Withings ECG App

Product Guide: Instructions for Use

Disclaimer: Information in this guide may change without notice.

This leaflet explains how to use the Withings ECG App on your watch.

Important notice

This guide explains how to use the Withings ECG App with your ScanWatch 2.
Instructions for Use of ScanWatch 2 are described in the User Guide provided with the product.

Please read the following information carefully before using the Withings ECG App.

Please contact Withings when in need of assistance, setting up, using or maintaining the device or to report unexpected operations or events.
Any serious incident that has occurred in relation to the Withings ECG App or ScanWatch 2 should be reported to Withings and regulatory/competent authorities in your country of residence.

Withings **2 rue Maurice Hartmann** **92130** **Issy-les-Moulineaux,** **FRANCE**	CE 1282

Indications for Use

(Intended for US region)

The Withings ECG App is a software-only device intended for use with ScanWatch to create, record, store, transfer and display single channel electrocardiogram (ECG) similar to a Lead I ECG. The Withings ECG App determines the presence of atrial fibrillation (AFib), sinus rhythm, and high heart rate (no detected AFib with heart rate 100-150 bpm) on a classifiable waveform. The Withings ECG App is not recommended for users with other known arrhythmias.

The Withings ECG App is intended for over-the-counter (OTC) use. The ECG data displayed by the Withings ECG App is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment.

The ECG acquired by ScanWatch is not intended for manual and/or automated measurement of QT-interval.

The ECG app is not intended for use by people under 22 years old.

Warnings and precautions ⚠

The Withings ECG App cannot check for signs of heart attacks or ischemic heart conditions. If you experience chest pain, pressure, tightness or what you think is a heart attack, call emergency services. If you believe you are having a medical emergency, call emergency services.

DO NOT take recordings when the device is in close proximity to strong electromagnetic fields (for example, X-Ray equipment, electromagnetic anti-theft systems, and metal detectors).



Do NOT take recording during a medical procedure (e.g. magnetic resonance imaging (MRI), diathermy, and electrocautery).

Do NOT take an ECG recording while traveling on an airplane.

DO NOT use the Withings ECG App if ScanWatch is damaged. Use of a damaged device could cause patient injury or equipment.

The power cord of the charger may cause a strangulation effect due to excessive length. Keep it away from children and pets.

Interpretations made by Withings ECG App are potential findings, Withings ECG App cannot diagnose cardiac conditions. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.

The waveform generated by Withings ECG App is meant to supplement rhythm classification for the purposes of discriminating Afib from sinus rhythm and high heart rate and not intended to replace traditional methods of diagnosis or treatment.

Factors and conditions impacting performance:

- Skin and contact factors: Excessive arm hair, or dry skin may interfere with electrode contact and signal quality. Ensure skin is clean, and free of obstructions.
- Motion and activity: Movement, tremors, or vibrations can disrupt readings. Remain still, seated, and avoid external vibrations during the measurement.
- Anatomical variations: Scars and tattoos may reduce electrode contact quality. Adjust the wristband for a snug fit to optimize performance.
- Physiological conditions: Certain physiological conditions can prevent some people from having a strong enough signal for the Withings ECG App to detect and analyze.

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

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

Withings ECG App is not intended to identify heart-related conditions other than Afib.

Withings ECG App is not intended for use by individuals under the age of 22.

DO NOT take a recording during physical activity.

DO NOT take recordings when the device is outside the operational temperature range and humidity range indicated in the device user manual.

DO NOT use the Withings ECG App with a cardiac pacemaker, ICD, or other implanted electronic devices.

This device complies with applicable electromagnetic compatibility (EMC) requirements to ensure performance in the presence of electromagnetic disturbances.

Electromagnetic disturbances may cause temporary loss of function, degraded signal quality, or device interoperability. If this occurs:

- The device may fail to record or display ECG readings accurately.
- The user may receive a notification indicating an error or inability to record an ECG.
- Move the device to an environment free from electromagnetic interference (e.g., away from active RF transmitters or industrial machinery).
- Ensure all accessories and external equipment used with the device comply with EMC requirements specified in the technical documentation.
- Restart the device or reattempt the ECG recording after resolving interference.

