WITHINGS

PRODUCT GUIDE

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WITHINGS
BeamO

PRODUCT GUIDE

for **US regions only**

Go to page 30 for **NON-US regions**

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

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Important notice

Before using Withings BeamO, review the information in this guide. You may also find this guide online at: https://www.withings.com/guides

Retain this documentation for future reference. Installation instructions are available within the Quick Start Guide provided with this Product Guide. Please contact Withings when needing assistance, setting up, using, or maintaining the device, or reporting unexpected operations or events. Any serious incident concerning Withings BeamO should be reported to Withings and competent authorities in your country of residence.

Disclaimer

Information in this guide may change without notice. To use your Withings BeamO, you need an iOS (16.0 or higher) or Android (9.0 and higher) device to install it. Thereafter, the product can be used without your mobile device on you, thanks to the Wi-Fi, Bluetooth®, and optional cellular (LTE Cat M1) connections. For Bluetooth connection, you will need your phone to synchronize your results to see them in the Withings app.

Product Overview

Withings BeamO is a multifunctional device for at-home health checkups, featuring:

- A 1-lead electrocardiogram with two stainless steel electrodes,
- A pulse oximeter to self-monitor blood oxygen levels (SpO2) and pulse rate (PR),

Product Overview

- A contactless thermometer for body temperature measurements,
- A digital stethoscope to auscultate heart and lung sounds.

The measurements can be used on children and adults according to the table below:

Measurement	Infant & Child (>0 years old)	Adult* *For US region: ≥ 22 years old
Thermometer	✓	✓
Stethoscope	✓	✓
1-Lead Electrocardiogram	×	✓
Pulse oximeter	×	✓

This medical device is intended to be used or operated by adults only (referred to as active patients), with or without medical training. Withings BeamO is suitable for non-professional use at home and can transmit data remotely. It is also designed for use by healthcare professionals.

Intended use

Withings BeamO is a non-sterile, contactless, reusable clinical thermometer intended for the intermittent determination of human body temperature over the temporal artery as the measurement site on people of all ages.

Withings BeamO is also an electronic stethoscope that enables the recording and transmission of auscultation sound data. Withings BeamO is intended to be used by professional users in a clinical environment or by lay users in a non-clinical environment on people of all ages. The electronic stethoscope is for medical diagnostics purposes only. The device is not intended for self-diagnosis.

Withings BeamO is intended to record, display (when prescribed or used under the care of a physician), store, and transfer single-channel electrocardiogram (ECG) rhythms. It is indicated for use with individuals 22 years and older.

The Withings BeamO is also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (blood oxygen, or SpO2) and pulse rate (PR). It is indicated for use with individuals 22 years and older under no motion conditions. The blood oxygen result is not intended for use in the diagnosis or screening of lung disease, and treatment decisions using the device should only be under the advice of a healthcare provider.

Warnings

This device should still be handled with care:
- DO NOT USE the ECG feature with a pacemaker, a defibrilla or, or another electric implant.
- DO NOT USE the Thermometer feature on children born before term.
- The device 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 user.
- The device is intended to be used on intact skin only. Do not take measurements over irritated skin or scars. Do not perform auscultation if there are any wounds or abrasions within the spot examined.
- The device does not provide alarms.
- During pregnancy, accuracy may be impacted.
- This medical product can be operated by adults only. Temperature and stethoscope measurements on children must be performed by an adult. Do not perform ECG and SpO2 measurements on children.
- Withings BeamO contains an electronic stethoscope. It should be used solely for recording body auscultation sounds and transmitting them remotely. This medical product does not analyze the sounds recorded.
- The device contains an electrocardiograph. It should be used solely for the recording of an electrocardiogram, and transmitting ECG waveform remotely. This medical product does not analyze the ECG waveform.
- The power cord of the charger may pose a strangulation risk. Keep it away from children and pets.
- DO NOT take recordings while in proximity to or receiving medical treatment from other equipment (e.g., magnetic resonance imaging (MRI), diathermy (deep heating), lithotripsy, cauterization, and external defibrillation).
- DO NOT USE as an apnea monitor. Oxygen changes may be delayed from when your breathing actually stops.

Self-diagnosis and self-treatment are dangerous. Contact your physician in case of symptoms, doubt, questions, or the following cases:
- if you experience symptoms that could indicate you are experiencing a sudden and/or severe change in health.
- If the temperature increases in neonates and babies under 3 months, patients over 60 years old, immunocompromised patients, bedridden patients, and transplant patients.
- If other symptoms occur such as vomiting, diarrhea, pain, shivering, stiff eck, etc., even if there is no fever
- During pregnancy.

General precautions

- Follow operation and storage conditions as described in the technical specifications section of this guide. Otherwise, measurement results may be impacted.
- Exposing the device to prolonged lint or dust might damage the device or reduce its life.
- Do not submerge the device in water or liquids.
- The USB port should only be used for charging the device or connecting the provided adapter during stethoscope recordings. To recharge the battery, use a power cord that complies with the safety standards of the country in which it is used and that matches the voltage of the power outlet.
- Do not try to repair or modify this device yourself. Do not open or disassemble the device for battery replacement.
- The battery inside the device will stop charging when the temperature is less than 0ºC (+/-5ºC or) or over 45ºC (+/-5ºC).
- Do not use the device or the provided accessories if they are damaged. Do not shake the unit violently. Damaged sensors may lead to incorrect measurements. Inspect for warping, surface damage, or corrosion. The sensor lens is fragile: do not touch it with your finge s
- Do not interconnect this equipment with other equipment or use accessories, detachable parts, or materials not described in the instructions for use. Use of parts and components other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of the device adjacent to other equipment should be avoided because it could result in improper operation such as poor recording with the ECG measurement. If such use is necessary, the device and the other equipment should be observed to verify that they are operating normally.

Self-Monitoring Precautions (pulse oximeter)

- If blood oxygen (SpO2) values indicate hypoxemia, do not self-diagnose and self-medicate. Confirmation by a medical professional is required. Your physician uses the measurements along with other symptoms and your medical history in their treatment decision. This cannot be replaced by a pulse oximeter.
- Do not change your treatment plan on your own. Never alter oxygen delivery settings or medical treatment prescribed by your physician.
- Do not rely only on the readings. Reading can provide a false sense of security to a lung or health condition that has not yet affected your blood oxygen.
- Do self-monitor your oxygen and pulse rate as recommended by your healthcare provider. This does not mean diagnosing and treating.
- Do familiarize yourself with your normal (baseline) SpO2 levels. Focus on changes from your baseline over time and not solely on a single measurement at any given moment
- Do seek medical attention if you are not feeling well even if your readings are normal.
- Do review the information on the limitations and ways to improve the accuracy of the reading provided in this manual.

Factors that may degrade performance of the measurement of blood oxygen (pulse oximetry) include:

- Poor circulation, skin pigmentation, skin thickness, skin temperature, current tobacco use, and use of fingernail polis
- Bright sunlight
- Presence of strong electromagnetic field
- Failure to position finge tip on the device correctly
- Tattoos on the finge s in the region of the optical sensor
- Excessive motion of the arm or finge s
- 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 cuff , or infusion lines
- Hypotension, serious vasoconstriction, serious anemia, or hypothermia

How to take measurements

Withings BeamO allows you to take 4 types of measurements:

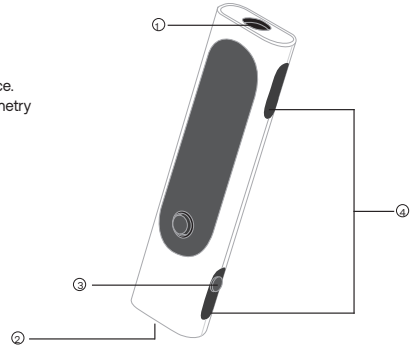
① Temperature measurements using the contactless thermometer.
② Heart and lung sound recordings using the digital stethoscope.
③ Blood oxygen (SpO2) and pulse rate (PR), using the pulse oximeter placed within the electrode surface.
④ Simultaneous ECG and SpO2 measurement with pulse rate (PR), using two electrodes and pulse oximetry sensor.

