Withings ScanWatch
with Scan Monitor

ScanWatch Information Guide (also referred to as Regulatory Leaflet)
Disclaimer: Information in this guide may change without notice.

℞ Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

This brochure explains how to use the Scan Monitor functionalities on your ScanWatch.

Indications for use

(Intended for US region)

The Scan Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Scan Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor is prescribed or used under the care of a physician). The Scan Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals.

The Scan Monitor is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2). The Scan Monitor is intended for spot-checking of adult patients and can be used in clinical settings (e.g., physician's office, clinic, etc.) and also in the home environment. Home users are advised to contact their physician if any abnormal values are indicated.

Contraindications ⚠

Scan Monitor is not intended to continuously monitor vital signs in critical conditions or where the nature of the variations is such that it could result in immediate danger to the patient. Scan Monitor does not provide alarms.

Scan Monitor is not intended to provide or to replace a diagnosis by a physician or qualified health care professionals. Vital signs measurements, such as those taken with this device, cannot identify all diseases. If you think you may be having a heart attack (myocardial infarction) or are facing a medical emergency, call the emergency services.

Scan Monitor is not indicated for use:

- on patients with a pacemaker or other implanted electronic device
- for out-of-hospital transport by emergency medical services
- during medical procedures

The AF detection feature is not intended for patients diagnosed with an arrhythmia other than Atrial Fibrillation or diagnosed with bundle branch block.

Warnings ⚠

Regardless of the measurements taken using this device, you should consult your doctor immediately if you experience symptoms that could indicate you are experiencing a sudden and/or severe change in health.

The Scan Monitor cannot detect heart attacks or ischemic heart conditions. If you ever experience chest pain, pressure, tightness or what you think is a heart attack, call emergency services.

DO NOT self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.

The Scan Monitor cannot detect all instances of Atrial Fibrillation. You should contact your physician if you experience any changes to your health.

The Scan Monitor cannot detect arrhythmias other than Atrial Fibrillation. You should notify your physician if you detect possible changes in your health.

The functional oxygen saturation feature does not constantly monitor blood oxygen desaturation and should not be relied on as a continuous monitor.

Warnings ⚠

Factors that may degrade performance of reflectance **pulse oximetry (measurement of oxygen saturation)** include:

- Bright sunlight
- Presence of strong electromagnetic fields
- Failure to apply the device correctly (loose wristband application, not on top of the wrist)
- Tattoos on the wrist in the region of the optical sensor
- Excessive motion of the arm, wrist, or fingers
- Low blood perfusion caused by room temperature below the recommended operation range, or by certain conditions such as Raynaud's syndrome
- Significant levels of dysfunctional hemoglobin (carboxyhemoglobin, methemoglobin)
- Venous pulsations
- Intravascular dyes such as cardiogreen or methyl blue
- Blood-flow restrictions due to arterial catheters, blood pressure cuffs, or infusion lines
- Hypotension, serious vasoconstriction, serious anemia, or hypothermia
- Cardiac arrest or shock

Warnings ⚠

Misapplication of the ScanWatch with excessive pressure and for a prolonged period can cause injury.
Avoid using the ScanWatch on a wrist with poor skin integrity.

DO NOT sterilize using irradiation, steam or ethylene oxide. Refer to cleaning and disinfection instructions.
Use of cleaning agents other than specified may damage the device.

DO NOT use the ScanWatch if it is damaged. Use of a damaged device could cause patient injury or equipment failure.

DO NOT take recordings when ScanWatch is in close vicinity to strong electromagnetic fields (e.g., electromagnetic anti-theft systems, metal detectors).

DO NOT take recordings during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).

DO NOT take recordings when ScanWatch is outside of the operational temperature range (5°C - 40°C) indicated in the ScanWatch user manual and humidity range of 20% to 90% relative humidity.

DO NOT use to diagnose heart-related conditions.

DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.

DO NOT take a recording during physical activity.

A functional tester instrument cannot be used to assess the accuracy of pulse oximeter devices.

Warnings ⚠

No modification of this equipment is allowed.

DO NOT modify this equipment without authorization of the manufacturer.

The Power cord of the charger may cause strangulation effect due to excessive length, keep it away from children and pets.

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

The battery inside the watch will stop charging when the temperature is less than -10°C (+/-5°C) or over 50°C (+/-5°C).

