

## Telecardiology - 2018 short review

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From new smart stethoscopes to digital health investments and studies looking at the use of new technologies, 2018 was a remarkable year for innovation in telecardiology. The biggest news, however, came from Apple receiving FDA clearance for an algorithm detecting atrial fibrillation and an ECG to be built into its latest Apple Watch series. Here is a summary of some of the key developments in the area from the past year, presented in a timely manner.

### January: New products

#### **M3DICINE launches AI-enabled, wireless stethoscope called Stethee**

At the beginning of the year, Australian company M3DICINE launched a wireless stethoscope called Stethee that works with an accompanying app, available for both iOS and Android. M3DICINE says Stethee captures, filters and amplifies the sounds of a patient's heart or lungs, and the audio is then sent to users' Bluetooth-enabled devices or wired headphones. The platform's AI engine, called Aida, analyzes heart and lung sounds to build personal biometric signals, according to a statement from the company. Aida also tags geolocation and environmental data, which, encrypted and anonymized, can be reported back in the form of quantitative reports (data that is clinically actionable), and clinicians can view them through an online portal. The company said it worked in the development of Stethee with designers and engineers from the Massachusetts Institute of Technology and clinical experts from Mayo Clinic, among others. M3DICINE received FDA clearance for the product in 2017.

*Source: Company announcement*

### February: Investment

#### **Eko Devices raises \$5m after receiving FDA clearance for its Duo smart heart monitor**

Californian company Eko Devices announced in February that it raised \$5m in a Series A funding round, after securing 510 (k) FDA clearance in 2017 for its smart heart monitor Duo, a combined digital stethoscope and ECG. Clinicians can use the portable cardiac device as a screening tool or prescribe it to outpatients - Duo pairs with an app to enable remote monitoring and diagnosis by a specialist. In 2015, the company received FDA clearance for the Core smart stethoscope.

*Source: Company announcement*

### March: Research

#### **AliveCor announces results from two studies**

In March, AliveCor unveiled the findings of two studies at the American College of Cardiology's 2018 Annual Scientific Session, looking at the use of its portable ECG devices.

A Cleveland Clinic study set out to identify whether the company's medical device accessory KardiaBand, which is FDA-cleared, for Apple Watch could differentiate between atrial fibrillation and normal heart rhythm. Findings indicated that KardiaBand detected atrial fibrillation and normal sinus rhythm with an accuracy (interpreted with 93 percent sensitivity and 84 percent specificity) that they said was "comparable to clinicians interpreting the same ECGs".

A second study indicated that the device paired with AI technology could detect hyperkalemia (commonly associated with congestive heart failure and chronic kidney disease). More than two million ECGs linked to four million serum potassium values reportedly collected between 1994 and 2017 and prospective data from an AliveCor smartphone ECG device were used in the development of the AI algorithm. AliveCor said this could be commercialised through the KardiaBand for Apple Watch at the time. In September, it announced that its KardiaK Software Platform had achieved FDA Breakthrough Device Status, which means that the FDA will consider it on a track for accelerated clearance that is specific for devices “demonstrating the potential to address unmet medical needs for life-threatening or irreversibly debilitating diseases or conditions”. AliveCor planned at the time to use the solution for home-based hyperkalemia detection to help support patients with kidney disease.

*Source: Company announcements*

### **March: Research**

#### **App from University of Turku, Finland detecting atrial fibrillation**

A mobile app developed at the University of Turku’s Department of Future Technologies in Finland detected atrial fibrillation with a 96 percent accuracy in a study of three hundred patients with heart problems - half with atrial fibrillation - carried out by the university and the Heart Centre of the Turku University Hospital. The project was carried out as a blind study, with the hospital sending the University measurement data for analysis. In a press announcement issued in March, it was explained that the app could be commercialised through the University spin-off company Precordior.

