

Not for Sale in the USA - For Export Only

These operating instructions provide the necessary information for proper operation of all models of the Masimo W1. There may be information provided in this manual that is not relevant for your Masimo W1. Do not operate Masimo W1 without completely reading and understanding these instructions. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

See instructions for use for information, including indications, contraindications, warnings, and precautions.

Wireless Radio:
 Contains: FCC ID: VKF-MASIW1 | IC: 7362A-MASIW1 | Model: W1
 Contains: FCC ID: VKF-MASIW1CG | IC: 7362A-MASIW1CG | Model: Masimo Wireless Charger

Manufacturer
 Masimo Corporation
 52 Discovery, Irvine, CA 92618, USA
 Tel.: 1-949-297-7000
 Fax.: 1-949-297-7001
 www.masimo.com



Masimo®, Masimo W1®, Masimo SafetyNet®, SET®, RRP®, and are federally registered trademarks of Masimo Corporation. M-band® and SET+™ are trademarks of Masimo Corporation. Google Play and the Google Play logo are trademarks of Google LLC. App Store and App Store logo are registered trademarks of Apple Inc. The Bluetooth® word mark and logo are registered trademarks owned by Bluetooth SIG, Inc.

© 2024 Masimo Corporation

Patents: www.masimo.com/patents

About This Manual

This manual explains how to set up and use the Masimo W1®. Important safety information relating to general use of Masimo W1 appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A **warning** is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user. **WARNING:** This is an example of a warning statement.

A **caution** is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property. **CAUTION:** This is an example of a caution statement.

A **note** is given when additional general information is applicable. **Note:** This is an example of a note.

EU authorized representative for Masimo Corporation:

EC REP
 MDSS GmbH
 Schiffgraben 41
 D-30175 Hannover, Germany

Product Description, Features and Indications for Use

The Masimo W1® is a watch that provides spot-check ECG measurements and continuous measurements of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR), and respiration rate from the pleth (RRp®). The watch has a touchscreen display, a rechargeable battery, and Bluetooth® connectivity to pair to a smartphone app.

Key features of Masimo W1 include:

- Masimo SET+™ technology.
- Electrocardiogram (ECG) technology.
- Bluetooth® LE for the wireless communication.

Intended Use

Masimo W1® is intended to be worn on the wrist for the spot-checking of ECG and other continuous parameters (e.g., pulse oximetry). The watch is intended to be used in hospital, hospital-type facilities, long-term care facilities, and home.

Indications for Use

Masimo W1® watch and the integrated Masimo W1 Module are indicated for patients with suspected heart conditions and health-conscious individuals.

The Masimo W1® watch and the integrated Masimo W1 Module are indicated for the detection, display, recording, and transferring of a single lead ECG and determination of ECG parameters (e.g., Heart Rate, Atrial Fibrillation) on adults.

The Masimo W1® watch and the integrated Masimo W1 Module are indicated for non-invasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR), and respiration rate from the pleth (RRp) on adults.

The Masimo W1® provides these measurement features:

| | |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Heart Rate (HR) | Estimation of the number of heart beats per minute (BPM) based on the electrical signals detected in the ECG waveform. The electrical signal reflects the changes in polarization of the heart muscles during expansion and contraction or heartbeat. |
| Heart Rate Variability (HRV) | Variations in the amount of time between heart beats, which may provide insight in how consistently you are reacting to changes that affect your heart rate like exercise or stress. |
| Functional Oxygen Saturation of Arterial Hemoglobin (SpO₂) | Estimation of relative amount of oxygen available in the blood flowing to the tissues. The estimation is made by using the ratio of the amount of light absorbed by oxygenated hemoglobin and deoxygenated hemoglobin by different wavelengths of light. |
| Pulse Rate (PR) | Feature that reflects how often blood is being pushed through the body by the heart or pulse. Estimation of the number of times blood is pushed through the body by the heart per minute. The estimation is made from the pulsatile light absorption changes used for determining SpO ₂ . |
| Respiration Rate from Pleth (RRp) | Estimation of the number of times the lungs expand and contract per minute. The estimation is made based on cyclic variations in the photoplethysmogram (i.e., pleth or PPG). |
| Atrial Fibrillation (AFib) | An irregular heartbeat classification made on the ECG waveform. The classification is made based on the detection of electrical signals in the two upper chambers of the atria firing rapidly at the same time causing the heartbeat to get out of sync and faster. |
| Sinus Rhythm | A normal heartbeat classification made on the ECG waveform. The classification is made based on the detection of normal heart rhythms where the electrical pulse travels through the heart muscle correctly from the sinus node. |
| Perfusion (Pi) | Calculation of the relative strength of the pulsatile signal used for the SpO ₂ and Pulse Rate. The Pi increases with better blood circulation. Your SpO ₂ values may be more reliable when your Pi value is higher. Pi values 0.25 or below are typically considered low. If your Pi is low, try warming your hands or using a different finger. |
| Pleth Variability Index (PVI) | Calculation of the dynamic changes in the Perfusion Index (Pi) that occur during a respiratory cycle. The calculation is accomplished by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. |
| Pulse Rate Variability (PRV) | Calculation of the variation of the amount of time between pulses monitored during the pulse rate estimation. The calculation is made by analyzing the pulse rate and determining the difference in the amount of time between pulses in milliseconds (ms). |

Description

The Masimo W1 includes the following:

- Masimo W1 Watch
- Masimo W1 Wireless Charger

For a complete list of compatible accessories, visit www.masimo.com.



TOP

* Press and hold both buttons to reboot the watch

1 Main Menu/Back Button*

- Press and hold to turn the watch Off. When Off, press once to turn the watch On.
- From the watch face, press once to view the Main Menu OR to navigate backwards when viewing setting menus and other screens.

2 Live Screen Button*

- From the watch face, press once to view the live health data screen. Screen returns to the watch face after a few moments of inactivity.
- From the watch face, press two times to turn off the screen.
- Press once to return to the watch face when viewing setting menus and other screens.

3 Touch Screen

- Used to interact with the watch. See **Using the Touch Screen** section.

4 ECG Electrode

- ECG electrodes provided on the top and bottom bezels to be contacted with the fingers during ECG measurements.



BOTTOM

1 Bottom ECG Electrode

- ECG electrode on the bottom of the Masimo W1 that makes contact with the wrist.

2 Optical Pulse Oximeter Sensor

- Location of sensors for Vitals measurements.

3 Wrist M-band Release Button

- Press inward to remove the wrist M-band (watchband). Serial number and compliance information are located in the recesses behind the wrist M-band.

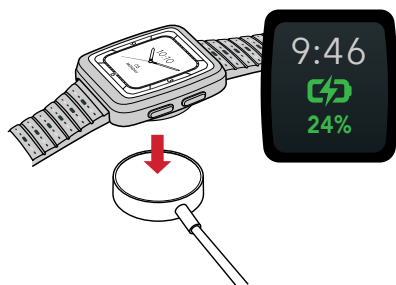
Basic Setup and Use

The following steps are for the basic setup and use for operating the Masimo W1.

Charge the Watch

Before using Masimo W1, fully charge the battery.

1. Plug the charging cable into a USB-A power source.
2. Place the bottom of the Masimo W1 on the charging cable base so that it is seated flush to begin charging. **Note:** The Masimo W1 may need to be connected to other side of the base if it does not sit flush.
3. Look for the "charging screen" to ensure the Masimo W1 is seated properly on the base. **Note:** Use only a Masimo authorized charger when charging Masimo W1.



Turn the Watch On

To turn the Masimo W1 on, press and hold the top button until the watch turns On. To turn off, press and hold the top button again until the watch turns Off.

Download the Masimo Health or Masimo SafetyNet App

The Masimo App collects and displays health data from the Masimo W1 and other paired devices. The App is available directly from the Google Play or Apple App Store. The Masimo SafetyNet app or the Masimo Health app are required to support software updates to the Masimo W1 watch. This prevents unauthorized upgrades to the Masimo W1.

- Patients using telehealth services should download and install the **Masimo SafetyNet App**.
- Consumers should download and install the **Masimo Health App**.

Pair Masimo W1 to the Masimo App

Pair Masimo W1 to the mobile device to view data from the watch on the Masimo App.