Important Notes

The Scan Monitor measures two separate outputs: **(1) ECG for Atrial Fibrillation**; and **(2) Pulse Oximetry for Oxygen Saturation (SpO2)**.

The measurement of SpO2 in the 70-100% range has been clinically validated on healthy adult volunteers, at rest, against a laboratory co-oximeter.

The device conforms to IP22 requirements.

This device has no alarm system in case of low saturation.

The Scan Monitor is intended for use in adults (22 years or older in the U.S.) and with no restrictions on weight.

The oximeter is calibrated in the factory before sale. There is no need to calibrate it during its lifecycle. SpO2 is calculated over a 30-second window (the value is updated every second).

The screen of the watch will display the percentage of charge when it is plugged.

Use a power cord that matches the voltage of the power outlet, which has been approved and complies with the safety standard of your particular country.

The patient is an intended operator of the watch and Scan Monitor features.

Important Notes

The expected service life for Scan Monitor is 2 years.

When in need of assistance on using, maintaining or to report unexpected event please contact manufacturer for further information (please see the last page of this leaflet).

No service or repairs should be performed on the Scan Monitor hardware other than the maintenance listed in this leaflet.

Inspect sensors for warping, surface damage or corrosion and check for any other form of damage.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

Please note that the device has not been clinically validated for heart rates higher than 140 bpm.

For healthcare professionals: to verify operation of the pulse oximeter: The ScanWatch utilizes a reflective oximeter sensor on the bottom surface of the watch. The ScanWatch pulse oximeter operation can be verified by a responsible organization (biomedical engineering department, etc.) using a model AECG100 Test System (WhaleTeq, Taipei City, Taiwan). As clinical accuracy cannot be verified with a simulator, some differences in ScanWatch readings versus set-point may be observed.

Using the Scan Monitor

Before you start:

- Before being able to use the Scan Monitor, you have to download the companion app Health Mate in order to activate it
- Scan Monitor is only available for Withings ScanWatch when it is paired with a smartphone with iOS 12 or later or Android 8 or later
- Use a trusted Wi-Fi network with your companion app. Do not use a public Wi-Fi network you don’t know
- Do not install the device on a smartphone that you do not own
- The mobile application is not intended to be used on a computer. No indication of anti-virus software is needed
- Only use official app stores to download the app. To ensure that the app is the official Health Mate app, use the following link: go.withings.com

Using the Scan Monitor

Setup:

- Open the Withings Health Mate app after having downloaded it on stores (App store and Google Play store)
- In the Devices tab, select “Install a device”, then select “Watches”
- Select the product “ScanWatch”
- Follow the on-screen instructions. You will be prompted to pair your device via Bluetooth. Then you will be able to go through tutorials to setup the watch
- You may exit on-boarding at any time by tapping Cancel

What is an ECG?

How ScanWatch obtains an ECG:

- ECG, or electrocardiogram, is the graphical representation of the electrical activity of the heart. It can detect certain cardiovascular pathologies.

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

- In a doctor's office, a standard 12-lead ECG is usually taken. This 12-lead ECG records electrical signals from different angles in the heart to produce twelve different waveforms. ScanWatch measures a waveform similar to one of those twelve waveforms. This configuration is known as single-lead ECG.

- A single-lead ECG is able to provide information about heart rate and heart rhythm and enables classification of Atrial Fibrillation (AFib). However, a single-lead ECG cannot be used to identify some other conditions, like heart attacks. Single-lead ECGs are often prescribed by doctors for people to wear at home or within the hospital so that the doctor can get a better look at the underlying rate and rhythm of the heart.

Taking an ECG

How to take an ECG recording:

- Make sure your ScanWatch is snug on the wrist that you selected in the companion app to be your measurement wrist. You can modify your measurement wrist in the companion app, in Devices > ScanWatch > More Settings > Device Orientation.

- Rest your arms on a table, and hold the top electrode with your other hand (as shown in Fig. 1). You do not need to press the bezel during the session.

