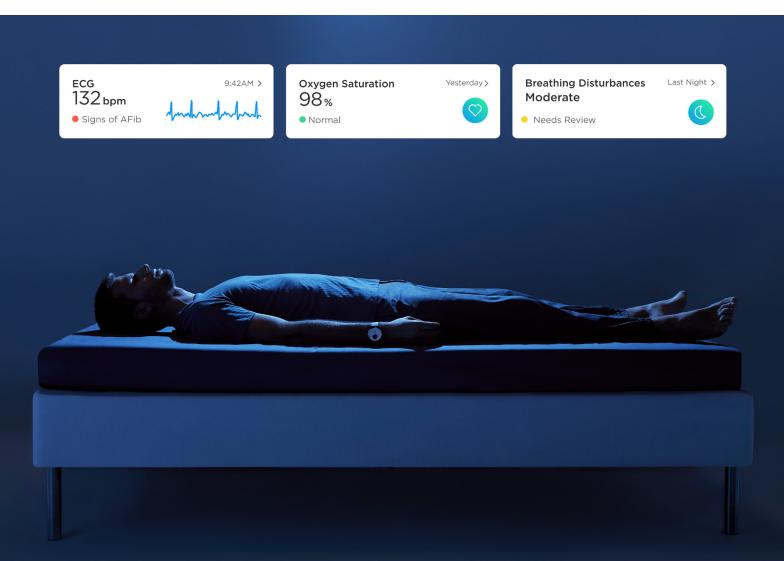


The Tech Behind the Measurement

Medical sleep analysis involves wearing multiple electrophysiological sensors during the night. Therefore, it can be both costly and uncomfortable. Also, because of the amount of time required for analysis, your results may not be instantly available, and the process can't be easily reproduced from one night to another.

ScanWatch embeds sensors to scan your night. It uses its PPG (photoplethysmography) sensor to measure your heart rate and heart rhythm, your breathing rate and respiratory effort, and your oxygen saturation continuously. It also uses an accelerometer to monitor your actigraphy (rest and activity cycles). Consequently, ScanWatch can detect breathing disturbances during your sleep.

As oxygen saturation in the blood (or SpO2) is often mentioned as the fifth vital sign, along with pulse, respiratory rate, blood pressure, and body temperature, ScanWatch allows the wearer to take a manual SpO2 measurement to monitor it during the day as well as during the night.



The development of ScanWatch

We all spend one-third of our life sleeping. Like breathing or digestion, sleep is a vital bodily function. It plays an important role in learning and memorization. It is also essential to our overall well-being [1] and to our immune system [2]. Sleep enables us to recover from physical and psychological fatigue accumulated during the day [3].

But reaching your sleep quota can be difficult. Studies have shown that some environments in developed countries can disturb sleep and your circadian rhythm [4]. Factors that may also influence the quality of your sleep include: whether you work nights or often change work shifts in a way that affects your sleep, your social lifestyle, the now-common use of devices that emit blue light, such as smartphones, tablets and readers in bed. Blue light is known for blocking the sleep hormone production, also known as melatonin [5], excess heat, humidity, or noise [6], your age [7].

It is well known that sleep quality is linked to several chronic conditions. For instance, lack of sleep has been identified as a risk factor for several disorders, including high blood pressure and obesity [8,9]. You may also experience chronic disorders while you sleep: widely underdiagnosed conditions such as insomnia or sleep apnea can have a major impact on your health and wellbeing, 80% of people with moderate to severe sleep apnea are still not aware of their condition for instance. [10]

The established practice of sleep measurement in the medical field involves wearing multiple electrophysiological sensors during the night, which results in an analysis that is both costly and uncomfortable. Also, because of the amount of time required for analysis, your results may not be instantly available, and this process can't be easily reproduced from one night to another.

ScanWatch algorithm for breathing disturbances detection has been developed and calibrated in collaboration with sleep experts from Hôpital Béclère in Paris, France to provide the most in-depth and accurate insights. It detects breathing disturbances simply by wearing it at night.

