Withings HWA10 ScanWatch 2 with Scan Monitor User Manual

WITHINGS

Rx

Contents

HWA10 ScanWatch 2 with Scan Monitor

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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 2.

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 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

⚠ Before using the equipment, be sure to read this equipment manual carefully

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.
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 2 if it is damaged. Use of a damaged device could cause patient injury or equipment failure.
DO NOT take recordings when ScanWatch 2 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 2 is outside of the operational temperature range (5°C – 40°C) indicated in the ScanWatch 2 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. No modification of this equipment is allowed.
DO NOT modify this equipment without authorization of the manufacturer. As the power cord of the charger can cause strangulation 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) or over 50°C (+/-5°C).

Important notes

The Scan Monitor one output: ECG for Atrial Fibrillation
The device conforms to IP22 requirements.
The Scan Monitor is intended for use in adults (22 years or older in the U.S.) and with no restrictions on weight.
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 feature.
The expected service life for Scan Monitor and its accessories is 2 years.
When in need of assistance on using, maintaining or to report unexpected events please contact the 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.
Exposing the device to prolonged lint, dust or sunlight might reduce its life or damage it. A damaged electrode or sensor may lead to incorrect measurements.

Using the Scan Monitor

Before you start: – Before being able to use the Scan Monitor, you have to download the Withings app in order to activate it – Scan Monitor is only available for Withings ScanWatch 2 when it is paired with a smartphone with iOS 15 or later or Android 9 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 Withings app, use the following link: **go.withings.com**
Setup:
– Open the Withings app after having downloaded it from stores (App store or Google Play store)
– In the Devices tab, select “Install a device”, then select “Watches”
– Select the product “ScanWatch 2”
– 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 2 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 2 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 2 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.

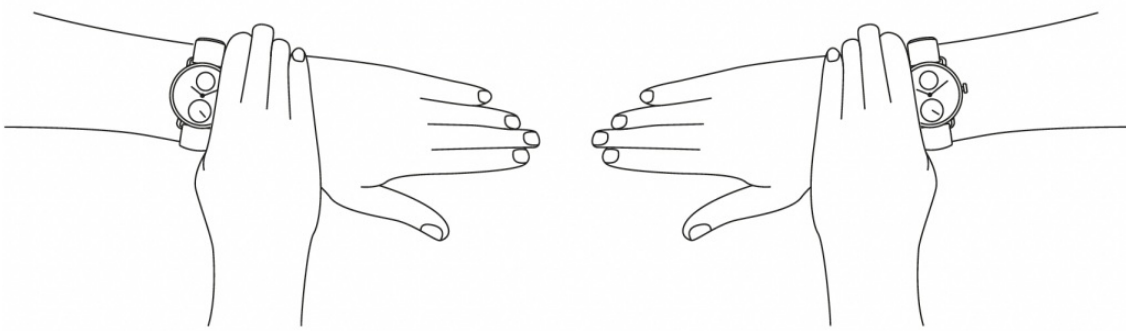

Fig. 1 – How to place the second hand to get an ECG measurement

– 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 Withings 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 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.

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 Withings 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.
Possible outputs in the Withings app:

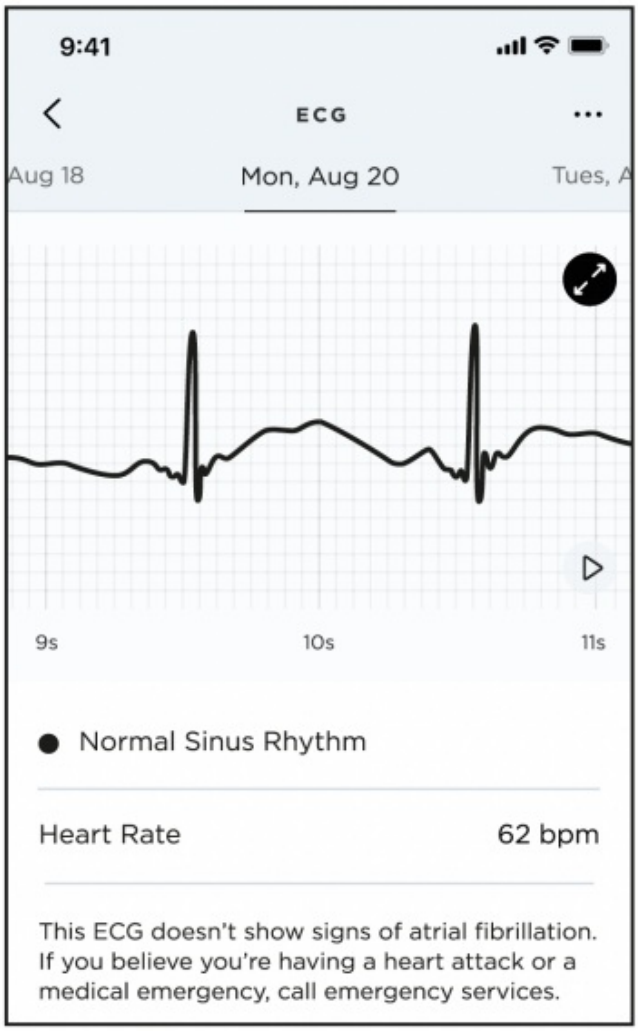

Fig. 3.1 Normal Sinus Rhythm

Fig. 3.2 Signs of Atrial Fibrillation

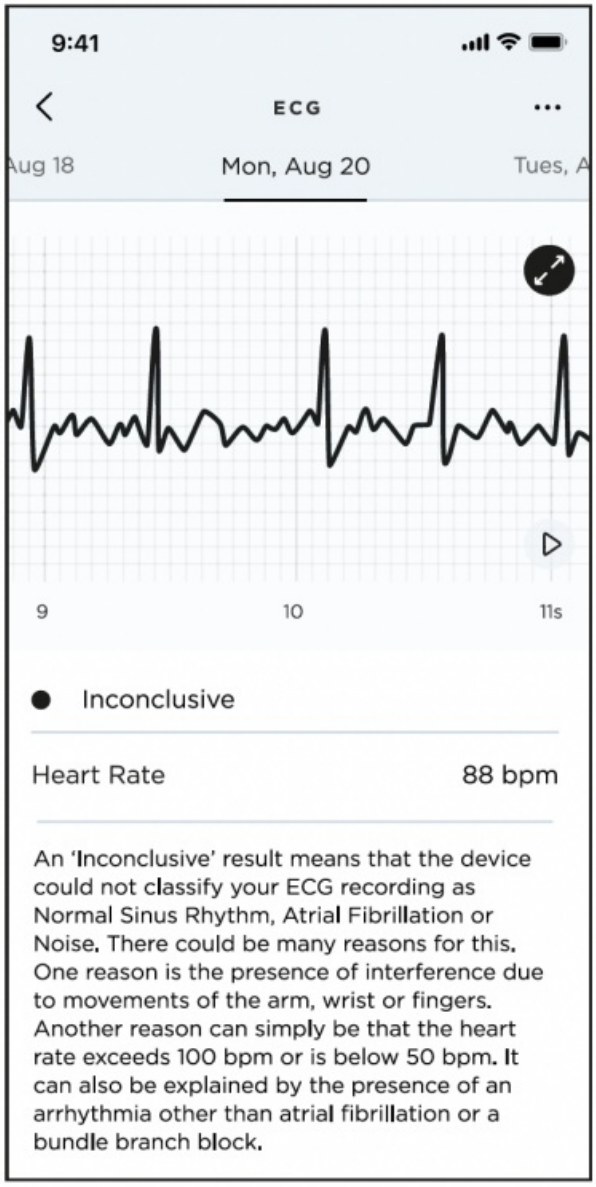

Fig. 3.3 Inconclusive

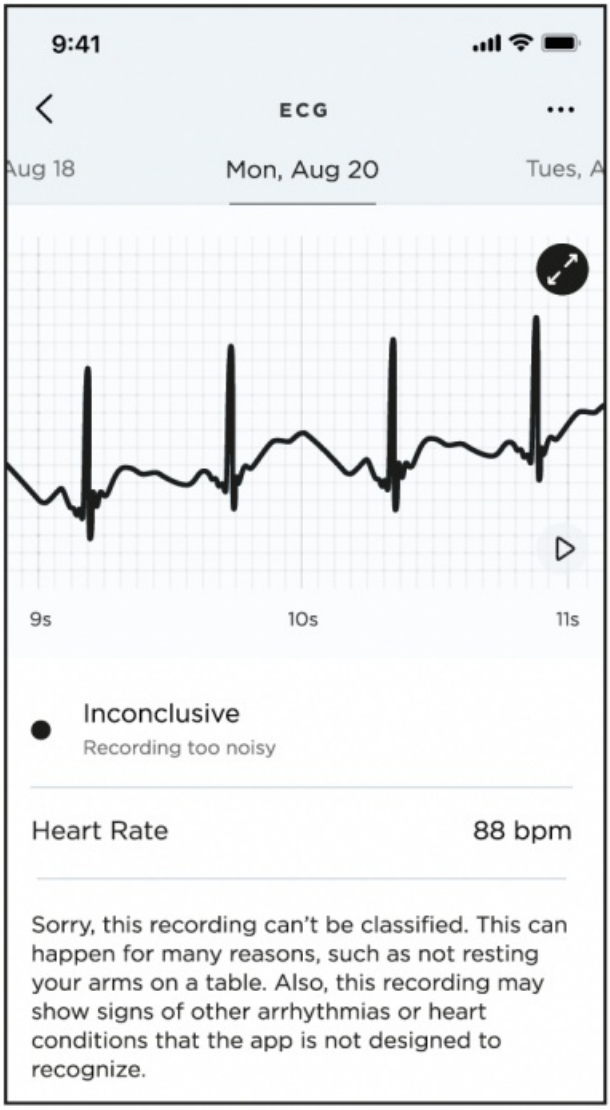

Fig. 3.4 Noise

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, Withings app. generated by the Withings 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