Using the Withings ECG App with ScanWatch 2

Before you start:

- Before being able to use the Withings ECG App, you need to download the Withings companion app on your phone or tablet and create an account;
- Only use official app stores to download the app. To ensure that the app is the official Withings app, use the following link: https://go.withings.com.
- The Withings ECG app is compatible with smartphones or tablets with iOS 15 or later, or with 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;
- The mobile application is not intended to be used on a computer. No anti-virus software is needed.

You are now ready to set up ScanWatch 2 with the Withings companion app on your iOS or Android device. Please note that the Withings ECG App is intended to be used with ScanWatch 2.

Using the Withings ECG App

Setup and Onboarding:

- Once you have downloaded the Withings companion app from the official store (App store or Google Play store), open the app - see previous page for more information.
- 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.
- After pairing, a tutorial section will be available. Follow the ECG tutorial in order to activate Withings ECG App. You may exit on-boarding at any time by tapping Cancel, but you will not be able to take any ECG recording in this case.

What is an ECG?

How Withings ECG App 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. The Withings ECG App measures a waveform similar to one of those twelve waveforms. This configuration is known as a lead I ECG.
- A lead I ECG is able to provide information about heart rate and heart rhythm and enables classification of Atrial Fibrillation (AFib).

Recording an ECG

How to take an ECG recording:

- Select your measurement wrist on the companion app in Devices > ScanWatch 2 > ECG. Make sure your ScanWatch 2 is snug on the wrist.
- Launch 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 measurement from the Withings companion app.
- Rest your arms on a table, and cover the top electrode with your other hand (as shown in Fig. 1). You do not need to press the bezel during the session.

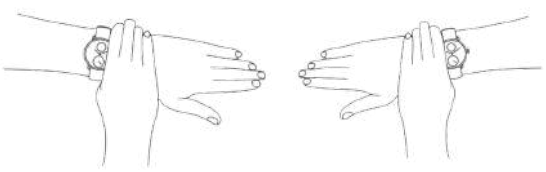


Fig. 1 - How to place the second hand to get an ECG measurement

- 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 the second vibration.

ECG Outputs

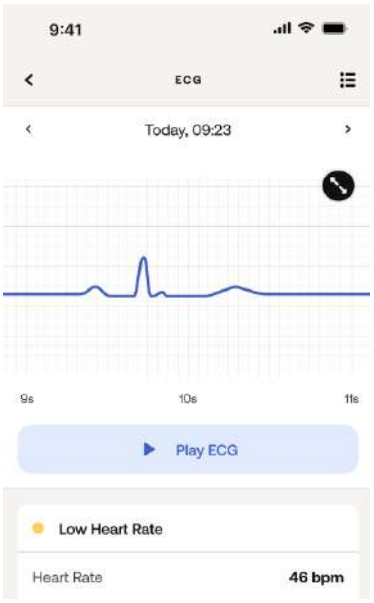
ECG classification:

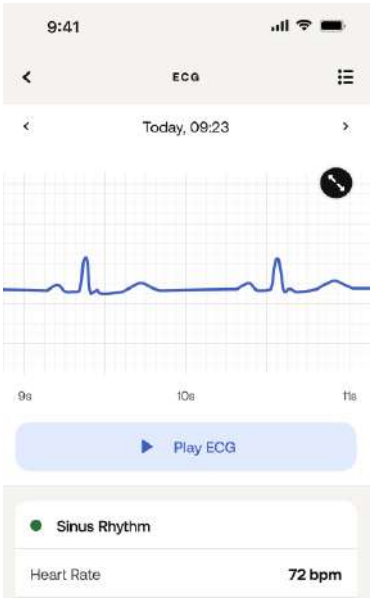
After an ECG recording, you will see one of the following classifications for the recording:

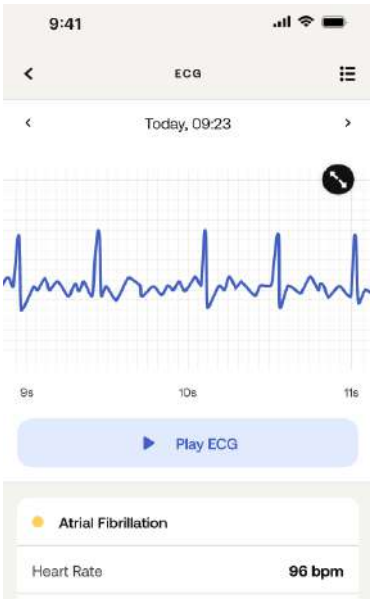
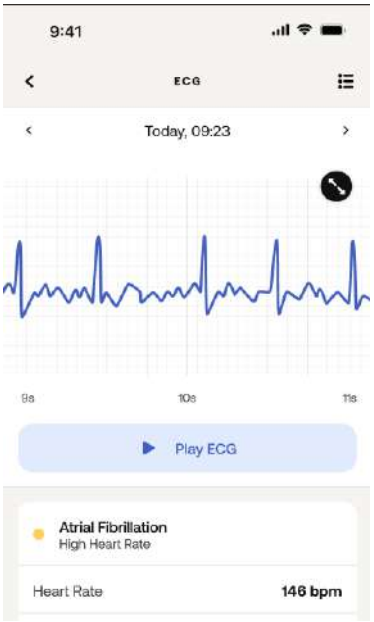
- Low Heart Rate (heart rate < 50 bpm)
- High Heart Rate (heart rate > 150 bpm)
- Sinus Rhythm (heart rate between 50-99 bpm)
- High Heart Rate (No signs of AFib) (heart rate between 100-150 bpm)
- Atrial Fibrillation (heart rate between 50-99 bpm)
- Atrial Fibrillation - High Heart Rate (heart rate between 100-150 bpm)
- Inconclusive
- Poor Recording

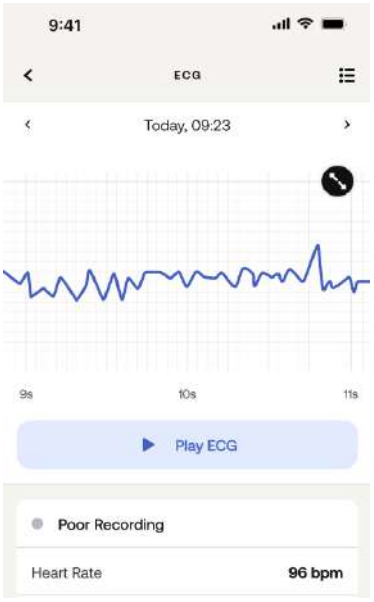
After the ECG recording you will also see your median heart rate and your ECG tracing.
Heart Rate Measurement Range: 30 bpm to 220 bpm

Understanding ECG classifications:

Device	App	Explanation
		**Low Heart Rate** Note: Withings ECG App never checks for heart attacks. A *Low Heart Rate* result means your heart is beating less than 50 beats per minute (bpm). This recording cannot be classified by Withings ECG App. A low heart rate can happen if electrical signals are not properly conducted through the heart. Some medicines can also cause a low heart rate. Some elite athletes may also have a low heart rate. Talk to your doctor if you have questions about your ECG recording.
		**High Heart Rate** Note: Withings ECG App never checks for heart attacks. A *High Heart Rate* result means your heart is beating above 150 beats per minute (bpm). This recording cannot be classified by Withings ECG App. Many different things can cause a high heart rate. A heart rate may be high because of exercise, stress, dehydration, infection, AFib, another arrhythmia or another cause. Talk to your doctor if you have questions about your ECG recording.

		**Sinus Rhythm** Note: Withings ECG App never checks for heart attacks. A *Sinus Rhythm* result means your heart rate is between 50 and 99 beats per minute (bpm) and is beating regularly.
		**High Heart Rate (No signs of AFib)** Note: Withings ECG App never checks for heart attacks. A *High Heart Rate (No signs of AFib)* result means the heart rate is beating between 100 and 150 beats per minute (bpm) and does not show any signs of Atrial Fibrillation. Many different things can cause a high heart rate. A heart rate may be high because of exercise, stress, dehydration, infection, an arrhythmia, or another cause. Talk to your doctor if you have questions about your ECG recording.

 *Note: this text ("Atrial Fibrillation") will scroll across the watch screen.*		**Atrial Fibrillation** Note: Withings ECG App never checks for heart attacks. An Atrial Fibrillation result means the heart rate is between 50 and 99 beats per minute (bpm) and is beating in an irregular pattern.. Talk to your doctor if you have questions about your ECG recording.
 *Note: this text ("Atrial Fibrillation") will scroll across the watch screen.*		**Atrial Fibrillation - High Heart Rate** Note: Withings ECG App never checks for heart attacks. An Atrial Fibrillation - High HR result means your heart rate is beating between 100 and 150 beats per minute and is beating in an irregular pattern. Talk to your doctor if you have questions about your ECG recording.