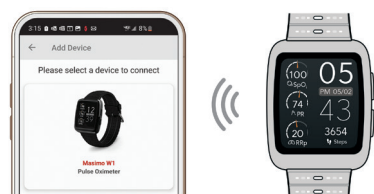
Note: Masimo SafetyNet App is shown in the example.

To pair the watch to the **Masimo SafetyNet App**, from the **My Devices** screen on the App, choose "+" to add a device.

To pair the watch to the **Masimo Health App**, from the **Devices** screen on the App, choose **Add Device**.

Click on Masimo W1 under the **Add a Device** or **Select a Device** screen and follow the instructions for pairing the watch to the mobile device.

Note: The connection needs to be confirmed to complete the pairing process.



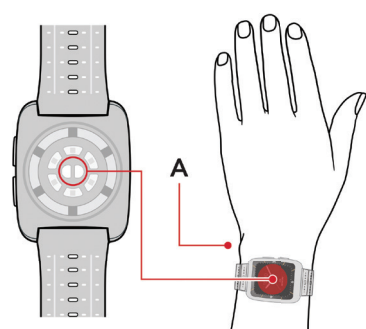
Put on the Watch

1. Place the watch with the screen facing up, on a flat part of the wrist avoiding the wrist bone (A). The buttons should be towards your hand.
2. Tighten the strap so the watch does not slip and then tighten the watch 1 to 2 more notches so that it does not slide but is comfortable.

Note: The watch has an indicator if the wrist M-band is too loose. See **Watch Status Screen** for wrist M-band status.

Note: Make sure the bottom of the watch is fully touching the wrist and does not slide back and forth.

Note: Remove the watch before swimming, bathing or similar activities.



Using the Touch Screen

When interacting with the watch, use the following gestures to navigate the touch screen.



Touch/Tap

Momentarily touch and release one finger on the screen.



Touch and Hold

Touch and hold an item on the screen.



Swipe

Touch and move one finger on the screen left, right, up or down.

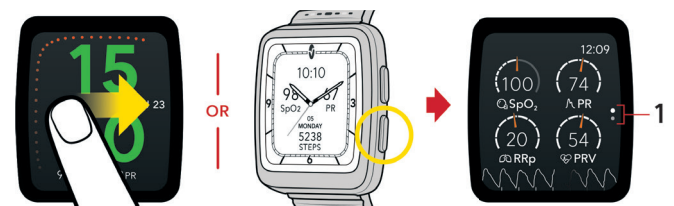
Turn On Health Data

The continuous health data can be turned on by selecting the **Vitals** icon and following the steps below. The **Vitals** icon can be found from either the **Main Menu** or the **Watch Status screen**. See **Main Menu** or **Watch Status Screen** section.

1. Select the **Vitals Measurement** icon to turn on the Continuous Health Data.
2. Check that the bottom of the watch makes good contact with the top of your wrist.
3. Check that the watch is secured comfortably to prevent it from slipping (1 or 2 notches tighter after it no longer slides on the wrist).

To view the **Live Health Data (Vitals)** screen, swipe left or right across the watch face using one finger until the screen displays OR press the lower button on the side of the Masimo W1.

Swipe up and down (1) using one finger to navigate the **Live Health Data** screen and view all available health data.



See **Live Health Data (Vitals) Screen** section for complete information about the **Live Health Data (Vitals)** screen.

Take an ECG Heart Rate Measurement

The ECG Heart Rate Measurement can be accessed by touching the ECG icon from the **Main Menu** and following the steps below. See **Main Menu** section. Ensure the Masimo W1 is on the wrist identified in the **Orientation** settings to ensure a proper ECG measurement. See **Watch Settings Options and Information** section.

1. Access the **ECG measurement** screen by touching the **ECG** icon from the **Main Menu**.
2. Check that the electrode pad on the bottom of the watch makes good contact to the wrist.
3. Place your thumb on the electrode pad on the lower bezel (below the lower portion of the watch screen) and index finger on the upper bezel (above the upper portion of the watch screen) until the results screen is displayed.

Note: Do not move during the ECG measurement. The measurement will take approximately 30 seconds.



