WITHINGS

THE TECH BEHIND

ScanWatch

On-demand electrocardiogram

Hybrid smartwatch with ECG, heart rate and oximeter

CLINICALLY VALIDATED

The Tech Behind the Measurement

Heart disease is the leading cause of death among both men and women, according to the Centers for Disease Control. Worldwide, the statistics are startling—17.9 million people die each year from cardiovascular disease, according to the World Health Organization. Early detection of heart disease can be crucial. Because some conditions can be asymptomatic or paroxysmal during their early stages, they may not be detected during infrequent physician or hospital visits.

An ECG, or electrocardiogram, is a graphical representation of the electrical activity of the heart. It can detect certain cardiovascular pathologies. One of the most prevalent of these pathologies is atrial fibrillation, or AFib.

Drawing an electrocardiogram is a medical exam typically conducted with a medical device using 10 electrodes attached to different points of the body. This device was long reserved for hospital use and requires an operator trained in its use.

Withings has developed a watch that can record an ECG in 30 seconds anytime, anywhere, thanks to 3 electrodes discreetly embedded in the watch. To perform an ECG using ScanWatch, the user must place their opposite hand on the watch, allowing the measurement of a one-lead ECG.

The development of ScanWatch

WHAT IS AFIB?

Atrial fibrillation (AFib) is the most prevalent type of arrhythmia, affecting the electrical conduction that controls the heart muscle.
It is one of the leading causes of stroke, heart failure, and cardiovascular morbidity in the world [1]. AFib has an average prevalence between 0.4% and 2%, depending on the study. It rises with age, from 2.3% in those older than 40 years to 5.9% in those older than 65 years.
It may be symptomatic (palpitations) or—more often—asymptomatic. In this case, it can remain "silent," which is why earlier detection of the disease could enable better care and help to avoid complications.
Silent, undetected AFib is common [2, 3], and severe consequences may include stroke and death [4, 5]. Prompt recording of an ECG is an effective and cost-effective method to document chronic forms of AFib [6].
The specificity of atrial fibrillation is such that it can be assessed from any lead of an ECG.

HOW IS AFIB DIAGNOSED TODAY?

The gold standard for the diagnosis of AFib is the electrocardiogram.
Recent recommendations encourage early detection of AFib via an ECG. Several studies report an interest in systematically screening at-risk populations by performing an ECG [7, 8].
Until recently, diagnosis of AFib required an ECG recorded in the doctor's office. Therefore, the "diagnostic window" for AFib detection was restricted to the duration of the medical consultation.
Having to record an ECG made the diagnosis difficult during the early stage of the disease, as episodes of AFib are temporary, and may not often be registered during a cardiologist's visit. The main issue with diagnosing AFib is the ability to record an episode when the disease is at its early stage (paroxysmal) or asymptomatic.

WHY HAS WITHINGS PUT AN ECG IN A WATCH?

Withings wanted to offer the opportunity to perform an ECG outside the doctor's office, thus increasing the probability to record AFib episodes early enough to treat it.
Withings worked with cardiologists to understand all the details of an ECG, which can contain a lot of information if we know how to read it. Adding the electrodes needed to a device that already contained numerous componants and sensors was possible due to Withings watchmaking expertise.
Taking an ECG measurement is now more seamless and less intrusive than other methods to detect AFib. The watch form factor allows any user to wear a small ECG lab, and to take measurements anytime, anywhere.
Besides, ScanWatch measures your heart rate, and prompts you to take an ECG measurement in case irregular heartbeat is detected.

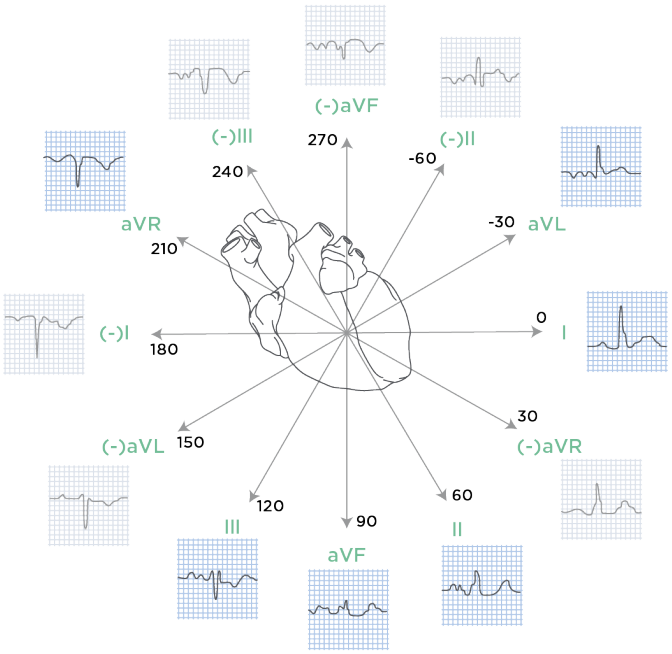
Dive into the tech behind the manual measurement of the heart

With each heartbeat, an electrical wave travels through your heart. This wave causes your heart to contract and pump blood.