To set up your device, follow the information in the Quick Start Guide and in the Withings application.

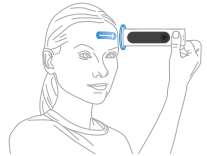
To start a measurement:

1. Press the button to TURN ON the device.
2. Select the correct user.
3. Select the measure to start.

To TURN OFF the device press the ⏻ icon. There is an automatic switch-off after 30 seconds.



Temperature measurement

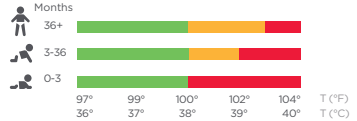


⚠ **Before you start:**
- The device and the patient should stay in the same ambient temperature room for 10 minutes before taking a measurement.
- Infant body temperature may vary more than adult body temperature. Avoid taking measurements on babies after nursing or while they are crying. It is recommended to take measurements on children when they are calm.
- For children under 3 months, perform 3 measurements in a row. If the 3 measurements are different, always take the highest one.
- If the patient has taken a bath or exercised, please wait for 15 minutes before taking a measurement.
- Move hair out of the way and dry any sweat before taking a measurement.

Taking your temperature:
1. Slowly scan once from the middle of the forehead to the top of the ear, as close as possible to the skin.
2. The device will vibrate when the measurement is complete. The temperature will be displayed on the device and the colored icon indicates the fever level according to the user's age.
The unit is either in °F or °C. You can change the unit in the Withings app setting .

LED Colors meaning:
- No fever
- Mild fever
- High fever

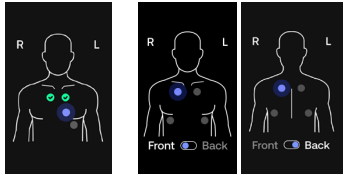
Normal body temperature according to age:



Stethoscope measurement

There are 3 available recording modes:

Heart: Recordings performed on 4 positions on the chest to listen to cardiac sounds.
Lungs: Recordings performed on 8 positions on the chest and back to listen to respiratory sounds.
Wide: Recordings performed positioning the device freely on the body.



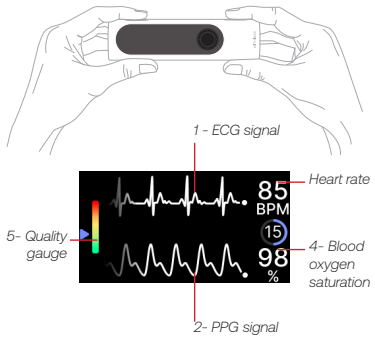
Heart Lung

Before you start:
- Choose a calm, quiet room. Noises or murmurs may hurt the quality of recordings.
- Ensure you are in a comfortable position (preferably sitting down) with support for your hands (thighs or table).
- Do not speak or move during the measurement.
- Place the stethoscope directly on bare skin or wear at most one thin layer of clothing.

Taking a stethoscope recording:
1. Select either Heart, Lungs, or Wide (free position) mode on the device screen.
2. Place the stethoscope at the precise point indicated on the device screen.
3. When you are ready, press the button to start recording at the selected position. Make sure that the stethoscope stays in contact with your body during the whole duration of the measurement.

You can listen to the auscultation sounds during the recording by connecting your headphones to the provided adapter and the USB-C port on the device.
You may end the exam before completing recordings in all indicated positions.

Electrocardiogram (ECG) and and blood oxygen (SpO2) measurements



Before you start:
- Choose a calm, quiet room.
- Ensure you are in a comfortable position (preferably sitting d wn) with a support for your hands (thighs or table).
- Do not speak or move during the measurement.

Recording a simultaneous ECG and SpO2 measurement:
Place your index finge s on the electrodes. Your finger s ould cover the full length of the electrodes. Your finger con act should be light.
The quality gauge (5) guides you to keep good, light contact throughout the measurement. Try to stay in the green zone.

1. Select ECGxSpO2 in the menu screen. Launch the measurement by pressing the button.
- **Note:** if the ECG feature has already been activated, the measurement will start; otherwise, the screen will display an invitation to activate the feature.

Electrocardiogram (ECG) and and blood oxygen (SpO2) measurements

2. The recording will last for 30 seconds.
3. The end of the measurement is confir ed by a vibration.

- For users located in the U.S., the fi st 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 ECG reading will be displayed in the Withings app.

What is an ECG?
- ECG, or electrocardiogram, is the graphical representation of the electrical activity of the heart.
- With each heartbeat, an electrical wave travels through your heart. This wave causes your heart to contract and pump blood.
- In a doctor's offi , 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 device measures a waveform similar to one of those twelve waveforms. This configu ation is known as a single-lead ECG.

Electrocardiogram (ECG) and and blood oxygen (SpO2) measurements

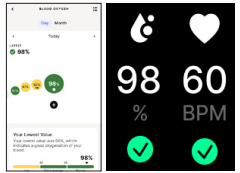
Recording a standalone SpO2 measurement:
Place your index finger on t e electrode with the pulse oximetry sensor. Your finger s ould cover the full length of the electrode. Your finger con act should be light.
The quality gauge guides you to keep good, light contact throughout the measurement. Try to stay in the green zone.
1. Select SpO2 in the menu screen. Launch the measurement by pressing the button.
2. The recording will last for 15 seconds.
3. The end of the measurement is confir ed by a vibration

What is SpO2 and pulse rate?
-SpO2 stands for functional oxygen saturation of arterial hemoglobin, an estimate of the amount of usable oxygen in the blood. It is the percentage of oxygenated hemoglobin compared to the total amount of hemoglobin in the blood.
- Pulse rate is a measure of the number of times your heart beats per minute. The average pulse rate is typically 65 to 100 beats per minute.

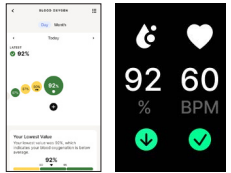
SpO2 and Pulse Rate Classification

SpO2 Output Results

A normal resting SpO2 levels are typically 95% or greater. However, normal values can be lower for individuals with lung disease, advanced age, or those living at high altitude.
SpO2 values generally vary between 90 and 100%:

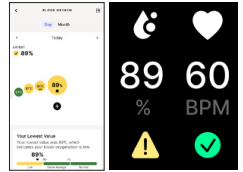


Between 95% to 100%: Normal.



Between 60% to 94%: Below Average.
This measurement detects that your blood oxygen level is below average but still normal. The results can vary based on a number of factors, including but not limited to your health profile (whether you are a smoker, if you have asthma, if you are very athletic or not, if you have tattoos in the light path of the pulse oximeter, if you have known conditions such as hypotension, anemia, etc.), your environment (altitude, temperature), the way the measurement is done (standing/sitting position, etc.). We suggest you check for best practices and train to improve your gesture.

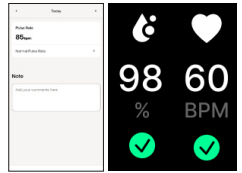
SpO2 and Pulse Rate Classification



Below 60%: Low.
The value can be a possible sign of hypoxemia. The results can vary based on a number of factors including your health profil , your environment, and the way the measurement is done. If you repeatedly get this result or you're not feeling well, you should talk to your doctor. Symptoms include being short of breath after exertion, coughing, fast or slow heart rate, rapid breathing, sweating.

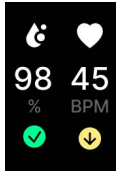
Pulse Rate Output Results

The average pulse rate is typically 65 to 100 beats per minute.

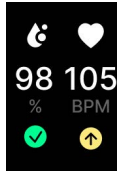


Between 60 to 100 bpm: Normal.