Understanding the ECG Results Screen.

ECG is the electrical activity within the heart that controls the heartbeat. The Masimo W1 can record a single lead ECG, similar to lead I. The Masimo W1 measures heart rate and checks the ECG rhythm for signs of atrial fibrillation (a common form of arrhythmia) for heart rates of 50 to 150 bpm.

CAUTION: Masimo W1 does not display a screen message (classification) if the measurement is outside of the operational range.

The following are explanations of the messages for the ECG measurement:

| Screen Message | Explanation |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Normal Sinus Rhythm | Medical term for normal heart rhythm. This refers to the normal electrical activity of your heart when blood is pumping efficiently between the upper and lower chambers and throughout your body. WARNING: It is important to remember that this only applies to the duration of the spot-check measurement and does not fully exclude cardiac arrhythmias. If you're not feeling well, you should follow up with your healthcare provider. |
| Atrial Fibrillation (AFib) | Medical term for a type of abnormal heart rhythm. A common abnormal heart rhythm beginning in the upper chambers of your heart resulting in an irregular pulse rate that is sometimes very fast with poor movement of blood into the lower chambers of your heart. Note: If you have not been previously diagnosed with atrial fibrillation and consistently receive this result, or if you're not feeling well, you should consult with your healthcare provider. |
| Low Heart Rate | A low heart rate ECG classification will indicate a heart rate below 50 bpm, which can be commonly due to benign causes such as certain medication effects and is considered a normal finding during rest among well-conditioned athletes or other cardiovascular fit individuals. WARNING: If you're not feeling well, you should follow up with your healthcare provider as very low heart rates can sometimes indicate an underlying cardiovascular condition. |
| High Heart Rate | A high heart rate ECG classification will indicate heart rate greater than 100 bpm, which can be due to exercise, stress, the presence of cardiac arrhythmia, or consumption of alcohol, stimulants, or caffeinated drinks. WARNING: If you're not feeling well, you should follow up with your healthcare provider. |
| Inconclusive | This is not a classification of the ECG. This message means that the ECG recording could not be classified, which may be due to a number of reasons such as other types of arrhythmias, pacing, or heart conditions that Masimo W1 is not designed to detect. It is recommended to repeat the measurement in a few minutes if you get this result. An inconclusive reading does not indicate the presence or absence of any arrhythmias (Including AFib) or other heart conditions. Note: If you consistently receive this result, you should follow up with your healthcare provider, particularly if you're feeling unwell. |
| Noise | This is not a classification of the ECG. The message means the ECG waveform quality and performance were compromised and the device cannot report any measurements from the ECG. See Troubleshooting section for possible reasons and how to get the best results from Masimo W1 ECG. |

Operation

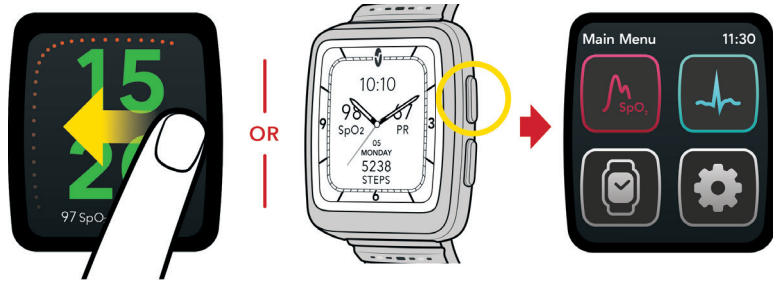
The following information are for the additional features available that go beyond the basic set up and use.

User Interface (Display)

Main Menu

The *Main Menu* displays a list of available apps.

