



NEWS RELEASE

Fitbit Receives Regulatory Clearance in Both the United States and Europe for ECG App to Identify Atrial Fibrillation (AFib)

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With FDA 510(k) clearance and CE mark, the Fitbit ECG App may help prevent serious complications like stroke by allowing users to spot check for signs of AFib from their wrist

SAN FRANCISCO--(BUSINESS WIRE)-- **Fitbit** (NYSE:FIT) has received 510(k) clearance from the U.S. Food and Drug Administration (FDA), as well as Conformité Européenne (CE) marking in the European Union, for its electrocardiogram (ECG) app to assess heart rhythm for atrial fibrillation (AFib), a condition that affects more than 33.5 million people globally.¹ The Fitbit ECG App, unveiled in Fitbit's recent **fall product launch**, will be available in October 2020 to users on **Fitbit Sense™** in the following countries: the United States, United Kingdom, Germany, Austria, Luxembourg, the Netherlands, Sweden, Switzerland, Czech Republic, Poland, Belgium, Portugal, Romania, Ireland, Italy, Spain, France, Hong Kong and India.^{2,3}

This press release features multimedia. View the full release here:
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Fitbit Sense is the company's first device compatible with an ECG app that enables users to take a spot check reading of their heart that can be analyzed for the heart rhythm irregularity atrial fibrillation. (Photo: Business Wire)

Heart disease continues to be the leading cause of death worldwide, despite being one of the most preventable

conditions. AFib, an irregular heart rhythm that increases the risk of serious complications like stroke, can be particularly difficult to detect, as episodes can sometimes show no symptoms. Some studies suggest that as many



as 25 percent of people who have an AFib-related stroke find out they have AFib only after a stroke has occurred.⁴

“Helping people understand and manage their heart health has always been a priority for Fitbit, and our new ECG app is designed for those users who want to assess themselves in the moment and review the reading later with their doctor,” said Eric Friedman, Fitbit co-founder and CTO. “Early detection of AFib is critical, and I’m incredibly excited that we are making these innovations accessible to people around the world to help them improve their heart health, prevent more serious conditions and potentially save lives.”

As part of the submission process to regulatory agencies, Fitbit conducted a multi-site clinical trial in regions across the U.S. The study evaluated our algorithm’s ability to accurately detect AFib from normal sinus rhythm and to generate an ECG trace, or recording of a heart’s electrical rhythm, that is qualitatively similar to a Lead I ECG. The study showed that the algorithm exceeded target performance, demonstrating the ability to detect 98.7% of AFib cases (sensitivity) and was 100% accurate in identifying study participants with normal sinus rhythm (specificity).

Fitbit’s new on-device compatible ECG app helps analyze the heart’s rhythm for signs of AFib. ECG is a measurement of the electrical activity of the heart, and the Fitbit ECG App is a simple way people can take an on-the-spot reading of their heart rhythm at any time, including whenever they notice any unusual cardiac symptoms.

“Physicians are often flying blind as to the day-to-day lives of our patients in between office visits. I’ve long believed in the potential for wearable devices to help us stay better connected, and use real-world, individual data to deliver more informed, personalized care,” said Dr. Venkatesh Raman, interventional cardiologist at MedStar Georgetown Hospital and Principal Investigator for the U.S. clinical study on Fitbit’s ECG App. “Given the toll that AFib continues to take on individuals and families around the world, I’m very enthusiastic about the potential of this tool to help people detect possible AFib, a clinically important rhythm abnormality, even after they leave the physician’s office.”

Fitbit Sense is the company’s first device compatible with an ECG app that enables users to take a spot check reading of their heart that can be analyzed for the heart rhythm irregularity AFib. Users simply hold their fingers to the stainless steel ring on the watch while being still for 30 seconds to get a reading that can be downloaded and shared with a doctor. **Fitbit Sense** is the company’s most advanced health smartwatch, with the world’s first electrodermal activity (EDA) sensor on a smartwatch to help manage stress, and an on-wrist skin temperature sensor⁵, all powered by 6+ days of battery life⁶ to help users take control of their health and wellbeing during this unprecedented time.

Broader Commitment to Heart Health

The new ECG app is part of Fitbit’s broader approach to heart health innovation. Fitbit pioneered the use of heart rate tracking on the wrist with its **PurePulse technology** in 2014, which uses photoplethysmography (or PPG) to

monitor the tiny blood volume fluctuations in the wrist as the heart beats, and we continue to develop innovative tools that help people better understand and manage their heart health.