SpO2 and Pulse Rate Classification



Below 60 bpm: Low Pulse Rate.
This means your heart is beating less than 50 beats per minute (bpm). Some medicines can cause a low pulse rate. Talk to your doctor if you have questions about your pulse rate reading.



Above 100 bpm: High Pulse Rate.
This means your heart is beating above 100 beats per minute (bpm). A high pulse rate may be high because of exercise, stress, dehydration, infection, AFib, another arrhythmia or another cause. If you repeatedly get this result or you're not feeling well, you should talk to your doctor.

Sharing Results

Sharing a PDF: You can share your results with a physician via a PDF fil , generated by the Withings app. This PDF can be used for immediate sharing or in preparation for a later televisit.

Sharing a HealthLink: Share your health record and measurements history during a televisit or at any time.
- Tap on the share tab
- Tap on Share a HealthLink and choose how you will share the measurements. The link is valid for 7 days and can be revoked at any time in the app.

The HealthLink and PDF can include the following information:
For ECG results:
- The ECG strip

For pulse oximeter results:
- The average pulse rate (in bpm)
- The blood oxygen result (in percentage)

For stethoscope recordings:
- The stethoscope recording
- The type (heart, lung, and wide) and positions associated with the recording

For temperature results:
- The value of temperature and its indication of the fever status

Troubleshooting

If you cannot fix the problem using the following troubleshooting instructions, please contact Withings or go to: withings.com/support

Problems	Solution
The low battery icon is displayed on the screen	Charge the device with the cable provided
The measured temperature is too low	The temperature is outside the range. i.e lower than 34.0°C (93.2°F) or higher than 42.2°C (108.0°F). Take a new temperature measurement, referring to the user manual.
Device is outside of operating temperature range	The unit has been stored in a room outside of the operating range. Place the device in an ambient temperature room for 10 minutes and try again.
The temperature seems too low	The skin has sweat or hair covering the area. Ensure that there is no hair in front of the sensor. Clean the skin with a dry cloth and wait for 5 minutes before taking a measurement. The patient has been in a cold room. Wait until the patient is warmer before taking a measurement. Measurement was not taken on the temple. Please refer to the user manual to make the correct gesture with the sensor.
Temperature accuracy	The thermometer is calibrated during manufacture. If this device is used according to the use instructions, periodic re-calibration is not required. You should not perform calibration. Contact Withings in case of doubt.
Bluetooth does not seem to work	Smartphone is out of range. Please bring your smartphone closer to your device. Smartphone's Bluetooth is OFF. Please switch your smartphone's Bluetooth ON.

Troubleshooting

Problems	Solution
WiFi does not seem to work	Device is out of range from the Wi-Fi source. Please get your smartphone and device closer to your Wi-Fi source.
Stethoscope recording seems too noisy	This issue can be due to excessive movement, speaking during a recording, or ambient noise in the room, which causes a signal of poor quality. You can review the best practices on how to take a stethoscope by tapping Take a Stethoscope Recording in the Stethoscope section of the Withings app on your smartphone.
ECG result screen displays "Measurement failed" or "Poor recording"	The recording quality is too low to be reviewed by a physician. Some things that can cause this type of result are excessive movement that causes a signal of poor quality; proximity to an electrical device that generates strong electromagnetic fields OR not following best practices for the gestures to be adopted; 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. If you think you may be having a heart attack (myocardial infarction) or are facing a medical emergency, call the emergency services.
SpO2 result screen displays "Measurement failed" or "Poor recording"	The recording quality is too low to start the measurement OR correctly measure the SpO2 and pulse rate. Some things that can cause this type of result are excessive movement that causes a signal of poor quality; proximity to an electrical device that generates strong electromagnetic fields; OR not following best practices for the gestures to be adopted. You may try to re-record your SpO2. You can review how to take an SpO2 measurement during setup or by tapping Best Practices in the SpO2 section of the Withings app on your smartphone.

Technical specifications

Product Name: Withings BeamO
Model: SCT02
ECG Sensors: 2 Stainless steel electrodes
Stethoscope sensor: Piezoelectric Sensor
Auscultation Frequency Ranges: Heart: 20 Hz - 400 Hz, Lung: 60 Hz - 600 Hz, Wide: 20 Hz - 1000 Hz
Thermometer sensor: Thermopile
Temperature Display: 3 digits (°C and °F)
Temperature Measuring Range: 34.0°C - 42.2°C (93.2°F - 108.0°F)
Temperature Clinical Accuracy: ±± 0.2°C on 35.5°C - 42°C range (± 0.4°F on 95.9°F - 107.6°F range) ± 0.3°C (0.5°F) outside this range. ASTM laboratory accuracy requirements in the display range of 37 to 39 °C (98 to 102 °F) for IR thermometers is ± 0.2 °C (± 0.4 °F), whereas for mercury in-glass and electronic thermometers, the requirement per ASTM Standards E 667-86 and E 1112-86 is ± 0.1 °C (± 0.2 °F).
Unadjusted Temperature Test Mode Accuracy (for laboratory tests only): ± 0.3°C (± 0.5°F) on 34.0°C - 42.2°C (93.2°F - 108.0°F) range
Heart Rate Measuring Range (from ECG): 30-220 bpm
Heart Rate Accuracy (from ECG): Within +/- 2 BPM
SpO2 Measuring Range: 70 to 100 %
SpO2 accuracy: 2.5%
PPG sensor LEDs wavelengths and maximal optical output power: Green 525 nm/0.17 mW, Red 660 nm/0.28 mW, Infrared 950 nm/0.2 mW
Pulse Rate Measuring Range (from PPG): 40 to 200 BPM
Pulse Rate Accuracy (from PPG): Within +/-3 BPM
Battery Operated: 8 months use on a single charge
Power Source: 3.7 VDC Lithium-ion Battery (use the USB-C charging cable provided) and a DC 5V power adapter
Operation time: 3 minutes
Parts in contact with the skin: Entire product surface
Transport and storage conditions: -25 to 70°C, 20-90% RH, atmospheric 86kPa~106kPa,
Operation conditions: 15 to 40°C, 20 to 90% RH, atmospheric 86kPa~106kPa, altitude: 2000m
IP Protection level: IP22
Mode of operation: Intermittent operation
Expected minimum product life: 3 years
Wireless Transmission: Wi-Fi, BLE, and optional LTE Cat M1 (Cellular)
Weight: Approx. 80g
Dimensions: 3.7 x 1.9 x 13.6 cm (1.465x0.765x5.355 in)
Packaging content: Main unit, USB-C charging cable, USB-C to jack adapter, Travel pouch, Quick Start Guide, Product Guide.

Wireless information

Mode	Frequency Band (MHz)	Maximum Output Power (dBm)
BT LE	2402-2480	6
WLAN	2412-2484	15
LTE Cat M1 (Cellular)	1920-1980 (B1)	23
	1850-1910 (B2)	23
	1710-1785 (B3)	23
	1710-1755 (B4)	23
	880-915 (B8)	23
	699-716 (B12)	23
	777-787 (B13)	23
	832-862 (B20)	23
	703-748 (B28)	23

Wireless Specifications:

Wireless Technology	Bluetooth BLE
Version	Supported BT5.1
Operation Frequency	2402MHz - 2480MHz
Transmission power	6 dBm (max)
Modulation	GFSK
Receiver sensitivity	-96dBm

The wireless communication of the device is supported by BLE, Wi-Fi, and optional cellular communication. The communication is encrypted through an exchange of a paired key and established between the device and the Withings app for BLE and Wi-Fi. The communication latency between the device and the Withings app takes less than 10 seconds when the device and the smartphone are less than 16 feet (5 meters) apart.
The communication between the device and the Withings app is not modified with sources of interference located within 5 meters. Wireless coexistence has been tested by the following standards:
- ANSI C63.27:2017 and, AAMI TIR69:2017

Cleaning, Maintenance and Storage

- Clean the device with a soft and dry cloth before use. Do not use an alcohol-based or solvent agent.
- [**FOR HOSPITAL USE ONLY**] For disinfection you may use Liquinox (Alconox).
- Do not submerge the device in water.
- Do not use the device while cleaning or charging.
- While the device is charging, it cannot be used. The USB-C port does not supply power during use.
- Store the device and the components in a clean and safe location.
- If you see changes to the exterior of the device (corrosion, surface damage, warping) , it may be at the end of its reuse life. Performance may start to become affected. If this occurs, you should stop using the device.