*Source: University announcement*

### **April: New products**

#### **Steth IO unveils digital stethoscope integrated into a smartphone’s case**

Steth IO launched in April a digital stethoscope integrated into a smartphone’s case that works with an accompanying app, allowing clinicians to listen and measure heart rates or lung sounds by holding the mobile up to a patient’s chest. The device received FDA clearance in 2016.

*Source: Company announcement*

### **June: Research**

#### **Leveraging behavioral economics to support patients with cardiovascular disease**

A study published in the *Journal of the American Heart Association* in June found that combining wearable devices with “personalized goal-setting” and a financial incentive led to an increase in levels of physical activity among ischemic heart disease patients involved in the trial. However, researchers found that wearables alone were not effective in generating improvements in physical activity levels.

The study included 105 patients with ischemic heart disease, taking place over a period of 24 weeks, but researchers noted that limitations of the study included the fact that the only levels of physical activity evaluated were based on steps. However, they argued that the findings indicated that “digital health interventions that leverage insights from behavioral economics offer a promising approach to change health behaviors among patients with cardiovascular disease”.

*Source: Journal of the American Heart Association study*

### **August: Device integration**

#### **Cardiogram heart health app and Garmin wearables integration**

In August, Garmin International announced that its wearable devices featuring optical heart rate would become compatible with the Cardiogram heart health app. Using data from wearables, the

Cardiogram app provides insights to help users understand the effects of activity and sleep on their overall health. Working with the Department of Cardiology of the University of California, San Francisco, Cardiogram has combined data from optical heart rate sensors and an AI-based algorithm called DeepHeart developed by them for the detection of major conditions. Clinical studies indicated that DeepHeart had demonstrated that it could detect the following: atrial fibrillation, sleep apnea, hypertension, and diabetes.

Cardiogram co-founder Johnson Hsieh explained in a statement that there had been high demand for the app to support Garmin wearables, integrated through an application programming interface (API) to enable access to insights generated.

*Source: Company announcement*

### **September: Regulatory news, new products**

#### **Apple delving further into healthcare with first FDA clearance**

In September, Apple made waves in the digital health world after announcing that it had received FDA De Novo clearance for an algorithm to detect atrial fibrillation from heart rate data and an ECG to be built into its Series 4 Apple Watch by adding electrodes to the digital crown and the back of the device. Users can take an ECG in around half a minute. The ECG waveform and its classifications, along with any other symptoms recorded, are saved in the Apple Health app, and a PDF can be shared with doctors.

*Source: Company announcement*

### **September: JAMA Network Open study**

Findings from a [study released by JAMA Network Open](#) in September last year showed that, in a cluster randomized trial of 326 patients with uncontrolled hypertension, home blood pressure telemonitoring combined with pharmacist management lowered blood pressure more than usual care in the first 18 months. However, results indicated significantly lower blood pressure in the group that received the intervention for up to 24 months and not through the entire 54 months. Researchers argued in the study that “long-term maintenance strategies may be needed” in order for the effects to be sustained over the course of multiple years.

*Source: JAMA Network Open study*

### **November: Research**

AliveCor announced in November that a research version of its mobile technology could identify STEMI (ST-elevation myocardial infarction), after a study found that it was able to detect the condition with “good correlation and high sensitivity”, according to a press announcement, compared to a standard 12-lead ECG or traditional ECG technology. Two months before that, AliveCor announced that it was working on a six-lead smartphone ECG, labelled Project Triangle.

*Source: Company presentation and interview with US outlet CNBC*

### **December: Investment**

#### **AI-focused Myia Labs start-up raises \$6.75m in seed funding**

Myia Labs announced towards the end of 2018 that it secured \$6.75m in seed funding, and the interesting part was that the round saw participation from the American College of Cardiology. The start-up uses data from wearables to monitor patients with chronic illnesses, examining metrics such as heart rate, blood pressure and others, and applies machine learning to issue alerts to those caring for them in case major changes are identified.

*Source: Company announcement*

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