		**Inconclusive** Note: Withings ECG App never checks for heart attacks. This ECG is inconclusive. If you repeatedly get this result or you are not feeling well, you should talk to your doctor.
		**Poor Recording** Note: Withings ECG App never checks for heart attacks. A Poor Recording result means the recording quality is low and the ECG cannot be classified. This may be caused by errors during the measurement. Some things that can cause this type of result are: excessive movement that causes a signal of poor quality; OR proximity to an electrical device that generates strong electromagnetic fields; OR not covering the electrodes correctly. A small percentage of people may have certain physiological conditions that prevent them from creating enough signal to produce a quality recording. You may 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 Withings app on your smartphone.

Sharing ECG Results

How to share your ECG with your physician:

Once the ECG measurement feature is activated, the results of the ECG can be shared with a physician as a pdf, generated by the Withings companion app.

The pdf includes the following information:

- The ECG strip.
- The median heart rate, derived from the ECG.
- The classification of the ECG according to the detection algorithm.

Safety and Performance

Withings ECG App's ability to accurately classify an ECG recording into Atrial Fibrillation and normal sinus rhythm categories was tested in a clinical study with 626 subjects. Rhythm classification by Withings ECG App was compared to 12-lead ECG recordings simultaneously and was reviewed by cardiologists. The Withings ECG App demonstrated 99.7 % sensitivity in classifying Afib (HR 50-150 bpm) and 99.8% specificity in classifying normal sinus rhythm (HR 50-150 bpm) in classifiable recordings.

The performance of the ECG function has been tested against ANSI/AAMI/IEC 60601-2-47:2012: Requirements for the Basic Safety and Essential Performance of Ambulatory Electrocardiographic Systems.

ML algorithm training and testing

The user datasets (Deep Train and Heartbeats) were used to run 4-Fold cross validations and act as train and test sets for hyperparameters tuning. Demographic information is summarized in Table 1.

	"Deep train" (n=11701)	**"Heartbeats"** (n=5089)
Geography	European Union	United States
Race and Ethnicity	Not captured*	Not captured*
Sex	73% male, 27% female	76% male, 24% female
Mean age (std)	59.2 (16.3) years	51.3 (14.5) years
Mean BMI (std)	27.3 (4.8)	28.3 (5.6)
Mean systolic blood pressure (std)	128.7 (15.3) mmHg	127.3 (15.9) mmHg
Mean diastolic blood pressure	79.9 (10.6) mmHg	79.2 (10.9) mmHg

Table 1: Demographic datasets used for training and testing of the ML algorithm.

* Due to GDPR regulations, Servers are in Europe do not the right to hold users' race and ethnicity data

Three of the clinical study datasets (HWA08 test, HWA08 CE, WEFA HWA09 part 1) were used as a first layer of validation sets to verify that the models trained were capable of generalizing. A fourth dataset, WEFA HWA09 part 2, was used as a second layer of validation after the software freeze ("locked algorithm") to verify that the hyperparameters tuning were not overfit. Table 2 summarizes the demographic information of the 4 datasets.

	HWA08 test (n=131)	**HWA08 CE** (n=137)	**WEFA HWA09 part 1** (n=162)	**WEFA HWA09 part 2** (n=100)
Age	Not Available	66.6 (13.5)	69.6 (13.6)	65.2 (16.4)
Gender		M: 59%, F: 41%	M: 64%, F: 36%	M: 56%, F: 44%
Race and Ethnicity Asian African American Caucasian Other		Not available	included in Other 9% 78% 13%	
BMI		27.8 (5.9)	28.0 (6.1)	26.7 (4.7)
Hypertension		43%	49%	56%
Dyslipidemia		21%	35%	33%
Overweight or obesity		55%	43%	41%
Diabetes		22%	22%	21%
VHD		9.5%	22%	10%
CAD		9.5%	23%	34%
HF		17.5%	2%	22%
MI, ischemic cardiopathy		7.3%	5%	23%
TIA or stroke		9.5%	4%	6%
POAD or AAA		-	4%	16%

Table 2: Demographic information of the datasets used for the pre-clinical validation of the ML algorithm.

Troubleshooting – Syncing with the Withings 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, please install it.
- Make sure your ScanWatch 2 has enough battery life. Recharge your watch if necessary using the included power cable. When in charge, your ScanWatch 2 will display the percentage of battery left.
- 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 with operating your Withings ECG App, refer to the troubleshooting guide below.