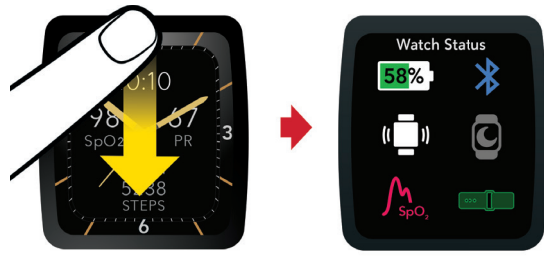
- To open the *Main Menu*, swipe left or right across the watch face using one finger until the screen displays or press the upper button on the side of the Masimo W1.
- Open an app by tapping on its icon.



| | |
|--|-----------------------------------------------------------------------------------------------------------------------------------|
| | Vitals Measurement * - Feature to start or stop health data measurements. See Turn On Health Data section. |
| | ECG Measurement - Feature to perform an ECG spot check. See Take an ECG Heart Rate Measurement section. |
| | Watch Face Settings - Feature to change watch face. See Change Watch Face section. |
| | Settings Menu - Access watch settings and information. See Watch Settings Options and Information section. |

* The *Vitals* icon background color changes when active.

Watch Status Screen



To view the *Watch Status* screen, swipe downward on the watch face with one finger, or press the bottom button on the watch. Touch an icon to view status or access settings.

| | |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Battery Level - Battery level in percentage displays on the <i>Watch Status</i> screen. When battery charge is low, a notification displays. |
| | Bluetooth Status - Off, On, Connected |
| | Vibration Mode - Touch the icon to display the <i>Vibration</i> screen. This feature can be turned on or off from the <i>Vibration</i> screen. |
| | Bedtime Setting - Touch the icon to display the <i>Bedtime</i> screen and change the settings. See Watch Settings Options and Information section for complete information. |
| | Health Data - Touch the icon to display the <i>Vitals</i> screen. Vitals can be started and stopped from this screen. See Turn On Health Data section. |
| | Watch M-band Tightness - Undetermined, Correct, Too Loose, Too Tight |

Watch Face



The Watch Face displays Date, Time, Daily Step Count, and *Health Data (Blood Oxygen Content (SpO2%), Pulse Rate (PR/bpm), and Respiration Rate (RRp/rpm)). See [Change Watch Face](#) below to display a different face design.

* Displays when *Vitals* is enabled. See [Turn On Health Data](#) section.

Note: The watch face may be difficult to view when in direct sunlight.

Change Watch Face

To change the Masimo W1 face, open the *Main Menu*.

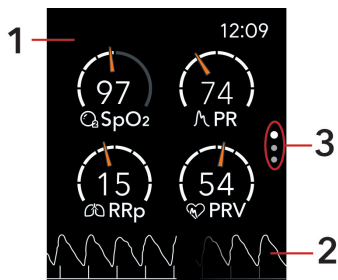
- Touch the Watch Face icon.
- Swipe left or right on watch face with one finger to choose a new watch face.
- When the desired watch face displays - stop swiping, this is now the watch face.

Software Updates

Software updates for Masimo W1 are installed using the supported app.

- On the supported app go to *Devices* and select the connected Masimo W1.
- On the *Device Info* screen, under *Software*, if an update is available, it is shown here. Follow the in-app instructions to update the Masimo W1 software.

Live Health Data (Vitals) Screen

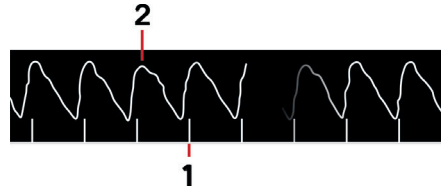


This screen contains the following information:

- Health Data (Vitals)**
When Vitals are enabled, Health Data displays*. If Vitals are not enabled, the options to **Start Vitals** displays. See [Turn On Health Data](#) section.
- Waveform and Signal Quality Indicators**
See [Waveform and Signal Quality Indicators](#) section for information.
- View Additional Screens**
Swipe up/down to view additional screens that display more vitals measurements as well as activity data (daily step count, calories burned, and miles walked on this date). Activity data resets daily.

* Touch a Vitals measurement to show information about that measurement. Press the top button on the side of the Masimo W1 to return to the screen.

Waveform and Signal Quality Indicators



Signal IQ (SIQ) indicators are displayed as vertical bars (1) within the Pleth Waveform (2) for each individual pulsation. The height of the bar provides an assessment of the confidence in the SpO2 measurement displayed.

Low Confidence Indicator



When confidence in the displayed measurement is low, the reading is dimmer (1) than the others (SpO2 measurement shown, others similar).