Both long-term heart rhythm assessment (PPG) and spot check (ECG) technology have important roles to play and Fitbit aims to provide both options to users based on their individual needs. Long-term heart rhythm assessment could give our users the ability to identify asymptomatic AFib that could otherwise go undetected, while a spot check approach with new Fitbit ECG App can help those who want to screen themselves for possible AFib and record an ECG trace they can review with their healthcare provider.

In May 2020, the **Fitbit Heart Study** launched to validate the use of Fitbit's PPG technology to identify episodes of irregular heart rhythm suggestive of AFib. In just over four months, the Fitbit Heart Study has enrolled more than 400,000 participants.⁷ Fitbit users in the United States interested in participating can visit the **study website** or open the Fitbit app to find the Fitbit Heart Study on the Discover tab under Assessments & Reports. The results of the study will be used to support Fitbit's regulatory submissions globally for its long-term heart rhythm assessment feature.

Continuing the legacy of heart health innovation, Fitbit **released** PurePulse 2.0 in August 2020, delivering the company's most advanced heart rate technology yet, using an all-new multi-path heart rate sensor and improved algorithm. This enhanced technology provides users with on-device and in-app notifications if their heart rate goes above or below their set heart rate threshold.⁸ Users who receive a notification can also take a survey in the Fitbit app to share with their doctor.

Availability

Fitbit Sense is available today for pre-order on **Fitbit.com** and online at select retailers, with broad worldwide availability starting later this month. Fitbit Sense is available for \$329.95 (USD) in carbon/graphite stainless steel and lunar white/soft gold stainless steel.

About Fitbit, Inc. (NYSE: FIT)

Fitbit helps people lead healthier, more active lives by empowering them with data, inspiration and guidance to reach their goals. Fitbit designs products and experiences that track and provide motivation for everyday health and fitness. Fitbit's diverse line of innovative and popular products include **Fitbit Sense™**, the **Fitbit Versa™** family of smartwatches, **Fitbit Charge 4™**, **Fitbit Inspire 2™**, and **Fitbit Ace 2™** activity trackers, and **Fitbit Aria Air** smart scale. Fitbit products are carried in approximately 39,000 retail stores and in 100+ countries around the globe. The Fitbit platform delivers personalized experiences, insights and guidance through leading software and interactive tools, including the Fitbit and Fitbit Coach apps, and Fitbit OS for smartwatches. Fitbit's paid subscription service,

Fitbit Premium, provides advanced analytics and actionable guidance in the Fitbit app to help you reach your health and fitness goals. **Fitbit Premium + Health Coaching** provides one-on-one virtual coaching with expert health coaches and personalized plans based on your Fitbit data. **Fitbit Health Solutions** develops health and wellness solutions designed to help increase engagement, improve health outcomes, and drive a positive return for employers, health plans and health systems.

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Forward Looking Statements

This press release contains forward-looking statements, within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties including, among other things, statements about the future availability and pricing of Fitbit Sense; future availability of our ECG App; expected performance and/or benefits of products or services described in this release, including but not limited to our ECG App, EDA sensor, skin temperature sensor, and PurePulse technology; and our ability to help users manage or improve their health and wellness.

These forward-looking statements are only predictions and may differ materially from actual results due to a variety of factors, including the effects of the highly competitive market in which we operate, including competition from much larger technology companies; any inability to successfully develop and introduce new products, features, and services or enhance existing products and services; product liability issues, security breaches or other defects; the impact of COVID-19; and other factors discussed under the heading "Risk Factors" in our most recent report on Form 10-Q filed with the Securities and Exchange Commission. All forward-looking statements contained herein are based on information available to us as of the date hereof and we do not assume any obligation to update these statements as a result of new information or future events.

1 Chugh S, Havmoeller R, Narayanan K, Singh D, Rienstra M, Benjamin E, Gillum R, Kim YH, McAnulty Jr JH, Zheng ZJ. Worldwide Epidemiology of Atrial Fibrillation: Global Burden of Disease 2010 Study. *Circulation*. 2014; 129: 837-847.

2 Not intended for use by people under 22 years old. See fitbit.com/ecg for more details.

3 The Fitbit ECG App will be available to consumers in India upon Fitbit Sense availability, anticipated November 2020.

4 Freedman B, Potpara TS, Lip GY. Stroke prevention in atrial fibrillation. Lancet. 2016;388:806–817.

5 Skin temperature variation only available in select markets.

6 Battery life varies with use and other factors.

7 The Fitbit Heart Study is available in the U.S. only. Participants must be 22 years or older.

8 Heart rate notifications are sent after you appear to be inactive for at least 10 minutes.

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