If you cannot fix the problem using the troubleshooting instructions, please contact Withings.

I cannot get the Withings ECG App to take an ECG reading.
Solutions:

- Dry or cool skin, not enough skin contact, hairy wrist, or user movement can cause the Withings ECG app to not start recording, or to stop recording.

Before taking an ECG:

- Put some moisturizing lotion on your hands and wrist.
- If your hands and arms are cold, remove your ScanWatch 2 and rub the wrist gently to warm up the skin. Put your ScanWatch 2 back on and try again to record an ECG.
- 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 artifacts, 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.
- Avoid close proximity to items that may cause 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 > ScanWatch 2 > ECG

Cleaning and Maintenance of Withings ScanWatch 2

- Use a lint-free cloth moistened with warm water to clean the glass and casing of your Withings ScanWatch 2.
- Run the wristband under warm water and rub it with hypoallergenic soap to clean it
- Dry the wrist band with a soft cloth

Notes:
- Avoid exposure to any chemical products such as solvents, detergents, perfumes, or cosmetics. They may damage the wristband or the casing of the watch.
- If the side button of your Withings ScanWatch 2 appears to be stuck, we advise you to rinse the casing of your watch with warm water and dry it using a lint-free cloth.
- If the altimeter opening of Withings ScanWatch 2 becomes dirty or clogged with debris or sweat, it can prevent the watch from accurately measuring elevation. If this occurs, please clean the case of ScanWatch 2 with warm, soapy water and then allow it to dry. The watch should also be cleaned anytime that you work out with it on.
- Withings does not recommend using an ultrasonic cleaner for Withings ScanWatch 2.
Avoid application of the Withings ScanWatch 2 on a wrist with poor skin integrity.

In case of skin irritation, we advise you to contact a dermatologist before resuming use of your device.

Skin reactions may be caused by:

- An allergic reaction to the materials used in the back casing of the watch,
- A photosensitizing medication.

Note that this device is compliant to IEC 62471 related to the photobiological safety of lamps and lamp systems.

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 Withings ScanWatch 2 is supported by a BLE communication. This communication is established between the Withings ScanWatch 2 and the Withings App. The communication between the Withings ScanWatch 2 and the Withings App is encrypted through an exchange of a paired key.
The communication latency between the Withings ScanWatch 2 and the Withings 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 Withings App 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 Withings ScanWatch 2.
The communication between the Withings ScanWatch 2 and the Withings App 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 C63.27:2021 and AAMI TIR69:2017 (R2020)

Electromagnetic disturbances have been tested in accordance with the standard IEC 60601-1-2:2014/A1:2020 and meets IEC TR 60601-4-2 standard.

RF statement

Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the accompanying documents. Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration-electromagnetic emissions

<table>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below.
The customer or the user of the device should ensure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>CE emissions CISPR11</td><td>Group 1</td><td rowspan="2">The device 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</td></tr>
<tr><td>RE emissions CISPR11</td><td>Class B</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td><td rowspan="2">The device 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</td></tr>
<tr><td>Voltage fluctuations/
Flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

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
Guidance and manufacturer's declaration-electromagnetic immunity

Withings ScanWatch 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Withings ScanWatch 2 should ensure that it is used in such an environment.			
Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms 150kHz to 80MHz	The EUT shall be placed on an insulating support 0.1 m above the ground reference plane (GRP). On all cables to be tested, coupling and decoupling devices shall be inserted. The coupling and decoupling devices shall be placed on the GRP, making direct contact with it at a distance of 0.1 m to 0.3 m from the EUT.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	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: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material the relative humidity 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 the kind used in a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	line(s) to line(s): +/- 1kV	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	Voltage Dips: 0% residual for 0.5 cycle Voltage Dips: 0% residual for 1 cycle Voltage Dips: 70% residual for 25 cycles Voltage Interruptions: 0% residual for 250 cycles	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 uninterruptible 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 or 60 Hz	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Federal Communication Commission interference statement

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.

FCC Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
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 or more 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.

NOTE:
"Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

IMPORTANT NOTE:
Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator & your body.
This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. Country Code selection feature to be disabled for products marketed to the US/CANADA.