An arrhythmia is an anomaly of this electrical activity. In particular, atrial fibrillation is caused by a disorganized firing of electrical impulses in the right atrium near the sinoatrial node—the area that acts as the natural pacemaker of the heart.

HOW DOES AN ECG MEASUREMENT WORK?

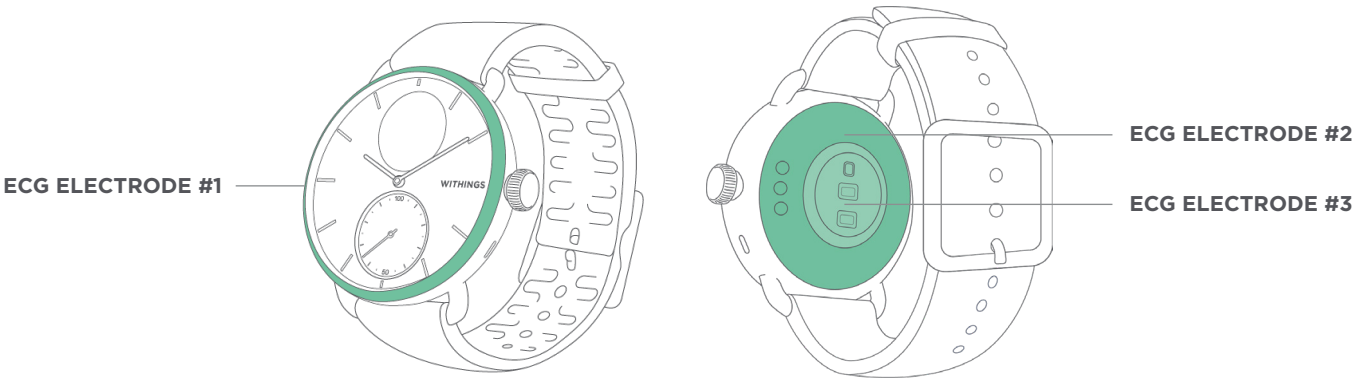
The gold-standard ECG records 12 lead (or ways) of the heart. ScanWatch senses the electrical activity of the heart at a distance through the left and right arm. This configuration is known as lead D1. This recording permits the identification of an episode of atrial fibrillation.



ScanWatch uses 3 independent electrodes built into the bezel (top ring) and the back of the watch. Each electrode is made of stainless steel 316L to ensure a medical-grade reading.

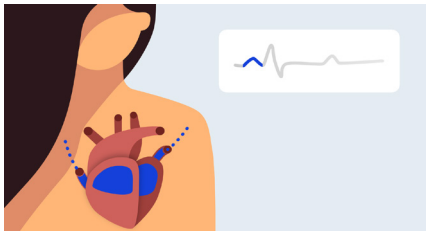
At each heart beat, an electrical wave travels through your heart. When the user touches the electrodes of ScanWatch, an artificial electrical circuit is made between the "+" and "-" electrodes, just like when a battery is connected to a lamp. This circuit is able to record the heart electrical wave and transmits it to the watch.

The Health Mate ECG module automatically acquires and filters the result to extract your heart's electrical impulses from other irrelevant signals such as muscular activity that is not related to the heart and breathing.

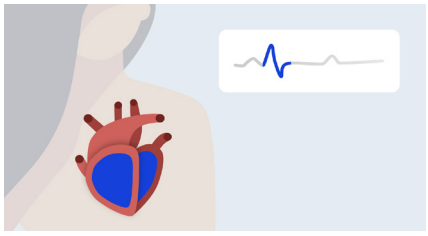


FROM ELECTRICAL RECORDING TO LEVERAGEABLE DATA FOR HEALTHCARE PRACTITIONERS

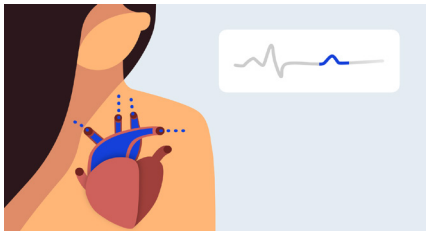
A normal heartbeat on the ECG graph will show the time the electric wave takes to move through your heart. There are 3 distinct patterns:



1. First wave: the "P wave"
The graph shows a first electrical wave as electricity moves into the left and right atrium.



2. Next wave: the "QRS Complex"
This second pattern shows electricity moving through the left and right ventricles



3. Final wave: the "T wave"
The final wave represents the return to a resting state for the ventricles.

By measuring time intervals on an ECG, practitioners can find out if this electricity travel is slow, normal, fast, or even irregular.