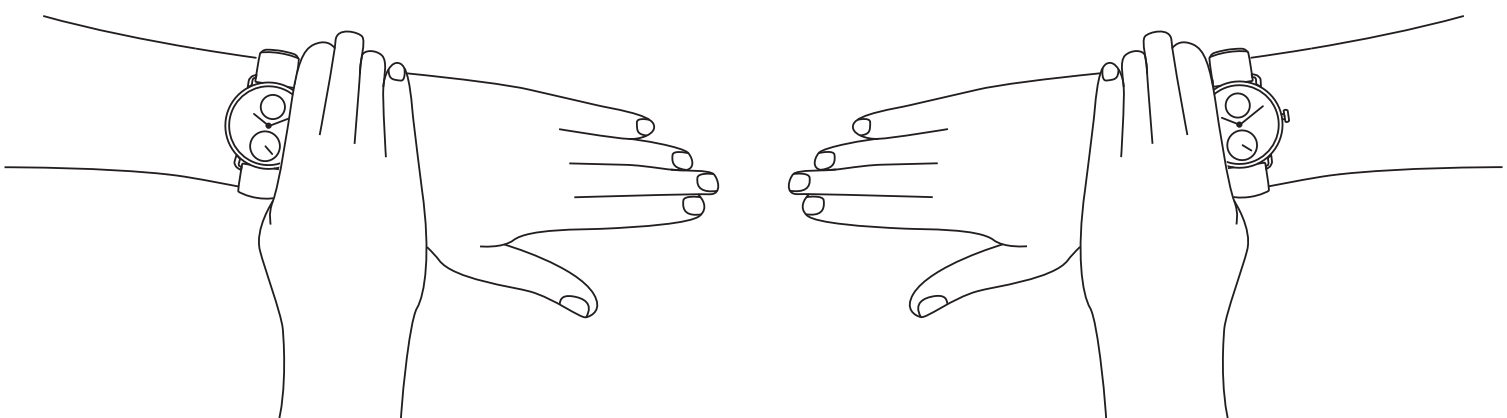

Fig. 1 - How to place the second hand to get an ECG measurement

Taking an ECG

How to take an ECG recording:

- Activate the ECG measure using the watch interface: press the button, then search for the ECG menu screen on the watch. Launch the measurement by pressing the button one more time. You cannot start an ECG from the Health Mate companion app.
- If the feature has been activated, the measurement starts, otherwise the screen displays an invitation to activate the feature.
- The recording starts after the first vibration.
- The recording lasts for 30 seconds.
- Wait for the measurement to end. A countdown indicates the remaining time.
- The end of the measurement is confirmed by a double vibration.
- For users located in the U.S., the first ECG recording will be reviewed by a healthcare professional. It should take less than 24 hours. Once completed, the feature will be unlocked, and the classification of the Atrial Fibrillation detection algorithm will be displayed in the app.

ECG Outputs

ECG classification:

After an ECG recording, you will be able to see one of the following classifications for the recording:

- **Normal Sinus Rhythm:** A sinus rhythm means your heart is beating in a uniform pattern.

- **Atrial Fibrillation:** Atrial Fibrillation occurs when the two upper chambers of the heart move randomly instead of pumping regularly. This does not allow for complete emptying of the chambers and thus, blood may become stagnant and create blood clots. You should contact your physician.

- **Inconclusive:** An 'Inconclusive' result means that the device could not classify your ECG recording as normal Sinus Rhythm, Atrial Fibrillation or Noise. There could be many reasons for this. One reason is the presence of interference due to movements of the arm, wrist or fingers. Another reason can simply be that the heart rate exceeds 100 bpm or is below 50 bpm. It can also be explained by the presence of an arrhythmia other than atrial fibrillation or a bundle branch block

- **Noise:** 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.

After the ECG recording you will also see your median heart rate, derived from the ECG and your ECG filtered trace.

ECG Outputs

ECG classification:

- A result of Normal Sinus Rhythm means your heart rate is between 50 and 100 beats per minute (bpm) and is beating in a regular pattern.

- Inconclusive ECG results may be caused by errors introduced during the measurement, such as **(1)** movements that cause a signal of poor quality, **(2)** by too much noise due to proximity with an electrical device that generates strong electromagnetic fields, **(3)** an arrhythmia other than AFib, OR **(4)** if your heart rate is below 50 bpm or above 100 bpm.

- A small percentage of people may have certain physiological conditions preventing the user from creating enough signal to produce a good recording. You can learn more about inconclusive ECG results during setup by accessing the educational information included in the ECG area of the Health Mate app.

- A heart rate may be low because of certain medications or if electrical signals are not properly conducted through the heart. Training to be an elite athlete can also potentially cause a low heart rate.