Safety and performance

- Clinical performance:
Withings BeamO's ability to accurately measure SpO2 and Pulse Rate via Photopletysmography (PPG) was validated in line with the standard EN ISO 80601-2-61:2019. In particular, a clinical study on 24 healthy subjects (6 dark skin, 13 medium skin and 5 light skin) under no motion conditions was conducted for SpO2 for comparison against a reference device, and a bench test was performed for pulse rate accuracy. Data were collected on each subject index and ring finge s undergoing mild, moderate and severe hypoxemias. Regarding the SpO2 measurement, the RMSE is below 2.5%. PPG Pulse Rate RMSE is below 3bpm.
For more details on the clinical performance of the clinical study, you may fi d the Withings BeamO Technical Guide online at htt s://www.withings.com/guides or by scanning the QR code below.

- RF Statement
Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following. | Portable and mobile RF communication equipment can affect Medical Electrical Equipment.

Safety and performance

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment — guidance
RF Emissions CISPRI11	Group 1	The BeamO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	This BeamO 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	

Safety and performance

- 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 Emissions and Immunity for equipment and systems that are not life-supporting and are specified or use only in a shielded location.
Federal Communications Commission (FCC) Statement: Model SCT02 FCC ID: XNASCT02 contains FCC ID: 2AAGMGM02SA
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 of the device. FCC Statement §15.21: You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment. §15.105(b): This equipment has been tested and found to comply with the limits for a Class B digital device, under 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 by 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 to 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.

IMPORTANT NOTE:
FCC RF Radiation Exposure Statement: This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Disposal

The device and its parts must be disposed of as appropriate, by national or regional regulations.

Warranty

Withings Two (2) Years Limited Warranty - Withings BeamO

Withings, 2 rue Maurice Hartmann, 92130 Issy-les-Moulineaux,(“Withings”) warrants the Withings-branded hardware product (“Withings Product”) against defects in materials and workmanship when used normally by Withings’ published guidelines for a period of TWO (2) YEARS from the date of original retail purchase by the end-user purchaser (“Warranty Period”). Withings’ published guidelines include but are not limited to information contained in technical specification , safety instructions, or Quick Start Guide. Withings does not warrant that the operation of the Withings Product will be uninterrupted or error-free. Withings is not responsible for damage arising from failure to follow instructions relating to the Withings Product’s use. AU: Our goods come with guarantees that cannot be excluded under the Australian Consumer Law.

You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Security

Withings recommends that you add a passcode (personal identification number [PIN]), Face ID, or Touch ID (fingerprin) 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 authentication guidelines when logging into the Withings app.

For more information on password requirements and two-factor authentication, please refer to support.withings.com. Users will receive email alerts in case of changes related to passwords, two-factor authentication, and recovery code. Users will also receive additional soft are update notification via the Withings app, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fi es. Users can see the currently installed fir ware in the Withings app, under Devices > Withings BeamO. 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 personal 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 soft are is needed. Only use officia app stores to download the Withings app. In case of doubt, use the link go.withings.com.

Security notifications:

You will receive emails when sensitive actions are performed by yourself such as password update.
Moreover, you can subscribe to our status webpage (status.withings.io) in order to be notified if t ere 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).

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.

Equipment Symbol Description

- Direct current
- Model Number
- Catalog number
- Do not use if package is damaged and consult instructions for use
- Caution
- Type BF applied part
- Regulatory Compliance Mark
- Consult instructions for use or consult electronic instructions for use
- Medical device
- Follow instructions for use
- Manufacturer
- Date of Manufacture
- Do not dispose of this product as unsorted municipal waste, take it to electronic recycling.
- The CE labeling certifi s that the product complies with the general safety and performance requirements of Regulation 2017/745 Medical device
- Cardboard
- Swiss Authorized Representative
- Importer
- Serial number
- Unique device identifie
- Temperature range
- Upper and lower limits of relative humidity
- Upper and lower limits of atmospheric pressure
- Ingress of water or particulate matter
- Keep dry
- WARNING: Cancer and Reproductive Harm www.P65Warnings.ca.gov

Australian Sponsor:
Emergo Australia, Level 20, Tower II
Darling Park, 201 Sussex Street- Sydney, NSW 2000
Australia

UK Responsible Person:
Emergo Consulting (UK) Limited c/o Cr360
UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ
United Kingdom

MedEnvoy Switzerland
Gottha detrasse 28
6302 Zug
Switzerland

WITHINGS

BeamO

PRODUCT GUIDE

for **NON-US regions**

It applies to users in the European Union, the United Kingdom, Switzerland, Australia, New Zealand and Hong Kong.

WITHINGS, 2 rue Maurice Hartmann,
92130 Issy-les-Moulineaux, FRANCE +33141460460

Important notice

Before using Withings BeamO, review the information in this guide. You may also find this guide online at: https://www.withings.com/guides

Retain this documentation for future reference. Installation instructions are available within the Quick Start Guide provided with this Product Guide. 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 device should be reported to Withings and competent authorities in your country of residence.

Disclaimer

Information in this guide may change without notice.
In order to use your device, you need an iOS (16.0 or higher) or Android (9.0 and higher) device to install it. Thereafter, the product can be used without your mobile device on you, thanks to the Wi-Fi, Bluetooth® and optional cellular (LTE Cat M1) connections. For Bluetooth connection, you will need your phone to synchronize your results to see them in the Withings Application.

Product Overview

Withings BeamO is a multifunctional device for at-home health checkups, embedding:
- A 1-lead electrocardiogram with two stainless steel electrodes,
- A pulse oximeter to measure blood oxygen levels (SpO2) and pulse rate (PR),
- A contactless thermometer for body temperature measurements,
- A digital stethoscope to auscultate heart and lung sounds,

The measurements can be used on children and adults according to the table below:

Measurement	**Infant & Child** (>0 years old)	**Adult*** *For US region: ≥ 22 years old
Thermometer	✓	✓
Stethoscope	✓	✓
1-Lead Electrocardiogram	×	✓
Pulse oximeter	×	✓

This medical device is intended to be used or operated by adults only with or without medical training.
The SCT02 is suitable for non-professional use at home and can transmit data remotely. It is also designed for use by healthcare professionals.

Intended use

Withng BeamO is a non-sterile, contactless, reusable clinical thermometer intended for the intermit-tent determination of human body temperature over the temporal artery as the measurement site on people of all ages.

Withings BeamO is also an electronic stethoscope that enables the recording and transmission of heart and lung auscultation sound data. Withings BeamO is intended to be used by professional users in a clinical environment or by lay users in a non-clinical environment on people of all ages.

Withings BeamO measures, transfers, records, and dis-plays lead I of an ECG. It calculates the heart rate and detects the presence of atrial fibrillation or sinus rhythm on a classifiable ECG waveform.

Withings BeamO is also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (blood oxygen, or SpO2) and pulse rate (PR). It is indicated for use with individuals 18 years and older.

Contraindications

- DO NOT USE the ECG feature if you have a pacemaker, a defibrillator or or other electric implant.
- DO NOT USE the device if you are pregnant, accuracy may be impacted
- DO NOT USE the ECG Afib Classification feature if you suffer from other arrhythmias.
- DO NOT USE the Thermometer feature on children born before term.