The form of each wave, and the time between each pattern, called time intervals, are relevant information to analyze the signal and detect arrhythmias.

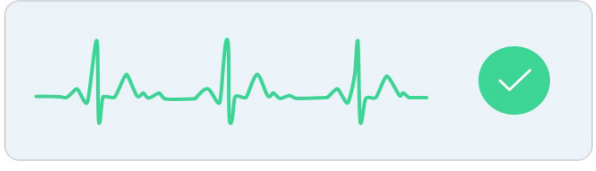
An ECG is commonly considered "normal" if it fulfills a list of conditions concerning the duration, form and amplitude of those patterns, along with time intervals between them.

Doctors are able to analyze an ECG trace by reading it. Withings developed specific algorithms for automatic and instantaneous analysis of the measurements with medical-grade precision. The recording that is produced is easy to read and easy to understand.

WHICH CONDITIONS CAN THE SCANWATCH DETECT?

ECGs can detect a range of conditions, from angina pectoris to severe heart attacks. Withings ScanWatch focuses on detecting atrial fibrillation. It cannot replace emergency services in case of a heart attack.

RESULTS YOU MAY SEE



1. Normal sinus rhythm
A sinus rhythm means your heart is beating in a uniform pattern.

2. Atrial fibrillation
Atrial fibrillation occurs when the two upper chambers of the heart move chaotically instead of pumping regularly.

The P wave on the ECG disappears and is replaced by a jumpy baseline. The QRS complex occurs at “irregularly irregular” intervals.

The algorithm is able to detect those behaviours with great accuracy: it reads the signal and detects the variations of the baseline and irregular durations between QRS complexes. In this case, AFib is suspected and the watch sends a warning so the user can consult a cardiologist for a follow-up examination.

3. Inconclusive
An inconclusive result means the recording can’t be classified. This can happen for many reasons:

- heart rate is low
The heart rate obtained cannot be classified as a recording. To obtain a full analysis, the heart rate must be above 50 bpm during the recording.

- heart rate is high
The recording does not appear to show any signs of atrial fibrillation, but complete diagnosis is not possible for a heart rate above 100 bpm. To obtain a full analysis, the heart rate must be below 100 bpm during the recording.

- signal is too noisy
There is too much interference for the recording to be classified. Place your arm on a table or on your thigh, relax, don’t talk, and don’t move during the recording. Refer to the best practices section to know the right gestures to be adopted and those to be avoided.

- signs of other arrhythmia
This sensor is capable of detecting atrial fibrillation, but is not able to diagnose other types of arrhythmias. This recording cannot be classified as normal rhythm or atrial fibrillation.

Certain conditions, such as a pacemaker or anatomical variations, may prevent a small percentage of users from creating enough signal to produce a good recording.

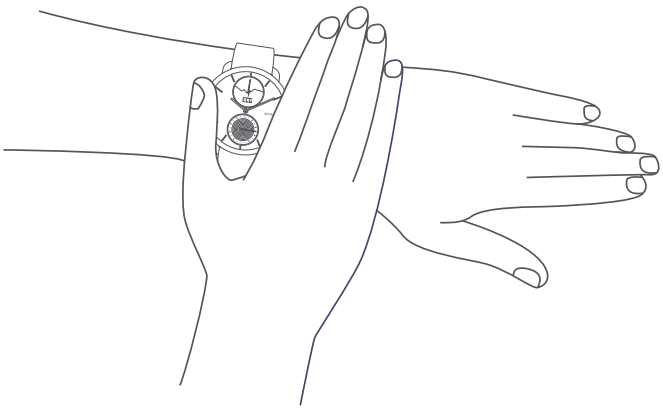
Seamless tech serving medical screening

WHEN SHOULD YOU TAKE A MEASUREMENT?

Either take measurements systematically (you can use the callback function in the Health Mate app) or if you feel you're having symptoms (for example, a rapid or skipped heartbeat).