- A heart rate may be high because of exercise, stress, nervousness, alcohol dehydration, infection, AFib, or another arrhythmia.

- If you receive an inconclusive result due to a poor recording, you might try to re-record your ECG. You can review how to take an ECG during setup or by tapping Take a Recording in the ECG section of the Health Mate app on your smartphone.

- All ECG results sync with Health Mate on your Android or iOS app. You may use the Health Mate app to share your ECG with a clinician.

ECG Outputs

Possible outputs on the device screen:

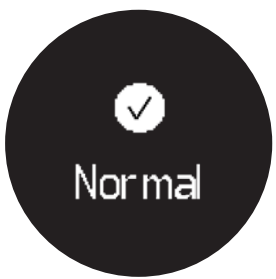

Fig. 2.1

Normal result on the device

Fig. 2.2

Atrial fibrillation result on the device

Fig. 2.3

Inconclusive result on the device

Fig. 2.4

Median heart rate

- The distinction between the four inconclusive classification types can be found in the Health Mate companion app, as described below.

- The classification of the ECG recording is for **informational use only**. It is meant to supplement, but not replace, traditional diagnosis methods. If you are experiencing any symptoms or have concerns, contact your physician. If you believe you are experiencing a medical emergency, contact emergency services.

- The heart rate output is the median value of the beat-by-beat heart rates over the 30 seconds of the recording.

ECG Outputs

Possible outputs in the Health Mate companion app:

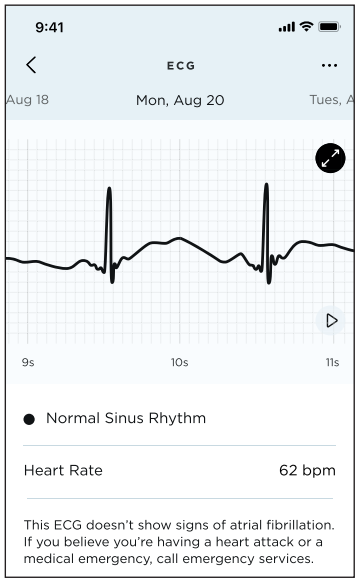

Fig. 3.1
Normal Sinus Rhythm

Fig. 3.2
Signs of Atrial Fibrillation

ECG Outputs

Possible outputs in the Health Mate companion app:

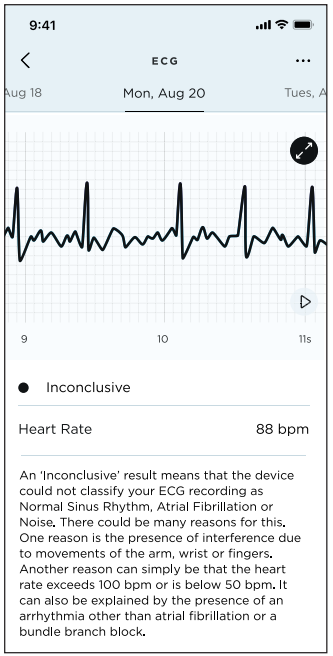

Fig. 3.3
Inconclusive

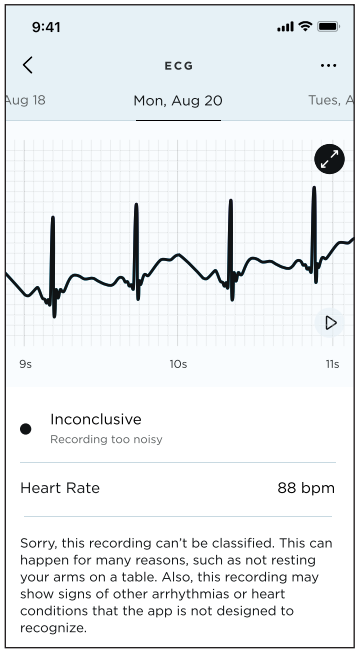

Fig. 3.4
Noise

Sharing ECG Results

How to share your ECG with your physician:

Once the feature is unlocked, the results of the ECG can be shared with a physician as a pdf, Health Mate companion app. generated by the Health Mate companion app.

The pdf includes the following information:

- The ECG strip
- The median heart rate, derived from the ECG
- The classification of the Atrial Fibrillation detection algorithm

What is an SpO2 Measurement?

How ScanWatch obtains an SpO2 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.

