chest requires training and can be done incorrectly. For patients using this on themselves outside of the hospital, it can also be hard to capture information quickly when symptoms are occurring since contact with the chest skin is required. The unique benefit of this system is that it is the only one that allows for comparison of murmurs and EKG data with time synchronization simultaneously.

Wearable EKG patch (Zio Patch)

Another device that measures a single precordial lead is the wearable Zio Patch. This device is designed to be sent to a user to wear for up to 14 days. The data from this device is kept either on the device itself to be sent back to a doctor for review or sent to a gateway device to be transmitted directly. A systematic literature review of the Zio Patch system found mean detection rates for atrial fibrillation overall were 12.2% (chronic/sustained atrial fibrillation was 5.6% and paroxysmal atrial fibrillation was 23.3%), supraventricular tachycardia or supraventricular ectopy was 45.5%, and ventricular tachycardia was 17.3% (*Curr Med Res Opin* 2019;35:1659-70). However, the rate of arrhythmia detection increased with monitoring durations >48 hours and continued to increase beyond seven days of monitoring. In a study of 146 patients, Barrett et al. found that the Zio Patch detected more



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arrhythmia events than the Holter monitor (96 vs. 61) (*Am J Med* 2014;127:95.e11-7).

Wellue wearable heart rate monitors consist of a chest strap or a tape-like strapless device that measures either Lead I or II or a chest lead. It is of greater use in athletes for measuring heart rate changes with exercise and valuable in prolonged monitoring due to comfort. It uses free AI technology to diagnose the rhythms as well. The company claims it can continuously monitor ECG for 24 hours, recording up to 360,000 ECG/EKG signals. However, comparisons and utility analyses are awaited. (asamonitor.pub/31BfqYz).

Wallet-sized EKG devices (KardiaMobile 6L)

The KardiaMobile 6L is a unique EKG device designed to be compact and easily carried in one's pocket. Kardia makes multiple different types of devices, some of which have been built into phone cases or are thin enough to fit in a wallet. Many of these only capture single-lead EKGs



Continued on next page

Dr. Gearhead: Portable EKGs

Continued from previous page

with contact from both hands, but some capture more. The KardiaMobile 6L is designed with three electrodes to contact both hands and a leg at the same time to capture a full 6-lead EKG.

Even single-lead versions of this device have been shown to have value. In a study of 100 patients scheduled for cardioversion, patients were assessed for the presence of atrial fibrillation with a 1-lead Kardia device and a simultaneous standard EKG beforehand. Blinded physician interpretation demonstrated 99% sensitivity and 83% specificity in comparison to ECG interpretations (*J Am Coll Cardiol* 2018;71:2381-88). The study found that eight out of 100 patients ultimately did not undergo cardioversion as they were found to be in sinus rhythm.

Another study of the KardiaMobile single-lead device found that, while it was noninferior compared to standard 12-lead ECG for detection of atrial fibrillation and atrial flutter, “the sensitivity of KM to detect pathological Q-wave was low compared to specificity (20.6% vs. 93.7%, respectively, $p < 0.001$). Basic intervals measured by the KM device, namely PQ, RR, and QT were significantly different (shorter) than those observed in the standard ECG method” (*Cardiol J* 2021;28:543-48).

Kardia advertises that their devices can automatically detect atrial fibrillation, bradycardia, tachycardia, PVCs,

	Withings Scanwatch	Eko DUO	Kardia 6L
AF algorithm	5% uninterpretable ✓ Sensitivity: 100% Specificity: 100%	N/A	31% uninterpretable ✗ Sensitivity: 100% Specificity: 97%
P-wave detection	70%	68%	89% ✓
QTc difference >40 msec	49% ✗	30%	26%
QRS morphology correct	89%	84% ✗	90% ✓
Patience preference	54% ✓	11%	23%
ECG quality (good or excellent)	51% ✗	70%	74%

✓ Significantly better ✗ Significantly worse

Figure: Side-by-side comparison of portable heart monitors.

supraventricular ectopy, and wide QRS for users who sign up for their KardiaCare membership, which also includes limited remote EKG reviews by their own cardiologists. With the KardiaMobile 6L, their AI automatically detects six rhythms, and their AliveCor technology has 24/7 readings by certified technicians when the KardiCare membership is purchased. However, there are only limited reviews by cardiologists per year.

Heart-to-heart comparison

How do these devices stack up when tested rigorously? One study of 176 adults with congenital heart disease compared the diagnostic accuracy of the Withings ScanWatch, Eko DUO, KardiaMobile 6L, and a standard 12-lead ECG on several tasks, including:

- 1) Atrial fibrillation classification (percentage correct)
- 2) QRS-morphology classification (percentage correct)

- 3) ECG intervals calculation (QTc time ≤ 40 ms difference) as well as patient preference (asamonitor.pub/3ipAFC4).

The following table from the study summarizes their findings.

Between the two devices with built-in atrial fibrillation detection, the Withings ScanWatch and the KardiaMobile 6L were both found to have high accuracy (Withings: 100%, KardiaMobile 6L: 97%), but the Withings algorithm classified fewer ECGs as inconclusive (5%) compared to 31% of Kardia ($P < 0.001$). The Eko DUO atrial fibrillation algorithm was not available at the time of the study. Physician evaluation of Kardia correctly classified QRS morphology more frequently (90% accuracy) compared to Eko DUO (84% accuracy) ($p = 0.03$). QTc was underestimated on all ECG-based devices ($P < 0.01$). They also found that QTc accuracy was acceptable in only 51% of Withings versus 70% Eko and 74% Kardia ($P < 0.001$ for both comparisons). Even with

the KardiaMobile 6L, measurement of QTc-interval was over- or underestimated by more than 40 ms in 26% of patients.

The participants were also asked two survey questions on device preference and willingness to use devices in daily life using a five-point Likert scale. The majority of participants (54%) reported a preference for the Withings ScanWatch ($p < 0.001$, compared to Eko DUO and KardiaMobile 6L). Fewer patients preferred Eko DUO (11%), KardiaMobile 6L (23%), or had no preference (10%).

Overall, the study's authors found that the KardiaMobile 6L had the closest correlation with the 12-lead intervals and was most accurate in overall evaluation such as QRS morphology and QTc duration, the Withings ScanWatch had an automatic atrial fibrillation algorithm with the fewest uninterpretable results and was most preferred by patients, and the Eko DUO scored poorly across the board but did have the unique ability to detect heart murmurs.

While greater access to advanced cardiac monitoring devices may enable improved detection of undiagnosed arrhythmias such as atrial fibrillation in the general population, it may also lead to a high physician burden of questions from patients who attempt to interpret their own ECGs without formal training. Ultimately, a full 12-lead ECG remains the standard of care, but these wearable devices still have a value in early detection and enabling patients to better monitor their own health. ■

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