Watch Settings Options and Information

The following settings are available through the Main Menu.

| | | | |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Brightness | Screen brightness can be adjusted from the Brightness screen. Default brightness is 7. Touch to select a brightness level from 1 (dim) to 10 (most bright). Note: A high brightness setting may reduce battery life. | Bedtime | The Bedtime screen is used to Turn Bedtime On or Off and set the Bedtime START and Bedtime END. This disables the Raise to Wake feature of the Masimo W1 during the set time. |
| Always On | Always On displays the screen even when your wrist is down. When your wrist is raised, all functions of the Masimo W1 are available. This feature is turned On or Off from the Always On screen. Default setting is Off. Note: When this feature is On, battery life may be reduced. | Set Time and Date | When connected to the Masimo App, the time and date for Masimo W1 are automatically set. The time or date can also be set manually. Touch the Edit Time or Edit Date tile to manually set the time or date. |
| Raise to Wake | The Raise to Wake feature sensitivity can be set to Low, Medium or High (On), or turned Off. Default setting is Medium. • When On, the screen turns on when your wrist is raised. When your wrist is lowered, the screen turns off. If the Masimo W1 does not wake when raised, check that the correct wrist orientation is selected. See Orientation . • When Off, to view you must touch the screen or press one of the buttons on the Masimo W1. If the Masimo W1 does not wake when the screen is touched or buttons are pressed, the battery may need to be charged. Note: A high sensitivity may shorten battery life. A low sensitivity or turning this feature Off may extend battery life. Note: This feature is disabled during the set hours when Bedtime is enabled. | Orientation | By default, the Masimo W1 is set to be worn on the left wrist. To set the watch to be worn on the right wrist, select Right from the options available on the Orientation screen. Note: Correctly setting the orientation is necessary for accurate ECG waveforms and Raise to Wake feature operation. |
| Vibration | Vibration is turned On or Off from the Vibration screen. When On, a vibration is felt when notifications are displayed on the Masimo W1. Default setting is On. | Step Sensitivity | Step sensitivity for the step counter can be set to Low, Medium or High. Default setting is Low. Note: A High step sensitivity may shorten battery life. |
| | | Bluetooth | Bluetooth is turned On or Off from the Bluetooth screen. Default setting is On. When Bluetooth is Off, Masimo W1 will not communicate with the Masimo App to share Health Data. |
| | | Line Frequency | Line frequency for the ECG measurement can be set to 50Hz or 60Hz. Default setting is 60Hz. |
| | | About | Displays software and regulatory information about watch. Serial number and compliance information are also located behind recess for the wrist M-band. |

Troubleshooting

Below are some possible issues and recommended solutions for Masimo W1.

| Error | Possible Causes | Recommended Solutions |
|------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Masimo W1 does not turn on | <ul style="list-style-type: none"> Low battery. Masimo W1 internal error. | <ul style="list-style-type: none"> Charge the battery. See Charge the Watch section. If problems persist, contact Masimo Support. |
| Masimo W1 does not charge | <ul style="list-style-type: none"> The charger is not properly connected. Poor connection between Masimo W1 and the charger. Masimo W1 internal error. | <ul style="list-style-type: none"> Check that the charger cable is properly connected to the USB Power Adapter. Check that the USB Power Adapter is plugged into the power outlet completely. Ensure no objects or foreign material is between the Masimo W1 and the charger. Ensure the back of the Masimo W1 is clean. Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds. If problems persist, contact Masimo Support. |
| Masimo W1 is not connected to the app on the smart device | <ul style="list-style-type: none"> App is incompatible with smart device. Connection issues between Masimo W1 and smart device. Masimo W1 may be too far away from the smart device. Masimo W1 internal error. | <ul style="list-style-type: none"> Ensure the correct app is being used. Ensure the latest version of the app is installed. Check that Masimo W1 Bluetooth is on. Check that Masimo W1 has been paired through the App and not just the smart device Bluetooth settings. See Pair Masimo W1 to the Masimo App section. Unpair and pair the Masimo W1 to the smart device again using the App. See Pair Masimo W1 to the Masimo App section. Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds and retry the pairing procedure on the App. See Pair Masimo W1 to the Masimo App section. Move the Masimo W1 closer to the smart device and recheck connection. Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds and retry the pairing procedure on the App. See Pair Masimo W1 to the Masimo App section. If problems persist, contact Masimo Support. |
| Vitals measurements display as dashes "--" | <ul style="list-style-type: none"> Readings may not have stabilized. Masimo W1 may not be worn properly. | <ul style="list-style-type: none"> Allow time for readings to stabilize. Check if blood flow to the arm/wrist is restricted. Check that Masimo W1 is worn properly and that the watchband is tight. See Watch Status Screen section. |
| Cannot perform ECG measurement | <ul style="list-style-type: none"> Masimo W1 may not be worn properly. Excessive movement during ECG measurement. Finger is placed incorrectly on the top electrode pad. Finger not held on the top electrode long enough. | <ul style="list-style-type: none"> Ensure Masimo W1 is worn properly on the wrist. See Put on the Watch section. Ensure the finger makes good contact with the bottom side of the bezel of the Masimo W1. See Take an ECG Heart Rate Measurement section. Hold finger steady for 30 seconds to process ECG measurement. |