- SpO2 is measured by pulse oximetry. It works by emitting and then absorbing a light wave reflecting the blood vessels, or capillaries, in the wrist.

- ScanWatch uses a multi-wavelength sensor called PPG (photoplethysmography) sensor that emits and measures red and infrared reflections on the blood vessels in the wrist. The algorithm then compares the reflection at each wavelength to compute the SpO2 value.

- 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 sleep disorders can affect your SpO2 level. If you are experiencing any symptoms or have concerns, contact your physician. If you believe you are experiencing a medical emergency, contact emergency services.

Taking an SpO2 Measurement

How to take an SpO2 measurement:

- Tighten the band so that the back of the watch is in contact with the skin of your wrist.
- Rest your arm on a table, with the hand relaxed and in an open position.
- Hold the watch with your other hand (as shown in Fig. 1). You do not need to press on the watch during the session.
- Activate the SpO2 measure using the watch interface: press the button, then search for the SpO2 menu screen on the watch. Launch the measurement by pressing the button one more time. You cannot start an SpO2 measure from the Health Mate companion app.
- If the feature has been activated, the measurement starts, otherwise the screen displays an invitation to activate the feature.
- The recording starts after a first vibration.
- The recording lasts 30 seconds. **Do not talk or move during the measurement.**
- Wait for the measurement to end. A countdown indicates the remaining time.
- The end of the measurement is confirmed by a double vibration.
- If the measurement fails (a cross is displayed on the watch screen, indicating that the signal has low amplitude, or is corrupted by motion artefacts), restart from the beginning and slightly push the watch with your right hand.

Taking an SpO2 Measurement

How to take an SpO2 measurement:

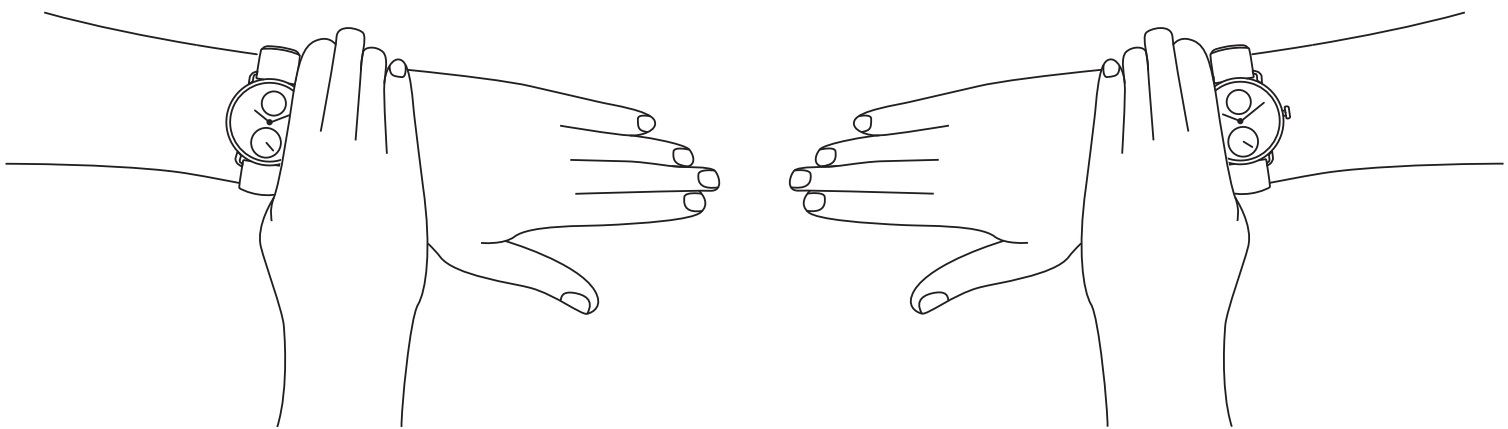

Fig. 4 - How to place the second hand to get an SpO2 measurement

SpO2 Outputs

Possible outputs on the device screen:

Fig. 5.1

Normal result on the device

Fig. 5.2

Low result on the device

Fig. 5.3

Inconclusive result on the device

- The Scan Monitor is validated for the range 70% to 100%. It is displayed on a gauge from 85% to 100%. Results between 70% and 85% are simply indicated as below 85% by the cursor on the gauge, as shown on Figure 6.