BREATHING DISTURBANCES

During sleep, it is possible to experience trouble breathing, and you may not remember it in the morning. Paused breathing can naturally occur a few times during the night for all adults, and won't have any noticeable impact on one's sleep, health, and daily life. But when breathing disturbances occur too many times during sleep, they can become a chronic condition known as sleep apnea.

The odds to experience breathing disturbances increases with age and weight, and is more likely to occur in men and postmenopausal women.

Oxygen saturation level drops can be a sign of breathing disturbances. When the brain senses that oxygen levels are getting too low, it triggers a safety alarm signal, waking you up to take a breath. After falling back to sleep, this can occur repeatedly during the night, which doesn't allow the body to recover properly. This can greatly affect the body's ability to recover during sleep, causing daytime sleepiness, among other symptoms, which may be dangerous in certain situations, including during industrial work and when driving motor vehicles.

In addition to poor sleep, impaired oxygenation may have other consequences, including negative impacts on the cardiovascular system and cognitive functions.

Assessing the availability of oxygen for delivery to the peripheral tissues is critical in the assessment and management of all patients at risk of respiratory dysfunction. Pulse oximetry (measuring oxygen saturation) plays a role in the monitoring and treatment of respiratory disease by detecting hypoxemia (low oxygen level in the blood vessels). Although it does not provide precise assessment of true arterial saturation in the critically ill, it has been shown to be adequate in guiding clinical decision making, such as the diagnosis of acute lung injury/ acute respiratory distress syndrome.

Currently, oxygen saturation is either measured at the point of care and requires drawing a blood sample, or it can be measured using a non-invasive pulse oximeter, generally worn at the finger and maintained with a clamp. Neither method is suitable for continuous saturation monitoring, which is why there is a growing interest in connected watches with a saturation sensor. However, only a handful of saturation-enabled watches have reached the level of accuracy of medical oxygen saturation sensors, because obtaining a good pulse signal at the wrist is notoriously difficult. We developed ScanWatch with a measurement method of sufficient quality to obtain a medical grade SpO2 measurement in order to detect pathologies, which implied using an oximetry sensor specifically designed for a wrist measurement, associated with a suitable algorithm.

ScanWatch is the first watch available in wide release capable of carrying out an accurate measurement of oxygen saturation, that meets medical standards. Measuring SpO2 requires to be perfectly at rest. Therefore we integrated SpO2 automatic measurement to ScanWatch's night respiratory scan to provide complete maps of your nights.

Dive into the tech behind the respiratory monitoring

ScanWatch uses pulse oximetry, which is an indirect, non-invasive method (meaning it does not involve the introduction of instruments into the body) to measure the heart rate, breathing rate and oxygen saturation. Pulse oximetry is an application of photoplethysmography: using optical methods to detect blood volume changes in the microvascular bed of tissue. In a photoplethysmography (PPG) sensor, a LED emits a light wave to the skin, a part of this wave will be reflected/scattered by the blood vessels of the wrist, turned back to the watch and recorded by a photodiode. ScanWatch uses a PPG sensor with three different LEDs: green, red and infrared.

HOW DOES RESPIRATORY MONITORING WORK?

OXYGEN SATURATION LEVEL MEASUREMENT

SpO2 stands for peripheral capillary oxygen saturation, an estimate of the amount of oxygen in the blood. More specifically, it is the percentage of oxygenated hemoglobin (hemoglobin containing oxygen) compared to the total amount of hemoglobin in the blood (oxygenated and non-oxygenated hemoglobin).

Hemoglobin is a protein that carries oxygen in the blood to your organs. It is found inside red blood cells and gives them their red color. Once oxygen is in our organs, it acts as the fuel that allows our cells to work.

Blood will reflect the light differently, depending on the level of oxygen in the vessels:

- Oxygen-rich blood absorbs infrared light better than oxygen-poor blood.

- Oxygen-poor blood absorbs red light better than oxygen-rich blood. This is why venous blood is darker than arterial blood.