Warnings

This device should be handled with care:
- The device 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 user.
- The data provided by the device is intended for preliminary assessment of different health conditions only, and is not intended to replace traditional methods of definitive diagnosis or treatment.
- The device is intended to be used on intact skin only. Do not take measurements over irritated skin or scars. Do not perform auscultation if there are any wounds or abrasions within the spot examined.
- The device does not provide alarms.
- This medical product can be operated by adults only. Temperature and stethoscope measurements on children must be performed by an adult. Do not perform ECG and SpO2 measurements on children.
- The device contains an electronic stethoscope. It should be used solely for recording body auscultation sounds, and transmitting them remotely. This medical product does not analyze the sounds recorded.
- The power cord of the charger may pose a strangulation risk. Keep it away from children and pets.
- DO NOT take recordings while in proximity to or receiving medical treatment from other equipment (e.g., magnetic resonance imaging (MRI), diathermy (deep heating), lithotripsy, cauterization, and external defibrillation)
- This device should not be used as an apnea monitor. Oxygen changes may be delayed from when your breathing actually stops.

The device is not intended for self-diagnosis. Self-diagnosis and self-treatment are dangerous. Contact your physician in case of symptoms, doubt, questions or the following cases:
- If atrial fibrillation (afib) is detected.
- if you experience symptoms that could indicate you are experiencing a sudden and/or severe change in health.
- If the temperature increases in neonates and babies under 3 months, patients over 60 years old, immunocompromised patients, bedridden patients, transplant patients.
- If other symptoms occur such as vomiting, diarrhea, pain, shivering, stiff neck, etc., even if there is no fever.

General precautions

- Follow operation and storage conditions as described in the technical specifications section of this guide. Otherwise, measurement results may be impacted.
- Exposing the device to prolonged lint or dust might damage the device or reduce its life.
- Do not submerge the device in water or liquids.
- The USB port should only be used for charging the device or connecting the provided USB-C to audio adapter during stethoscope recordings. To recharge the battery, use a power supply that complies with the safety standards of the country in which it is used and that matches the voltage of the power outlet.
- Do not try to repair or modify this device yourself. Do not open or disassemble the device for battery replacement.
- The battery inside the device will stop charging when the temperature is less than 0°C (+/-5°C or) or over 45°C (+/-5°C).
- Do not use the device or the provided accessories if they are damaged. Do not shake the unit violently. Damaged sensors may lead to incorrect measurements. Inspect for warping, surface damage or corrosion. The sensor lens is fragile, do not touch it with your finge s
- Do not interconnect this equipment with other equipment or use accessories, detachable parts, or materials not described in the instructions for use. Use of parts and components other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified y the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of the device adjacent to other equipment should be avoided because it could result in improper operation such as poor recording with the ECG measurement. If such use is necessary, the device and the other equipment should be observed to verify that they are operating normally.

Self-Monitoring Precautions (pulse oximeter)

- If blood oxygen (SpO2) values indicate hypoxemia, do not self-diagnose and self-medicate. Confirmation by a medical professional is required. Your physician uses the measurements along with other symptoms and your medical history in their treatment decision. This cannot be replaced by a pulse oximeter.
- Do not change your treatment plan on your own. Never alter oxygen delivery settings or medical treatment prescribed by your physician.
- Do not rely only on the readings. Reading can provide a false sense of security to a lung or health condition that has not yet affected your blood oxygen.
- Do self-monitor your oxygen and pulse rate as recommended by your healthcare provider. This does not mean diagnosing and treating.
- Do familiarize yourself with your normal (baseline) SpO2 levels. Focus on changes from your baseline over time and not solely on a single measurement at any given moment
- Do seek medical attention if you are not feeling well even if your readings are normal.
- Do review the information on the limitations and ways to improve the accuracy of the reading provided in this manual.

Factors that may degrade performance of the measurement of blood oxygen (pulse oximetry) include:
- Poor circulation, skin pigmentation, skin thickness, skin temperature, current tobacco use, and use of fi - gernail polish
- Bright sunlight
- Presence of strong electromagnetic field
- Failure to position finge tip on the device correctly
- Tattoos on the finge s in the region of the optical sensor
- Excessive motion of the arm or finge s
- 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 cuff , or infusion lines
- Hypotension, serious vasoconstriction, serious anemia, or hypothermia

Accessory:
The Withings BeamO is to be used with a soft are accessory, the Withings BeamO companion app. It allows the installation of the device and displays the results of performed measurements. It is part of the Withings App.

How to take measurements

Withings BeamO allows you to take 4 types of measurements:

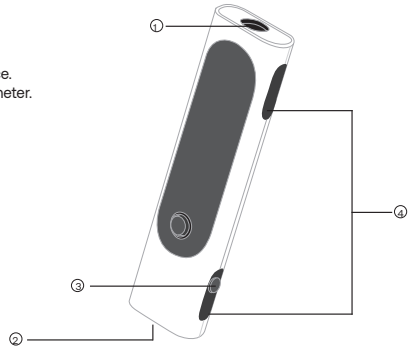
① Temperature measurements using the contactless thermometer.
② Heart and lung sound recordings using the stethoscope.
③ Blood oxygen (SpO2) and pulse rate (PR), using the pulse oximeter placed within the electrode surface.
④ Simultaneous ECG and SpO2 measurement with heart rate (HR), using two electrodes and pulse oximeter.

To set up your device, follow the information in the Quick Start Guide and in the Withings application

To start a measurement:

1. Press the button to TURN ON the device.
2. Select the correct user.
3. Select the measure to start.

To TURN OFF the device press the ⏻ icon. There is an automatic switch-off after 30 seconds



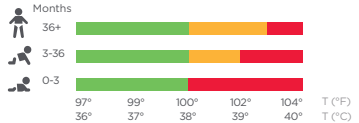
Temperature measurement

⚠ **Before you start:**
- The device and the patient should stay in the same ambient temperature room for 10 minutes prior to taking a measurement.
- Infant body temperature may vary more than adult body temperature. Avoid taking measurements on babies after nursing or while they are crying. It is recommended to take measurements on children when they are calm.
- For children under 3 months, perform 3 measurements in a row. If the 3 measurements are different, always take the highest one.
- If the patient has taken a bath or exercised, please wait for 15 minutes before taking a measurement.
- Move hair out of the way and dry any sweat before taking a measurement.

Taking your temperature:
1. Slowly scan once from the middle of the forehead to the top of the ear, as close as possible to the skin.
2. The device will vibrate when the measurement is complete. The temperature will be displayed on the device and the colored icon indicates the fever level according to the user's age. (table below is the same as SCT01, must exist in better quality) The unit is either in °F or °C. You can change this unit in the Withings app setting .

LED Colors meaning:
- No fever
- Mild fever
- High fever

Normal body temperature according to age:

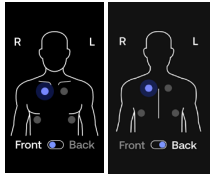


Stethoscope measurement

There are 3 available recording modes:

Heart: Recordings performed on 4 positions on the chest to listen to cardiac sounds.
Lungs: Recordings performed on 8 positions on the chest and back to listen to respiratory sounds.
Wide: Wide band recordings to listen to respiratory or cardiac sounds.

Heart



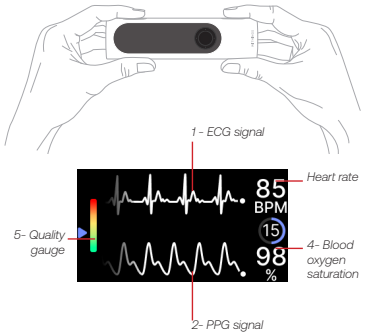
Lung

Before you start:
- Choose a calm, quiet room. Noises or murmurs may hurt the quality of recordings.
- Ensure you are in a comfortable position (preferably sitting down) with support for your hands (thighs or table).
- Do not speak or move during the measurement.
- Place the stethoscope directly on bare skin or wear at most one thin layer of clothing.