Security

Withings recommends that you add a passcode (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 should follow the one time code received by email and two-factor authentication guidelines when logging into Withings App. For more information on two-factor authentication refer to https://support.withings.com/hc/en-us/articles/4409345943697 for iOS users and refer to https://support.withings.com/hc/en-us/articles/21600361983633 for Android users. Users will receive email alerts in case of changes related to password, two-factor authentication and recovery code. Users will also receive additional software update notifications on the device via the Withings App, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes. Users are able to see the currently installed firmware in the Withings App, under Devices > ScanWatch 2. This tab also indicates if an update is available.

Do not install the device on a smartphone that you do not own. Do not use a public Wi-Fi network you don't know. Use a trusted Wi-Fi network with your device. Use a secure channel when you are sharing ECG information with your doctor. Withings also recommends upgrading your Withings App when an upgrade is available. The Withings App is not intended to be used on a computer. No anti-virus software is needed. Only use official app stores to download the Withings application. In case of doubt, use the link go.withings.com.

Device configurations

If needed, users can restore device configurations by following the factory reset procedure. For more information refer to https://support.withings.com/hc/en-us/articles/360010218558.

The device installation will set secured parameters by design. If you notice any cybersecurity vulnerability or incident, do not hesitate to reach the Withings customer support.

Back up mode: All data retrieved by the server and coming from the device is securely backed up everyday. You can download your data at any time by using the export feature within the mobile application (Settings > Download your data).

Security notifications

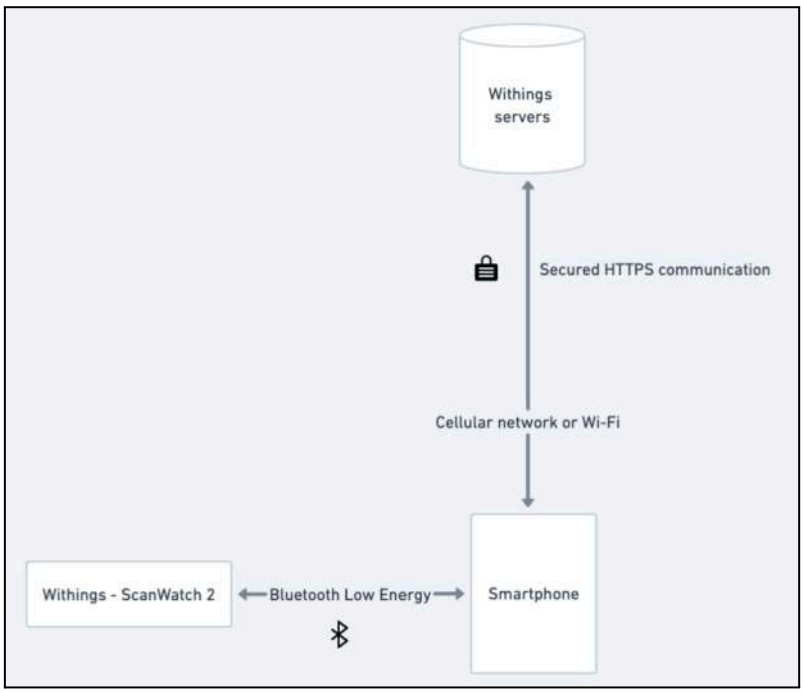
You will receive emails when sensitive actions are performed by yourself such as password update. You can subscribe to our status webpage (status.withings.io) in order to be notified if there is an incident or maintenance ongoing. More information about how Withings protects your data can be found through the Withings' security web page (withings.com/us/en/data-security).

Please note that log files about security events are kept for 1 year in order to investigate if necessary for security purposes. Files are securely stored on our servers in order to prevent any modification.

Decommissioning:

If you no longer use the device, we recommend that you perform a factory reset of your device in order to remove the personal data stored within the device.

Please find below an overview of the secured protocols used to exchange data between your device, your phone and Withings servers.



Libraries within the device

Review performed the 17th of January 2025. Relationships with other components are unknown.