Technical specifications

Product Name: Scan Monitor
Model: HWA10 ECG Sensor: 2 stainless steel electrodes (case back electrodes and bezel electrodes) or
– 1 stainless steel electrodes (case back electrodes) and 1 titanium electrode (bezel electrode) or
– 2 stainless steel electrodes coated with TiCN/Au
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
If storage conditions are different from the operating conditions indicated in the technical specifications, wait 30 minutes before using the device.
Battery Operated: 30 days typical use on a single charge
Power Source: 3.87 Vdc Lithium ion battery (Use the charging cable and Withings hwa10 watch charger ASM-13639 5 VDC 500mA) (included) and a DC 5V power adapter that was certificated by IEC 60601-1.
Wireless Transmission: BLE

Measurement Range (Heart Rate): 30 bpm to 230 bpm
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 Withings 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. A maximum operating distance of 5 meters allows a latency inferior to 10 seconds. The communication security is implemented by default (encrypted communication).
The Withings 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 15 or later or Android 9 or later.
In case of communication failure, you should follow the related troubleshooting. Measurements are stored within the ScanWatch 2.
The communication between the Scan Monitor and the companion is not modified with sources of interference 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.
Regarding safety, the ScanWatch 2 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.

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 intemal function. Therefore, its RF emissions are very low and are not likely lo cause any interference in Nearby electronic equipment.
RF 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 tow-voitage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Not applicable	Scan Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public tow-voitage power supply network that supplies buildings used for domestic purposes.

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 le vel	Electromagnetic environment – guida nce
Conducted	3 Vrms	N/A	N/A
RFIEC 61000-4-6	150kHz to 80MHz	N/A	N/A
Radiated RF IEC 61000 -4-3	10 V/m 80 MHz to 2.7 GHz	N/A	Portable and mobile RF communicati ons equipment should be used no clo ser to any part of the equipment or sy stem including cables than the recom mended separation distance calculat ed from the equation applicable to th e frequency of the transmitter. Interfe rence 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: ±2k V, ±4kV, ± 8k V, ±15kV	Floors should be wood, concrete or c eramic tile. If floors are covered with synthetic material, the relative humidi ty should be at least 30%.
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 t he 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 t he kind used in a typical commercial or hospital environment.
Voltage dips, short inter ruptions and voltage var iations on power supply input lines IEC 61000-4 -11	-5% UT (95% dip in UT) for N/A 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 t he kind used in a typical commercial or hospital environment. If the user of the equipment or system requires co ntinued 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/ 6 0Hz) 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 s hould be at levels characteristic of a t ypical location in a typical commercial or hospital environment.

Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device,pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:
– Reorient or relocate the receiving antenna.
– Increase the separation between the equipment and receiver.
– Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

– Consult the dealer or an experienced radio/TV technician for help.
FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
Accessing the FCCID E-Label:
Open the Withings app, go to "Devices" > Select your ScanWatch 2 > See more
IMPORTANT NOTE:
Radiation Exposure Statement:
IMPORTANT NOTE:
Radiation Exposure Statement:
The product comply with the US portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Troubleshooting Syncing with App

I'm having syncing issues with my watch.
Solutions:
– Make sure that your ScanWatch 2 appears in Devices in the Withings App, if not, you need to install it
– Select Device in the Withings app and make sure that your ScanWatch 2 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 2. 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 2 are clean and dry. Water and sweat can cause a poor recording
– Ensure that your ScanWatch 2, arms, and hands remain still during recordings
– Ensure that you have completed all of the setup steps in the Withings 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 The ECG waveforms appear upside down.
Solutions:
– The device orientation may be set to the wrong wrist. On your smartphone, go to the Withings app. Tap Devices > More Settings > Device Orientation
– All data recorded during an ECG measurement is saved to the Withings app on your smartphone. If you choose to, you can share that Information by creating a PDF

Cleaning and Disposal

Cleaning the ScanWatch 2:
– When needed, use a lint-free cloth moistened with warm water to clean the top housing and casing of your ScanWatch 2 – Run the wristband under warm water and rub it with hypoallergenic soap to clean it
– Dry the wristband with a soft cloth
Disposal:
ScanWatch 2 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

	Manufacturer
	Serial number
	Temperature limit
	Humidity limitation
	Atmospheric pressure Limitation
	Consult instructions for use
RX ONLY	Federal law (USA) restricts this device to sale by or on the order of a licensed practitione r
	Follow instructions for use
	Type BF applied part (case)
IP22	Ingress of water or particulate matter
	Complies with waste electrical and electronic equipment directive
	California Energy Commision approval
	Federal Communications Commission

support.withings.com
– 2 rue Maurice Hartmann, 92130 Issy-les-Moulineaux

Documents / Resources

	Withings HWA10 ScanWatch 2 with Scan Monitor [pdf] User Manual HWA10 ScanWatch 2 with Scan Monitor, HWA10, ScanWatch 2 with Scan Monitor, 2 with Scan Monitor, Scan Monitor, Monitor

References

- User Manual