The following messages may appear on Masimo W1.

| Message | Possible Causes | Recommended Solutions |
|--------------------------------------------------------------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device Overheated, Watch needs to cool down before using | Internal temperature safety limit reached. | <ul style="list-style-type: none"> Remove from charger. Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds. If problems persist, contact Masimo Support. |
| Something went wrong. Contact Masimo for further assistance | Internal error. | <ul style="list-style-type: none"> Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds. If problems persist, contact Masimo Support. |

Specifications

Display Range and Resolution

| Measurement | Display Range | Resolution |
|----------------------------------|-------------------|------------|
| Oxygen Level (SpO ₂) | 0% to 100% | 1 % |
| Pulse Rate (PR) | 25 bpm to 240 bpm | 1 bpm |
| Pi (Perfusion Index) | 0.02 to 0.99 | 0.01 |
| | 1.0 to 9.9 | 0.1 |
| | 10 to 20 | 1 |
| PVi (Pleth Variability Index) | 0 to 100 | 1 |
| RRp (Respiration Rate) | 4 rpm to 70 rpm | 1 rpm |
| Pulse Rate Variability (PRV) | 0 ms to 150 ms | 1 ms |
| HR (Heart Rate) | 25 bpm to 240 bpm | 1 bpm |
| HRV (Heart Rate Variability)* | 0 ms to 150 ms | 1 ms |
| ECG Waveforms | ≥ 10 mV | ≤ 1 μV |

* HRV is only available when ECG is classified as "Normal Sinus Rhythm".

The Masimo W1 includes LEDs that emit wavelengths in range of 500 nm to 1000 nm with a peak optical power less than 20 mW. This information about the wavelength range may be more useful for your healthcare professional.

Pulse-Oximetry Performance

| Parameter | Specification* |
|------------------------------------------------------|------------------------------------------------------------|
| SpO ₂ (No Motion) ^[1] | 2% ARMS, over the range 70% to 100% for Adults |
| SpO ₂ (Low Perfusion) ^[2] | 2% ARMS, over the range 70% to 100% for Adults |
| Pulse Rate (No Motion) | 3 bpm ARMS, over the range of 25 bpm to 240 bpm for Adults |
| Respiration Rate by Pleth (No Motion) ^[3] | 3 rpm ARMS, over the range 4 RPM - 70 RPM, for Adults |

* ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.

ECG Performance

| Parameter | Specification* |
|-----------------|---------------------------------------------|
| Heart Rate (HR) | ≤ 5 bpm over the range of 25 bpm to 240 bpm |

* ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.