Taking a stethoscope recording: 1. Select either Heart, Lungs, or Wide (free position) mode on the device screen. 2. Select the position and place the stethoscope at the precise point indicated on the device screen. 3. When you are ready, press the button to start recording. Make sure that the stethoscope stays in contact with your body during the whole duration of the measurement.

You can listen to the auscultation sounds during the recording by connecting your headphones to the provided adapter and the USB-C port on the device. To adjust the volume, click up or down with the button before starting the recording. You can modify the order of the recording positions by selecting another position on the device. You may also end the exam before completing recordings in all indicated positions.

Electrocardiogram (ECG) and and blood oxygen (SpO2) measurements



Before you start:
- Choose a calm, quiet room.
- Ensure you are in a comfortable position (preferably sitting d wn) with a support for your hands (thighs or table).
- Do not speak or move during the measurement.

Recording a simultaneous ECG and SpO2 measurement:
Place your index finge s on the electrodes. Your finger s ould cover the full length of the electrodes. Your finger con act should be light.
The quality gauge guides you to keep a good, light contact throughout the measurement. Try to stay in the green zone.

1. Select ECGxSpO2 in the menu screen. Launch the measurement by pressing the button.
2. The recording will last for 30 seconds.
3. The end of the measurement is confir ed by a vibration.

Electrocardiogram (ECG) and and blood oxygen (SpO2) measurements

What is an ECG?

- ECG, or electrocardiogram, is the graphical representation of the electrical activity of the heart.
- With each heartbeat, an electrical wave travels through your heart. This wave causes your heart to contract and pump blood.
- In a doctor's offi , 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 device measures a waveform similar to one of those twelve waveforms. This configu ation is known as single-lead ECG.
- A single-lead ECG is able to provide information about heart rate and heart rhythm and enables classification f 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 take measurements at home or in hospital sothe doctor can get a better look at the underlying heart rate and rhythm.

Electrocardiogram (ECG) and and blood oxygen (SpO2) measurements

Recording a standalone SpO2 measurement:

Place your index finger on t e right electrode. Your finger s ould cover the full length of the electrode. Your finger con act should be light.

The quality gauge guides you to keep good, light contact throughout the measurement. Try to stay in the green zone.

1. Select SpO2 in the menu screen. Launch the measurement by pressing the button.
2. The recording will last for 15 seconds.
3. The end of the measurement is confir ed by a vibration

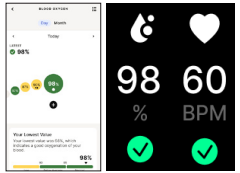
What is SpO2 and pulse rate?

- SpO2 stands for peripheral capillary oxygen saturation, an estimate of the amount of usable oxygen in the blood. It is the percentage of oxygenated hemoglobin compared to the total amount of hemoglobin in the blood.
- Pulse rate is a measure of the number of times your heart beats per minute. The average pulse rate is typically 65 to 100 beats per minute.

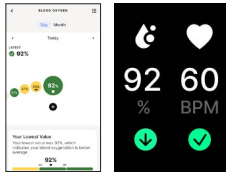
SpO2 and Pulse Rate Classification outputs

SpO2 Output Results

A normal resting SpO2 levels are typically 95% or greater. However, normal values can be lower for individuals with lung disease, advanced age, or those living at high altitude.
SpO2 values generally vary between 90 and 100%:

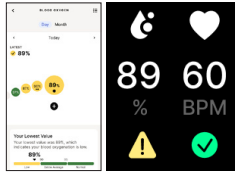


Between 95% to 100%: Normal.



Between 90% to 94%: Below Average.
This measurement detects that your blood oxygen level is below average but still normal. The results can vary based on a number of factors, including but not limited to your health profile (whether you are a smoker, if you have asthma, if you are very athletic or not, if you have tattoos in the light path of the pulse oximeter, if you have known conditions such as hypotension, anemia, etc.), your environment (altitude, temperature), the way the measurement is done (standing/sitting position, etc.). We suggest you check for best practices and train to improve your gesture.

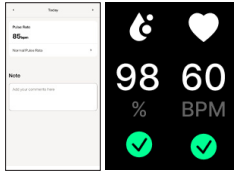
SpO2 and Pulse Rate Classification outputs



Below 90%: Low.
The value can be a possible sign of hypoxemia. The results can vary based on a number of factors including your health profil , your environment, and the way the measurement is done. If you repeatedly get this result or you're not feeling well, you should talk to your doctor. Symptoms include being short of breath after exertion, coughing, fast or slow heart rate, rapid breathing, sweating.

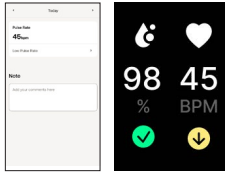
Pulse Rate Output Results

The average pulse rate is typically 65 to 100 beats per minute.

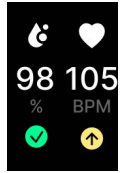


Between 60 to 100 bpm: Normal.

SpO2 and Pulse Rate Classification outputs



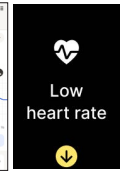
Below 60 bpm: Low Pulse Rate.
This means your heart is beating less than 50 beats per minute (bpm). Some medicines can cause a low pulse rate. Talk to your doctor if you have questions about your pulse rate reading.



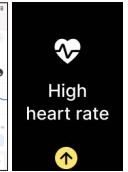
Above 100 bpm: High Pulse Rate.
This means your heart is beating above 100 beats per minute (bpm). A high pulse rate may be high because of exercise, stress, dehydration, infection, AFib, another arrhythmia or another cause. If you repeatedly get this result or you're not feeling well, you should talk to your doctor..

ECG classification outputs

After an ECG recording, you will see one of the following classifications for the recording in the Withings App (cf. left picture of the figu e below) and on the device screen (cf. right picture of the figu e below):

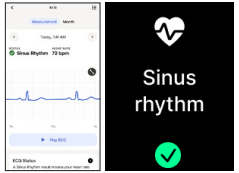


Low Heart Rate (heart rate < 50 bpm):
A Low Heart Rate result means your heart is beating less than 50 beats per minute (bpm). This recording cannot be classified by the device. A low heart rate can happen if electrical signals are not properly conducted through the heart. Some medicines can also cause a low heart rate. Talk to your doctor if you have questions about your ECG recording.

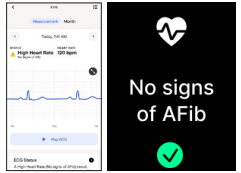


High Heart Rate (heart rate > 150 bpm):
A High Heart Rate result means your heart is beating above 150 beats per minute (bpm). This recording cannot be classified by the device. Many different things can cause a high heart rate. A heart rate may be high because of exercise, stress, dehydration, infection, AFib, another arrhythmia or another cause. Talk to your doctor if you have questions about your ECG recording.

ECG classification outputs



Sinus Rhythm (heart rate between 50-99 bpm):
A Sinus Rhythm result means your heart rate is between 50 and 99 beats per minute (bpm) and is beating regularly.



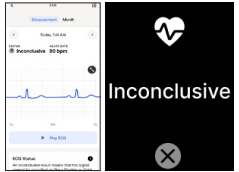
High Heart Rate (No signs of Afib):
High Heart Rate (No signs of AFib) result means the heart rate is beating between 100 and 150 beats per minute (bpm) and does not show any signs of Atrial Fibrillation. Many different things can cause a high heart rate. A heart rate may be high because of exercise, stress, dehydration, infection, an arrhythmia, or another cause. Talk to your doctor if you have questions about your ECG recording..

ECG classification outputs

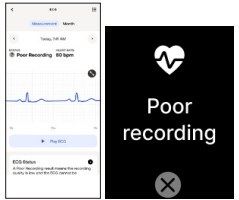
Atrial Fibrillation (heart rate between 50-99 bpm):
An Atrial Fibrillation result means the heart rate is between 50 and 99 beats per minute (bpm) and is beating irregularly. If you have not been diagnosed with AFib before, you should talk to your doctor.

