Withings Announces the FDA Clearance of ScanWatch — Its Most Medically Advanced Hybrid Smartwatch

ScanWatch becomes the first wearable to simultaneously receive FDA clearance for atrial fibrillation detection through medical grade ECG and measuring SpO2 levels from the wrist.

Issy-les-Moulineaux, France – October 12, 2021, Today, Withings, pioneers of the connected health revolution, is pleased to announce ScanWatch, its globally acclaimed and most medically advanced wearable, has received FDA clearance.

With state-of-the-art technology that can monitor heart rate, atrial fibrillation through ECG, breathing disturbances, blood oxygen levels through SpO2, sleep, and physical activity, it has already impacted countless lives around the world since its launch in Europe and Australia and will now be available in the United States beginning of November 2021.

Having been rigorously assessed by the FDA, ScanWatch becomes the first wearable to simultaneously be cleared to record ECG & SpO2 measurements. Priced from $279, it will be available from www.withings.com, Best Buy, and Amazon from early November.

“ScanWatch received three CES Innovation Awards when it was announced and we are now thrilled to bring it to the United States following robust FDA scrutiny” said Mathieu Letombe, CEO of Withings. “At Withings our core mission is to create beautiful devices people choose to use and wear every day so the medical data they provide can make meaningful impacts on their lives. ScanWatch has been clinically validated to detect AFib and can aid in the detection of breathing disturbances at night, that can be signs of sleep apnea. It is our most ambitious medical watch to date and has the potential to benefit millions of people.”

Developed with cardiologists and sleep experts, ScanWatch has been validated in two clinical studies. It has already touched countless lives in Europe where it has also been used in a study to monitor COVID patients remotely in German hospitals. It is designed with a stainless-steel case and durable sapphire glass watch face and features a large digital display as well as easy navigation through a newly created crown dial. Additionally, ScanWatch is water-resistant up to 5 ATM and features an exceptional battery life of up to 30 days.

In-depth Cardiovascular Health Monitoring

AFib is the main form of irregular heart rhythm that is often underdiagnosed as it can be intermittent and easily missed if symptoms do not occur during infrequent doctors’ visits. ScanWatch can detect if a user has AFib thanks to its ability to take a medical-grade ECG on-demand. The device can monitor heart rate through its embedded PPG sensor, alerting the user to a potential heart event even if they don’t feel palpitations. In addition, when ScanWatch detects an irregular heartbeat through its heart rate sensor, it will prompt the user to record an ECG in just 30 seconds via the watch display.
ECG readings are displayed in the accompanying Withings Health Mate app where users can choose to send readings to their doctor or cardiologist.

**Blood oxygen level via SpO2 and respiratory disorders at night**

With FDA Clearance of its SpO2 functionality, ScanWatch can be used to monitor blood oxygen levels and can be used to help detect if someone is experiencing breathing disturbances. ScanWatch can also detect the presence of nighttime breathing disturbances (a sign of sleep apnea) with an exclusive algorithm that analyzes blood oxygen levels, heart rate, movement, and respiratory rate, all collected via the accelerometer and optical sensors.

In addition, ScanWatch provides sophisticated sleep monitoring and analysis of sleep patterns, including the length, depth, and quality of sleep, and can wake users up with a gentle vibration at the best time of their sleep cycle.

**Activity & Workout Tracking**
ScanWatch is a sophisticated activity monitor able to track parameters such as steps, calories, elevation, workout routes (via connected GPS) and can automatically recognize more than 30 daily activities such as walking, running, swimming, and cycling. In addition, it offers Fitness Level assessments through estimation of an indicator called VO2 Max, which measures the heart and muscle's ability to convert oxygen into energy during physical exercise.

Like all Withings devices, ScanWatch connects with the free Health Mate app, which provides data and insights and can schedule activity reminders, set goals, and manage achievements. In addition, Health Mate can be paired with more than 100 third-party apps, including Apple Health, Google Fit, Strava, and MyFitnessPal.

**Availability**
ScanWatch will be available early November, 2021 from withings.com, Amazon and Best Buy stores. It is priced at $279 (38mm) and $299 (42 mm) and comes in a choice of black or white faces. Customers are encouraged to visit the [ScanWatch page](#) on withings.com for early availability news.

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**About Withings**
Established in 2008, Withings, is a world leader in connected health technology. Its team of engineers, data scientists, and healthcare professionals have enthused everyday, elegant lifestyle objects with medical capabilities to efficiently track health vitals. Its range of medical-grade in-home devices can monitor more than 20 health parameters and are used daily by millions of people worldwide. Its portfolio of devices that includes connected scales, hybrid watches, smart thermometers, blood
pressure monitors, and sleep trackers empower individuals to take back control of their health, track chronic diseases and detect under-diagnosed conditions.