Supplier name	Component name	Version	UUID
Nordic Semiconductor	Nordic Semiconductor Softdevice S140	7.0.1	SPDXRef-SHA1-4cbb92469951b95cb55aae426a3737f38df9f853
AWS	FreeRTOS	10.0.1	cpe:2.3:o:amazon:freertos:10.0.1:*:*:*:*:*:*:*
Free Software foundation	GCC	13.1.2000	SPDXRef-SHA1-32c3257793c7ad5d813b1dbdcd068ace0f17cf12
ARM	CMSIS	5.6.2000	SPDXRef-SHA1-35551ead776071e6bdcee233df511a68041b8308
Packetizer	Packetizer SHA1	1.0	SPDXRef-SHA1-355bf98613feb09540e45adc22156d252d714155
Trusted firmware	mbedTLS	2.3.2000	SPDXRef-SHA1-111a5d725122b01f381e0c2743c0477d1ff93736
Joseph Birr-Pixton	cifra	1.0	SPDXRef-package-cifra
GreenTEG	GreenTEG Algorithms	20231023	SPDXRef-SHA1-3592e1c8ffa032344c4a3e97886494560392d87c

Libraries within the iOS application

Review performed the 17th of January 2025. Relationships with other components are unknown.

Supplier name	Component name	Version	UUID
Pointfreeco	swift-snapshot-testing	1.8.2002	pkg:github/pointfreeco/swift-snapshot-testing@1.8.2
Apple	swift-collections	1.0.3	pkg:github/apple/swift-collections@1.0.3
Mxcl	PromiseKit	6.13.3	pkg:github/mxcl/PromiseKit@6.13.3
Apple	swift-log	1.4.2000	pkg:github/apple/swift-log@1.4.0
Johnsundell	ink	0.5.0	pkg:github/johnsundell/ink@0.5.0
Airbnb	lottie-ios	3.4.2004	pkg:github/airbnb/lottie-ios@3.4.4
Marmelroy	PhoneNumberKit	3.3.2003	pkg:github/marmelroy/PhoneNumberKit@3.3.3

Libraries within the Android application

Review performed the 17th of January 2025. Relationships with other components are unknown.

Supplier name	Component name	Version	PURL (UUID)
Google	firebase-crashlytics-ktx	31.0.1	com.google.firebase:firebase-crashlytics-ktx:31:0:1
Google	firebase-crashlytics-ndk	31.0.1	com.google.firebase:firebase-crashlytics-ndk:31:0:1
Google	firebase-messaging	31.0.1	com.google.firebase:firebase-messaging:31:0:1
Open Source	coil-compose	2.4.0	io.coil-kt:coil-compose:2.4.0
Airbnb	lottie-compose	5.2.0	com.airbnb.android:lottie-compose:5.2.0
Google	accompanist-flowlayout	0.34.0	com.google.accompanist:accompanist-flowlayout:0:34:0
Google	accompanist-navigation-animation	0.34.0	com.google.accompanist:accompanist-navigation-animation:0:34:0
Google	accompanist-navigation-material	0.34.0	com.google.accompanist:accompanist-navigation-material:0:34:0
Google	accompanist-pager	0.34.0	com.google.accompanist:accompanist-pager:0:34:0
Google	accompanist-pager-indicators	0.34.0	com.google.accompanist:accompanist-pager-indicators:0:34:0
Google	accompanist-permissions	0.34.0	com.google.accompanist:accompanist-permissions:0:34:0
Google	accompanist-systemuicontroller	0.34.0	com.google.accompanist:accompanist-pager-indicators:0:34:0
Google	hilt-core	2.50	com.google.dagger:hilt-core:2.50
Open Source	joda-time	2.12.5	joda-time:joda-time:2.12.5
Google	gson	2.10.1	com.google.code.gson:gson:2.10.1
Square	okhttp	4.12.0	com.squareup.okhttp3:okhttp:4.12.0
Square	retrofit	1.9.0	com.squareup.retrofit:retrofit:1.9.0

Square	retrofit	2.9.0	com.squareup.retrofit2:retrofit:2.9.0
Square	converter-gson	2.9.0	com.squareup.retrofit2:converter-gson:2.9.0
Rudderstack	core	1.4.0	com.rudderstack.android.sdk:core:1.4.0

Equipment symbols

	Manufacturer
	Follow Instructions for Use
CE 1282	The CE labeling certifies that the product complies with the essential requirements of Medical Device Regulation 2017/745
Emergo Consulting (UK) Limited c/o Cr360 – UL International, Compass House, Vision Park Histon, Cambridge CB24 9BZ, United Kingdom	
Emergo Australia, Level 20, Tower II Darling Park, 201 Sussex Street- Sydney, NSW 2000 Australia	

WITHINGS

Withings ECG App | Compatible with Withings ScanWatch 2
V5.0 June 2025 © 2025 Withings. All rights reserved.
support.withings.com - 2 rue Maurice Hartmann, 92130 Issy-les-Moulineaux