Atrial Fibrillation High Heart Rate (heart rate between 100-150 bpm):
An Atrial Fibrillation — High HR result means your heart rate is beating between 100 and 150 beats per minute and is beating with an irregular pattern. If you have not been diagnosed with AFib before, you should talk to your doctor.

ECG classification outputs



Inconclusive:
An Inconclusive result means that the signal cannot be classified as Sinus Rhythm or Atrial Fibrillation, although the quality of the recording is good. This may be due to various conditions, including but not limited to other arrhythmias or other heart conditions. Talk to your doctor if you have questions about your ECG recording.



Poor Recording:
A poor recording result means the recording quality is low and the ECG cannot be classified. Some things that can cause this type of result are excessive movement that cause a signal of poor quality; or proximity to an electrical device that generates strong electromagnetic fields; OR not following best practices for the gestures to be adopted; 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. If you think you may be having a heart attack (myocardial infarction) or are facing a medical emergency, call the emergency services.

ECG classification outputs

- 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 average value of the beat-by-beat heart rates over the 30 seconds of the recording.

Sharing Results

Sharing a PDF: You can easily share your results with a physician via a PDF fil , generated by the Withings app. This PDF can be used for immediate sharing or in preparation for a later televisit.

Sharing a HealthLink: Share your health record and measurements history during a televisit or at any time.

Tap on the share tab
Tap on Share a HealthLink and choose how you will share the measurements. The link is valid for 7 days and can be revoked at any time in the app.

The PDF and HealthLink can include the following information:

For ECG results:
- The ECG strip and its classificatio
- The average heart rate, derived from the ECG

For pulse oximeter results:
- The average pulse rate, derived from the PPG
- The blood oxygen result

For stethoscope recordings:
- The stethoscope recording
- The type (heart, lung and wide) and position associated to the recording

For temperature results:
- The value of temperature and its indication of the fever status

Troubleshooting

If you cannot fix the problem using the following troubleshooting instructions, please contact Withings or go to: withings.com/support

Problems	Solution
The low battery icon is displayed on the screen	Charge the device with the cable provided
The measured temperature is too low	The temperature is outside the range. i.e lower than 35°C (95°F) or higher than 43.2°C (109.76°F). Take a new temperature measurement, referring to the user manual.
Device is outside of operating temperature range	The unit has been stored in a room outside of the operating range. Place the device in an ambient temperature room for 10 minutes and try again.
The temperature seems too low	The skin has sweat or hair covering the area. Ensure that there is no hair in front of the sensor. Clean the skin with a dry cloth and wait for 5 minutes prior to taking a measurement. The patient has been in a cold room. Wait until the patient is warmer before taking a measurement. Measurement was not taken on the temple. Please refer to the user manual to make the correct gesture with the sensor.
Temperature accuracy	The thermometer is calibrated during manufacture. If this device is used according to the use instructions, periodic re-calibration is not required. You should not perform calibration. Contact Withings in case of doubt.
Bluetooth does not seem to work	Smartphone is out of range. Please bring your smartphone closer to your device. Smartphone's Bluetooth is OFF. Please switch your smartphone's Bluetooth ON.

Troubleshooting

Problems	Solution
WiFi does not seem to work	Device is out of range from the Wi-Fi source. Please get your smartphone and device closer to your Wi-Fi source.
Stethoscope recording seems too noisy	Some things that can cause this are excessive movement, speaking during a recording or ambient noise in the room that cause a signal of poor quality. You can review the best practices on how to take a stethoscope by tapping Take a Stethoscope Recording in the Stethoscope section of the Withings app on your smartphone.
ECG result screen displays “Measurement failed” or “Poor recording”	The recording quality is too low to be reviewed by a physician. Some things that can cause this type of result are excessive movement that cause a signal of poor quality; or proximity to an electrical device that generates strong electromagnetic fields; OR not following best practices for the gestures to be adopted; 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. If you think you may be having a heart attack (myocardial infarction) or are facing a medical emergency, call the emergency services.
SpO2 result screen displays “Measurement failed” or “Poor recording”	The recording quality is too low to start the measurement OR correctly measure the SpO2 and pulse rate. Some things that can cause this type of result are excessive movement that causes a signal of poor quality; proximity to an electrical device that generates strong electromagnetic fields; OR not following best practices for the gestures to be adopted. You may try to re-record your SpO2. You can review how to take an SpO2 measurement during setup or by tapping Best Practices in the SpO2 section of the Withings app on your smartphone.

Technical specifications

Product Name: Withings BeamO
Model: SCT02
ECG Sensors: 2 Stainless steel electrodes
Stethoscope sensor: Piezoelectric Sensor
Auscultation Frequency Ranges: Heart: 20 Hz - 400 Hz, Lung: 60 Hz - 600 Hz, Wide: 20 Hz - 1000 Hz
Thermometer sensor: Thermopile
Temperature Display: 3 digits (°C and °F)
Temperature Measuring Range: 34.0°C - 42.2°C (93.2°F - 108.0°F)
Temperature Clinical Accuracy: ± 0.2°C on 35.5°C - 42°C range (± 0.4°F on 95.9°F - 107.6°F range) ± 0.3°C (0.5°F) outside this range.
Unadjusted Temperature Test Mode Accuracy (for laboratory tests only): ± 0.3°C (± 0.5°F) on 34.0°C - 42.2°C (93.2°F - 108.0°F) range
Heart Rate Measuring Range (from ECG): 30-220 bpm
Heart Rate Accuracy (from ECG): Within +/- 2 BPM
SpO2 Measuring Range: 70 to 100 %
SpO2 accuracy: 2.5%
PPG sensor LEDs wavelengths and maximal optical output power: Green 525 nm/0.17 mW, Red 660 nm/0.28 mW, Infrared 950 nm/0.2 mW
Pulse Rate Measuring Range (from PPG): 40 to 200 BPM
Pulse Rate Accuracy (from PPG): Within +/-3 BPM

Battery Operated: 8 months use on a single charge
Power Source: 3.7 VDC Lithium-ion Battery (use the USB-C charging cable provided) and a DC 5V power adapter
Operation time: 3 minutes
Parts in contact with the skin: Entire product surface
Transport and storage conditions: -25 to 70°C, 20-90% RH, atmospheric 86kPa~106kPa,
Operation conditions: 15 to 40°C, 20 to 90% RH, atmospheric 86kPa~106kPa, altitude: 2000m
IP Protection level: IP22
Mode of operation: Intermittent operation
Expected minimum product life: 3 years
Wireless Transmission: Wi-Fi, BLE, and optional LTE Cat M1 (Cellular)
Weight: Approx. 80g
Dimensions: 3.7 x 1.9 x 13.6 cm (1.465x0.765x5.355 in)
Packaging content: Main unit, USB-C charging cable, USB-C to jack adaptor, Quick Start Guide, Product Guide, protective pouch.

Wireless information

Mode	Frequency Band (MHz)	Maximum Output Power (dBm)
BT LE	2402-2480	6
WLAN	2412-2484	15
LTE Cat M1 (Cellular)	1920-1980 (B1)	23
	1850-1910 (B2)	23
	1710-1785 (B3)	23
	1710-1755 (B4)	23
	880-915 (B8)	23
	699-716 (B12)	23
	777-787 (B13)	23
	832-862 (B20)	23
	703-748 (B28)	23

Wireless Specifications:

Wireless Technology	Bluetooth BLE
Version	Supported BT5.1
Operation Frequency	2402MHz - 2480MHz
Transmission power	6 (max)
Modulation	GFSK
Receiver sensitivity	-96dBm

The wireless communication of the device is supported by BLE, Wi-Fi and cellular communication. The communication is encrypted through an exchange of a paired key and established between the device and the Withings application for BLE and Wi-Fi. The communication latency between the device and the Withings application takes less than 10 seconds when the device and the smartphone are less than 16 feet (5 meters) apart. The communication between the device and the Withings application is not modified with sources of interference located within 5 meters. Wireless coexistence has been tested in accordance with the following standards:
- ANSI C63.27:2017 and, AAMI TIR69:2017

Cleaning, Maintenance and Storage

- Clean the device with a soft and dry cloth before use. Do not use an alcohol-based or solvent agent.
- Do not submerge the device in water.
- [**FOR HOSPITAL USE ONLY**] For disinfection you may use Liquinox (Alconox).
- While the device is charging, it cannot be used. The USB-C port does not supply power during use.
- Store the device and the components in a clean and safe location.