That's why it's worth having the ability to record an ECG on your wrist—all day, every day—in 30 seconds with a single press of a button. Thanks to the rechargeable battery of ScanWatch, there is a better chance of not missing an episode.

HOW DO YOU TAKE A MEASUREMENT?



Simply press the side button, navigate through the menus to find ECG and press again to launch the reading. Gently place your opposite hand on the bezel (top ring) for 30 seconds. Stay still, don't move or talk, and relax—it's best to be seated or to place your arm on your leg, and try not to contract your arm and hand muscles. The watch will vibrate to notify the user that the reading is complete.

By placing his opposite hand on the watch, the user creates a closed electrical circuit with his arms and chest, allowing the measurement of a one-lead ECG.

There are two ways to record an ECG with Withings ScanWatch:

1. If you have your phone with you, open the Health Mate app (homescreen) and launch an ECG on the watch. It will automatically trigger the ECG module Live View within the app. You will then be able to enjoy the plot of your live signal on your screen's phone.

2. If you don't have your phone with you, that is not a problem at all. You can still record an ECG on the go. The Health Mate ECG module will show your results the next time you open the app.

You can still record an ECG on the go with a simple gesture on your watch. The Health Mate ECG module will show your results the next time you open the app.

Scanwatch, a game changer

WHY PUT ECG IN A WATCH?

“Technological advances allow screening for an irregular pulse using patient-operated ECG devices, smartphones, and a variety of other technologies. These may be very useful to detect silent, undiagnosed AFib.”
European Society of Cardiology Guidelines, 2016, p.58

WHAT IS THE BENEFIT OF HAVING AN ECG ON THE WRIST?

AFib is responsible for 30% of strokes. 90% of them could be avoided if AFib is detected at an early stage [9]. AFib is underdiagnosed because explicit atrial fibrillation episodes may not necessarily occur at the doctor’s office.

When a user feels symptoms such as palpitations, they can place their hand on the watch and, in 30 seconds, ScanWatch will record and display instantly whether the heart is beating in a normal pattern or whether there are signs of AFib.

HOW CAN YOU SHARE YOUR RESULTS OR ACT ON THEM?

Each ECG record and history can be easily found in the Health Mate app and shared with a doctor or a healthcare professional, which can help you assist with early diagnosis and prevention in case of an AFib detection.

The ECG records contain much more information than what ScanWatch automatically detects. Whenever you share your health report to a physician, they can read this data to make a diagnosis. For instance, the intervals between QRS complexes and T waves are of significant relevance, and can be read on the ECG trace stored in the app.

Clinically validated

In keeping with the expectations of medical cardiology societies, Withings has produced a tool that can be used on a daily basis and has received the CE marking following the Medical Device Directive 93/42/EEC as amended by the 2007/47/EC.

A clinical study was performed at the Centre de Cardiologie du Nord (CCN) and l'Hôpital Européen George Pompidou (HEGP) by comparing a one-lead ECG with ScanWatch to a reference 12-lead ECG.

The performance of an ECG Monitor is expressed as the sensitivity Se to detect an episode of atrial fibrillation and the specificity Sp in the detection of Normal Sinus Rhythm.

In 20.2% of the cases, ScanWatch classified the signals ‘’inconclusive.” That is, the algorithm was unable to make a reliable classification into either AFib of Normal Sinus Rhythm in these cases.

The purpose of the ”inconclusive” label is to avoid making erroneous classifications on poor signal quality or arrhythmia other than AFib. Removing the signals classified as ”inconclusive” by ScanWatch, a ”net performance” is calculated for the remaining patients:

ScanWatch correctly identified all the patients who were in Normal Sinus Rhythm, giving a specificity of Sp = 100%.

ScanWatch correctly classified all the patients who were in AFib according to the reference, giving a sensitivity of Se = 100%.

Though one fifth of the results are inconclusive, ScanWatch ECG records that get a result are reliable, which makes this watch the perfect everyday object detecting—with medical accuracy—one of the most prevalent and underdiagnosed heart diseases.

Bibliography

[1] : European Society of Cardiology Guidelines, 2016, p. 7

[2, 3] : European Society of Cardiology Guidelines, 2016, p. 120, 122

[4, 5] : European Society of Cardiology Guidelines, 2016, p. 123-125

[6] : European Society of Cardiology Guidelines, 2016, p. 126

[7, 8] : European Society of Cardiology Guidelines, 2016, p. 131-133

[9] : P. Kirchhof & al., 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS, European Heart Journal (2016), 37, 2893-2962.