SpO2 Outputs

Possible outputs in the Health Mate companion app:

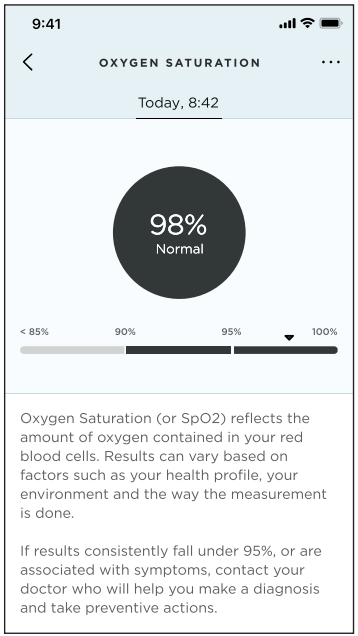

Fig. 6.1
Normal Result

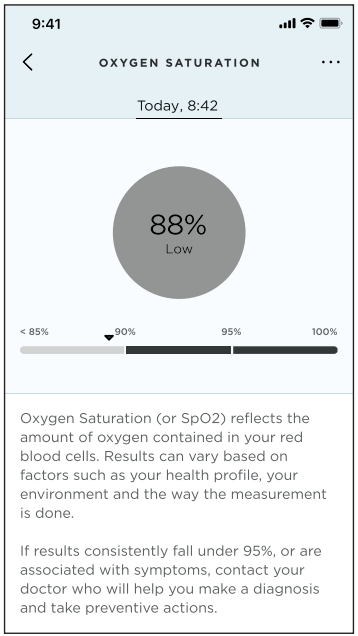

Fig. 6.2
Low Result

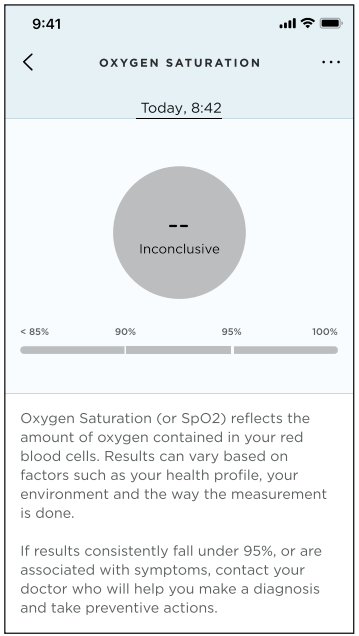

Fig. 6.3
Inconclusive

SpO2 Outputs

Note: The following table for evaluating your measurements does not apply to people with certain pre-existing conditions (e.g. asthma, heart failure, or respiratory diseases) or those who are at altitudes above 1500 meters. If you have a pre-existing condition, always consult your doctor to evaluate your measurements.

SpO2 (oxygen saturation) measurement in %	**Measures to be taken**	**Classification**
95-100	Normal	Normal
90-94	If results consistently fall under 95%, or are associated with symptoms, contact your doctor who will help you make a diagnosis and take preventive actions.	Below awerage
<90	You should take another measurement. If still < 90, seek urgent medical attention.	Low

SpO2 Measurement Information

Note: The following table informs you of the effects of various altitudes on oxygen saturation value and its impact on the human body. It does not apply to people with certain pre-existing conditions (e.g., asthma, heart failure, respiratory diseases). People with pre-existing conditions may show signs of illness, such as hypoxia, at lower altitudes.

Altitude	**Expected SpO2 value (oxygen saturation in %)**	**Impact on human body**
1500-2500m	>90	No altitude sickness (normally)
2500-3500m	90	Altitude sickness, acclimatization recommended
3500-5800m	<90	Very frequent altitude sickness, acclimatization absolutely essential
5800-7500m	<80	Severe hypoxia, only limited length of stay possible

Technical specifications

Product Name	**Scan Monitor**
Model	HWA09
ECG Sensor	3 stainless steel electrodes
SpO2 Sensor	Green wavelength: 530 nm (522-542 nm) Red wavelength: 655 nm (652-658 nm) Infrared (IR) wavelength: 940 nm (930-950 nm)
Maximum Optical Power	Green: 0.56 mW Red: 0.52 mW IR: 0.44 mW
Operating Conditions	+5°C to 40°C 20 to 90% relative humidity (non-condensing) -700-1060hPa
Storage and Transport Conditions	-25°C to 70°C 20 to 90% relative humidity (non condensing) - Max altitude: 2000m
Battery Operated	30 days typical use on a single charge
Power Source	3.6 Vdc Lithium ion battery (Use the charging cable Withings SA ASM-808 2.5W) (included) and a DC 5V power adapter
Wireless Transmission	BLE
Measurement Range (Heart Rate)	30 bpm to 230 bpm
Oxygen Saturation Display range	85% to 100% (≤3.5% RMSE)
Display	OLED on the watch and in-app