Besides, the amount of light reflected by the blood vessels depends on several factors:

- the heart rate (contraction/relaxation of the heart)
- the breathing rate
- wrist movements during the measurement
- measurement noise

ScanWatch uses the green, red and infrared reflections in the blood vessels in the wrist, and data from the accelerometer. When your heart beats, the blood flows in your wrist and the green light absorption is greater, ScanWatch can calculate your heart rate from the green signal. Then a specifically designed algorithm compares the heart rate, signals from the red and infrared sensors, and data from the accelerometer to separate the variation of the signal due to oxygenation from the rest. Then it computes the SpO2 value by calculating the difference in reflection rates between red and infrared filtered signals with great accuracy, in just a few seconds after the measurement.

BREATHING RATE MEASUREMENT

With the results of the green LED emission, ScanWatch derives the heart rate. To obtain the breathing rate, Withings developed a specific and innovative algorithm: it is obtained as a modulation of the heart rate, and of the amplitude variations of the alternating and continuous parts of the PPG signals.

Heart rate and breathing rate are two vital signs, ScanWatch records them and displays their variations in specifically designed graphs available after the night.

BREATHING DISTURBANCES

Breathing disturbances are characterized by lower respiratory effort, SpO2 drops, heart rate drops and micro-movements of the body.

ScanWatch combines automatic heart rate, breathing rate, actigraphy and SpO2 measurements to detect those episodes. The PPG sensor gets the heart rate, breathing rate and SpO2, whereas actigraphy data comes from the embedded accelerometer. It detects movements of your body during sleep.

A machine learning algorithm was used to learn to recognize the patterns formed by these breathing disturbances. By counting the occurences of those patterns, ScanWatch is able to count the number of breathing disturbances.

SLEEP STAGES

A night's sleep is broadly divided into two parts: Rapid Eye Movement (REM), or paradoxical sleep, during which we dream, and Non-Rapid Eye Movement (NREM), which includes light and deep sleep.

The night begins with a state during which we are neither fully asleep nor fully awake. Body movements are infrequent. We are sleeping, but a slight noise could easily wake us. It is light sleep.

During deep sleep, your body is immobile. There is very little brain activity or reaction to external stimuli. Your heart rate and breathing rate are slow and regular. Deep sleep phases are crucial times for the body to regenerate from physical fatigue. In REM sleep, your eyelids are closed, but your eyes move rapidly under the lids, indicating intense brain activity and dreaming. This stage allows you to recover from psychological fatigue and stress. It is common to wake up suddenly in the morning at the end of a phase of REM sleep.

By periodically measuring the heart rate, breathing rate and actigraphy, ScanWatch is able to understand when you are awake or asleep, which is key to detect breathing disturbances.

Besides, ScanWatch is also able to draw the map of your night, including light and deep sleep stages.

From a physiologic recording to leverageable data for healthcare practitioners

WHICH CONDITIONS CAN SCANWATCH DETECT?

SPO2

ScanWatch usually takes one heart rate measurement every 10 minutes. With this frequency of measurement, the watch is able to detect when you are awake and when you are asleep. But when you launch a Respiratory scan, ScanWatch will take more frequent measurements to be able to add breathing disturbances to your night map.

Variations in oxygen saturation are normal. But if you are short of breath or if you have pulmonary issues, oxygen saturation levels can drop, because less oxygen is entering your organs. Elevation, heart and lungs issues, and some sleep disorders can affect your SpO2 level. This is the reason why, besides the respiratory scan, ScanWatch allows you to launch a manual measurement, anytime.

The measured SpO2 value will vary greatly depending on the conditions of the measurement and the profile of the person who does it, however ScanWatch will help you understand your results: a SpO2 value is represented by a percentage. If your ScanWatch says 98%, this means that each red blood cell is made up of 98% oxygenated and 2% non-oxygenated hemoglobin.