Europe - EU Declaration of Conformity

Withings hereby declares that the device Withings BeamO and Withings BeamO companion app conform with the essential requirements and other relevant requirements of the applicable EU Directives and Regulations. The full text of the EU Declaration of Conformity can be found at: withings.com/compliance

Safety and performance

- Clinical Benefit /performance

Withings BeamO enables the intermittent monitoring of core body temperature and contributes to the detection of fever.
It provides medical-grade auscultation sounds for remote assessment of cardiac and pulmonary health by a healthcare professional.
It also provides clinically validated blood oxygen (SpO2) and pulse rate (PR) measurements for self-monitoring and contributes to the detection of hypoxemia.
It also enables the recording and transfer of clinically validated single-channel ECG to healthcare professionals, contributes to an early detection of Atrial Fibrillation, facilitates patient screening, helps physicians treat the disease earlier and thus attenuates the impact of the disease on the population.
Withings BeamO enables an overview of multiple physiological conditions through its varied measurements, enabling an increased awareness into the patient's health. This device can support initial observations that patients can share with healthcare professionals. It provides access to physiological data trends over time.

Safety and performance

Withings BeamO's ability to accurately measure temperature was validated based on the requirements of the standards EN ISO 80601-2-56: 2017/A1 : 2020. In particular, a clinical study was conducted and its accuracy in measuring temperature was validated compared with a reference device.

The performance of the stethoscope function of BeamO was verified by two series of tests. First, by testing the audio frequency range response (20Hz – 2kHz) and comparing the results with a reference device. Second, by testing the Signal-to-Noise Ratio and Dynamic Range against a reference device on a variety of pre-recorded heart and respiratory sounds.

Withings BeamO's ability to accurately classify an ECG recording into Atrial Fibrillation (AF) and Sinus Rhythm (SR) categories were tested in a clinical study including 335 patients. Rhythm classification by Withings BeamO was compared to the review by cardiologists of simultaneously recorded 12-lead ECG. 86.5% of sct02's recordings were conclusive (i.e. neither "inconclusive" nor "poor recording", and with a heart rate between 50 and 150 bpm). On conclusive recordings, the sensitivity in classifying Atrial Fibrillation was 100.0% (lower bound of the 95% confide ce interval: 98.1%) and the specificity in detecting normal sinus rhythm was 100.0% (lower bound of the 95% confide ce interval: 98.5%). In addition, Withings BeamO accurately classifi s AF and SR into subgroups by heart rate < or ≥ 100 bpm.
The mean difference between the algorithm calculated heart rate from Withings BeamO's strips (median over 30 seconds) and the heart rate measured by cardiologists on the 12-lead ECGs was -0.19 bpm (standard deviation: 1.42 bpm).
The quality of the ECG waveforms was assessed by the visibility and polarity of the P, QRS and T waves. The accuracy of the 6 endpoints ranged between 97.9% and 100%. In addition, the mean difference (standard deviation) for PR, QRS, and QT intervals was -0.5 (14.7) ms, -8.2 (19.7) ms, and 8.8 (18.8) ms respectively.

The performance of the ECG function passed the applicable requirements on ECG waveform and heart rate measurements specified in ANSI/AAMI/IEC 60601-2-47:2012 Requirements for the Basic Safety and Essential

Safety and performance

Performance of Ambulatory Electrocardiographic Systems and ANSI/AAMI EC57:2012 (R2020) Testing And Reporting Performance Results Of Cardiac Rhythm And ST Segment Measurement Algorithms.

Withings BeamO's ability to accurately measure SpO2 and Pulse Rate via Photopletysmography (PPG) was validated in line with the standard EN ISO 80601-2-61:2019. In particular, a clinical study was conducted for SpO2 for comparison against a reference device, and a bench test was performed for pulse rate accuracy. Regarding the SpO2 measurement, the RMSE is below 2.5%. PPG Pulse Rate RMSE is below 3bpm.

- RF Statement
Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following. Portable and mobile RF communication equipment can affect Medical Electrical Equipment.

Safety and performance

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment — guidance
RF Emissions CISPRI11	Group 1	The BeamO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	This BeamO 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	

Disposal

Actuation of European directive 2012/19/EU, for the reduction in use of dangerous substances in electric and electronic devices and for garbage disposal. The symbol applied on the device or its packaging means that at the end of its useful life, the product must not be disposed of with domestic waste. At the end of the device's useful life, the user must deliver it to a collection center for electric and electronic garbage, or return it to the retailer when purchasing a new device. Disposing of the product separately prevents possible negative environmental and health consequences deriving from inadequate disposal. It also allows the recovery of materials it is composed of to save energy and resources and avoid negative effects to the environment and health. In case of abusive disposal of devices by the user, will be applied administrative endorsements in compliance with current standards. The device and its parts must be disposed of as appropriate, in accordance with national or regional regulations.

Warranty

Withings Two (2) Years Limited Warranty - Withings BeamO

Withings, 2 rue Maurice Hartmann, 92130 Issy-les-Moulineaux,(“Withings”) warrants the Withings-branded hardware product (“Withings Product”) against defects in materials and workmanship when used normally in accordance with Withings’ published guidelines for a period of TWO (2) YEARS from the date of original retail purchase by the end-user purchaser (“Warranty Period”). Withings’ published guidelines include, but are not limited to, information contained in technical specification , safety instructions or Quick Start Guide. Withings does not warrant that the operation of the Withings Product will be uninterrupted or error-free. Withings is not responsible for damage arising from failure to follow instructions relating to the Withings Product’s use.

AU: Our goods come with guarantees that cannot be excluded under the Australian Consumer Law.You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Security

Withings recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprin) 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 authentication guidelines when logging into Withings App. For more information on password requirements refer to htt s://support.withings.com/hc/articles/360012727737. For more information on two-factor authentication refer to htt s://support.withings.com/hc/en-us/articles/21866853734545 for iOS users and refer to htt s://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 soft are update notifications via the Withings App, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fi es. Users are able to see the currently installed fir ware in the Withings App, under Devices > Withings BeamO. 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 personal 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 soft are is needed. Only use officia app stores to download the Withings application. In case of doubt, use the link go.withings.com.
If needed, users can restore device configu ations by following the factory reset procedure.

Equipment Symbol Description

- Direct current
- Model Number
- Catalog number
- Do not use if package is damaged and consult instructions for use
- Caution
- Type BF applied part
- Regulatory Compliance Mark
- Consult instructions for use or consult electronic instructions for use
- Medical device
- Follow instructions for use
- Manufacturer
- Date of Manufacture
- Do not dispose of this product as unsorted municipal waste, take it to electronic recycling.
- CE 1282 The CE labeling certifi s that the product complies with the general safety and performance requirements of Regulation 2017/745 Medical device
- Cardboard
- Swiss Authorized Representative
- Importer
- Serial number
- Unique device identifie
- Temperature range
- Upper and lower limits of relative humidity
- Upper and lower limits of atmospheric pressure
- IP22 Ingress of water or particulate matter
- Keep dry
- WARNING: Cancer and Reproductive Harm www.P65Warnings.ca.gov

Australian Sponsor:
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Australia

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