Wireless information

Wireless Specifications:

Wireless Technology	Bluetooth BLE
Version	Supported BT5.1
Operation Frequency	2402MHz- 2480MHz
Transmission power	+8dBm (max)
Modulation	GFSK
Receiver sensitivity	-96dBm

The wireless communication of the Scan Monitor is supported by a BLE communication. This communication is established between the Scan Monitor and the Health Mate Companion App. The communication between the Scan Monitor and the Companion app is encrypted through an exchange of a paired key.

The communication latency between the Scan Monitor and its companion app is inferior to 10 seconds.

Wireless information

A maximum operating distance of 5 meters allow to have a latency inferior to 10 seconds. The communication security is implemented by default (encrypted communication).

The Health Mate companion app shall be downloaded from official stores (App store and Google Play store) and smartphones shall be up to date.

Versions supported by the companion app and the Scan Monitor are iOS 12 or later or Android 8 or later.

In case of communication failure, you should follow the related troubleshooting. Measurements are stored within the ScanWatch.

The communication between the Scan Monitor and the companion is not modified with sources of interferences signals located within 5 meters.

This wireless coexistence has been tested in accordance with the following standards:
- ANSI C63.27:2017 and,
- AAMI TIR69:2017

Electromagnetic disturbances have been tested in accordance with the standard IEC 60601-1-2:2014.

Security

Withings recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your phone to add a layer of security. It is important to secure your phone since you will be storing personal health information. Users will also receive additional update notifications on the device via the app, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes.

Safety and Performance

Scan Monitor software's ability to accurately classify an ECG recording into Atrial Fibrillation and normal sinus rhythm categories was tested according to the IEC 60601-2-47* standard and a clinical study with 262 subjects. On five public databases, the Scan Monitor demonstrated 99.06% sensitivity in classifying Atrial Fibrillation and 98.66% specificity in classifying normal sinus rhythm in classifiable recordings. In the beat-to-beat detection of QRS complexes, Scan Monitor reached a F1-score of at least 99.19% on all the datasets, with the exception of NSTDB where the F1-score was 90.65% because of digitally added noise.

Rhythm classification by Scan Monitor was compared to ECG recordings reviewed by cardiologists in a clinical validation study with 262 patients. 19.5% of recordings were inconclusive. On conclusive recordings, the sensitivity in classifying Atrial Fibrillation was 96.3% (lower bound of the 95% confidence interval: 89.4%) and the specificity in detecting normal sinus rhythm was 100.0% (lower bound of the 95% confidence interval: 96.7%).

These results reflect use in a controlled environment. Real-world use of Scan Monitor may result in a greater number of strips being deemed inconclusive.

**IEC 60601-2-47:2012: Requirements for the Basic Safety and Essential Performance of Ambulatory Electrocardiographic Systems.*

Safety and Performance

Regarding safety, the ScanWatch has been tested and deemed in compliance according to IEC 60601-1 and its applicable collateral standards (IEC 60601-1-2:2014, IEC 60601-1-11:2015).

This device is in compliance with ISO 10993-1:2009.

The safety and performance of the pulse oximetry feature has been tested against IEC 80601-2-61:2017.

RF Statement:

Guidance and manufacturer's declaration-electromagnetic emissions

Scan Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Scan Monitor should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
CE emissions CISPR11	Group 1	Scan Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RE emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	Scan Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Declaration: Electromagnetic emissions and immunity for equipment and systems that are not life-supporting and are specified for use only in a shielded location.

Declaration: Electromagnetic immunity

Scan Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Scan Monitor should ensure that it is used in such an environment.

Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment—guidance
Conducted	3 Vrms	N/A	N/A
RFIEC 61000-4-6	150kHz to 80MHz	N/A	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the equipment or system including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±2kV, ±4kV, ±6kV, ± 8kV Air: ±2kV, ±4kV, ± 8kV, ±15kV	Contact: ±2kV, ±4kV, ±6kV, ± 8kV Air: ±2kV, ±4kV, ± 8kV, ±15kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment-guidance
Electrical fast transient/ burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	N/A	The main power quality should be of the kind used in a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	N/A	The main power quality should be of the kind used in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	-5% UT (95% dip in UT) for 0.5 cycles, -40% UT (60% dip in UT) for 5 cycles, -70% UT (30% dip in UT) for 25 cycles, -5% UT (95% dip in UT) for 5 sec	N/A	The main power quality should be of the kind used in a typical commercial or hospital environment. If the user of the equipment or system requires continued operation during power main interruptions, it is recommended that the equipment or system be powered from an interruptible power supply or a battery.
Power frequency (50/ 60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60Hz	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Troubleshooting – Syncing with App

I’m having syncing issues with my watch.

Solutions:

- Make sure that your ScanWatch appears in Devices in the Health Mate App, if not, you need to install it
- Select Device in the Health Mate app and make sure that your ScanWatch is connected
- If necessary, try to turn on the Airplane mode on your mobile device and then turn it back off
- If necessary, reboot your ScanWatch. Press and hold the button of your watch for 20 seconds
- If necessary, reboot your mobile phone

Troubleshooting – ECG

If you experience difficulties in operating your Scan Monitor, refer to the troubleshooting guide below.

I cannot get the Scan Monitor to take an ECG reading.
Solutions:

- Make sure your wrist and your ScanWatch are clean and dry. Water and sweat can cause a poor recording
- Ensure that your ScanWatch, arms, and hands remain still during recordings
- Ensure that you have completed all of the setup steps in the Health Mate app on your smartphone

I have an inconclusive measurement. It looks like the ECG recording has a lot of artefacts, noise, or interference.
Solutions:

- Rest your arms on a table while you take a recording. Try to relax and don't move too much
- Tighten the band so that the back of the watch is in contact with the skin of the wrist.
  When moving the watch slightly, the skin should move with it
- Move away from any electronics that are plugged into an outlet to avoid electrical interference

Troubleshooting – ECG

The ECG waveforms appear upside down.
Solutions:

- The device orientation may be set to the wrong wrist. On your smartphone, go to the Health Mate app. Tap Devices > More Settings > Device Orientation

- All data recorded during an ECG measurement is saved to the Health Mate app on your smartphone. If you choose to, you can share that Information by creating a PDF

Troubleshooting – SpO2

ScanWatch indicates that I am not staying still during SpO2 measurements.
Solutions:

- Ensure that your ScanWatch, arms, and hands remain still during recordings
- Ensure that your hand is comfortably resting on a flat surface
- Do not move or talk during the entirety of the measurement

Troubleshooting – SpO2

I have an inconclusive SpO2 measurement.
Solutions:

- Ensure that you have completed all of the setup steps in the Health Mate app on your smartphone
- Rest your arms on a table while you take a recording. Ensure that your palm is open and try to relax your hand
- If you have low skin perfusion (for instance, due to low temperatures), scrub your wrist at the watch location to increase skin perfusion
- Make sure that your ScanWatch is not loose on your wrist. Tighten the band until it is snug but comfortable, and ensure that the watch stays in place even when you are moving. Wearing the watch closer to the elbow can help you to obtain a better fit
- Push slightly on the top of the watch with two fingers to improve the contact between the skin and the watch
- A flexible strap (silicone or FKM type) helps to better fit your watch around your arms and thus more easily obtain a conclusive result.

Cleaning and Disposal

Cleaning the ScanWatch:

- When needed, use a lint-free cloth moistened with warm water to clean the top housing and casing of your ScanWatch
- Run the wristband under warm water and rub it with hypoallergenic soap to clean it
- Dry the wristband with a soft cloth

Disposal:

ScanWatch is classified as electrical and electronic equipment. Such items should not be mixed with general household waste and must be taken to dedicated collection points at the end of their working life for proper treatment, recovery and recycling.

Equipment symbols

Symbol	Description
	Manufacturer
SN	Serial number
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Consult instructions for use
RxOnly	Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner
	Follow instructions for use
	Type BF applied part
	No SpO2 Alarm
IP22	Ingress of water or particulate matter
	Complies with waste electrical and electronic equipment directive

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