95% to 100%: normal

90% to 94%: below average. This measurement detects that your blood oxygen level is below average but still normal. The results can vary based on a number of many factors, including but not limited to your health profile (whether you are a smoker, if you have asthma, if you are very athletic or not, if you have tattoos, if you have known conditions such as hypotension, anemia, etc.), your environment (altitude, temperature), the way the measurement is done (standing/ sitting position, wristband tightening, etc.).

We suggest you check for the best practices in the Health Mate app and train to improve your gesture.

Note: In the context of the Covid-19 pandemic, monitoring SpO2 is useful to follow the development of the virus. If you are a remote Covid-19 patient, please be very attentive to this value: if at least 5 consecutive measurements show a result below 95%, we suggest you contact your doctor who will help you take preventive actions.

Below 90%: low. Below 90%, the value can be a possible sign of hypoxemia (low oxygen level in your red blood cells). The results can vary based on a number of factors including your health profile, your environment and the way the measurement is done. We suggest you check for best practices in the Health Mate app and repeat the measurement.

In case results in this zone are associated with symptoms, contact your doctor or a health professional who will help you make a diagnosis and take preventive actions. Symptoms include being short of breath after exertion, coughing, fast or slow heart rate, rapid breathing, sweating.

BREATHING DISTURBANCES

ScanWatch provides three categories to grade the severity of breathing disturbances:

- Low
- Moderate
- High

Medical advice should be sought if you experience moderate or high breathing disturbances, or if you experience symptoms or have concerns.

SLEEP SCORE

By tracking physiological parameters like heart activity and wrist movement, ScanWatch can assess whether you're awake or asleep and which sleep stage you are in.

In addition to sleep stages, ScanWatch provides a Sleep Score with 4 parameters so you can see how restful the night was.

The Sleep Score has been developed with sleep physicians and implemented by the Withings team, which created a specific weighting that reflects the importance of each item for the human body during sleep from a physiological point of view. The most important parameter is sleep duration; this accounts for more than 50% of the Sleep Score. The second most important parameter is sleep depth (depending on the relative percentage of each sleep stage). The next parameters are interruptions and regularity.

Seamless tech serving medical screening

WHEN SHOULD YOU TAKE A MEASUREMENT?

RESPIRATORY SCAN

The Respiratory scan builds a complete map of your night. You will be able to choose between three types of experience:

- Always on: a Respiratory Scan will be completed every night, and you will get the results every morning. Your battery life might suffer from this mode. - Automatic: ScanWatch will automatically plan a Respiratory Scan for several nights in a row once every quarter. It will notify you the day before and ask if you want to reschedule later. This frequency is recommended by doctors to get the best results from this feature. - Off: No Respiratory Scan will be launched.

Don't forget to wear your watch during the night!

The Respiratory scan will measure your heart rate, respiratory rate and oxygen saturation level throughout the night. However if you wish to perform a one-time oxygen saturation measurement, you should do it when at rest (especially after physical activity, you should wait for a few minutes).

ON-DEMAND SP02

Simply press the side button once when on the SpO2 screen and 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. Low blood flow may prevent the measurement or cause an error. In this case, check that the watch is correctly positioned and try again.

Optimal SpO2 values vary between 95 and 100%:

- 95% to 100%: normal
- 90% to 94%: below average
- below 90%: low

The watch will vibrate to notify the user that the reading is complete, and directly give the output percentage value. In case of an inconclusive result, a cross will appear.

You can also find the results in the Withings Health Mate app.

Scanwatch, a game changer

WHAT IS THE BENEFIT OF HAVING A BREATHING DISTURBANCES DETECTOR ON THE WRIST?

Thanks to its innovative sensors and sleep tracking algorithms, ScanWatch is a non-invasive method to detect breathing disturbances. Every night, ScanWatch is able to create a complete map of your sleep, and give insights about your cardiovascular health.

HOW CAN YOU SHARE YOUR RESULTS OR ACT ON THEM?

Each night scan record and history can easily be found in the Health Mate app and can be easily shared as a PDF with a doctor or a healthcare professional, which can help you assist with early diagnosis and prevention in case of breathing disturbance detection.

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