Physical Characteristics

| | |
|-----------------------|--------------------------------------------------|
| Watch Face Size | 40 mm (1.57") |
| Weight with Watchband | 54 g (1.9 oz.) |
| Display Type | 16 bits color display with brightness adjustment |
| Expected Service Life | 3 Years |

Electrical

| Battery | |
|-------------|--------------------------------|
| Type | Internal Li-ion rechargeable |
| Capacity | Approx. 22 hrs. ^[4] |
| Charge Time | 3 hrs. ^[5] |

Environmental

| Environmental Conditions | |
|--------------------------------|----------------------------------------------|
| Operating Temperature | 0°C to 35°C (32°F to 95°F) |
| Storage/Transport Temperature | -20°C to 60°C (-4°F to 140°F) ^[6] |
| Operating Humidity | 10% to 95% RH (non-condensing) |
| Storage/Transport Humidity | 10% to 95% RH (non-condensing) |
| Operating Atmospheric Pressure | 540 mBar to 1060 mBar |

Compliance

| Masimo W1 Safety Standards Compliance | |
|---------------------------------------|----------------|
| IEC 60601-1 | IEC 60601-1-2 |
| EN ISO 80601-2-61 | IEC 60601-1-11 |

| Masimo W1 Equipment Classification per IEC 60601-1 | |
|-------------------------------------------------------|----------------------------------------------------------------------------------------------|
| Type of ME Equipment | Body Worn |
| Type of Protection | Internally powered (Battery power) |
| Degree of Protection of Electrical Shock | CF-Applied Part |
| Protection against harm from solid and liquid ingress | IP24, Protected from objects greater than 12 millimeters and water spray from any direction. |
| Mode of Operation | Continuous |
| Sterility | No part of Masimo W1 is supplied sterile |

Wireless Specifications

| Communication (Bluetooth) | |
|---------------------------|-------------------------------|
| Type | BLE |
| Frequency | 2402-2480 MHz |
| Max Peak Output Power | -3.6dBm or 0.44mW (Conducted) |
| Antenna Peak Gain | +3dBi |

| Radio Compliance | |
|------------------|--------------------------------------------------------|
| Radio Modes | Bluetooth LE |
| USA | Model: W1 FCC ID: VKF-MASIW1 |
| | Model: Masimo Wireless Charger FCC ID: VKF-MASIW1CG |

Citations

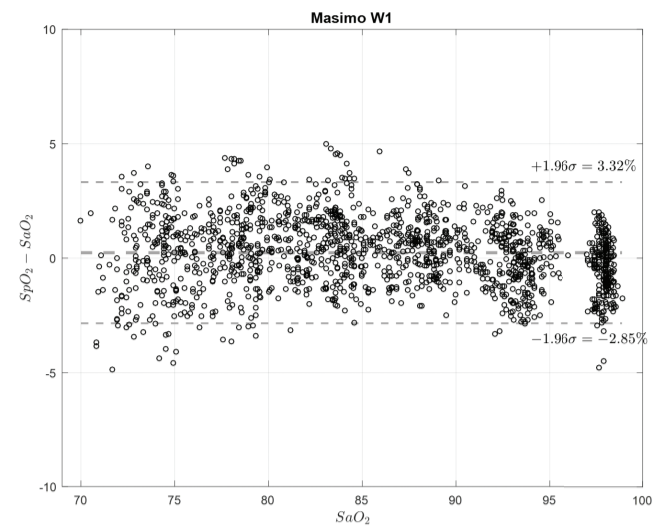
- ^[1]SpO₂ performance has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70%-100% against a laboratory co-oximeter.
- ^[2]SpO₂ performance has been validated under low perfusion (≤ 0.3 perfusion index) accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70%-100% against a laboratory co-oximeter.
- ^[3]RRp performance has been validated for no motion accuracy on healthy male and female volunteers against manual clinician-scored capnograms. RRp performance was validated across the entire range of 4 to 70 RPM through bench testing.
- ^[4]This represents approximate run time with Screen on-time: 0%, Bluetooth connection On, Active Measurement, SpO₂ and Heart Rate (Continuous Vitals On), ECG (10 Spot-Check measurements), using a fully charged battery.
- ^[5]The battery shall charge to 80% of battery capacity in no longer than 3 hours at ambient temperature and might not charge completely under elevated ambient temperature.
- ^[6]If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20°C to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

Oxygen Level (SpO₂) ARMS Performance Specifications

The table below provides ARMS (Accuracy Root Mean Square) values measured using the Masimo W1 under no motion in a clinical study.

| Measurement ARMS Values for Masimo W1 | |
|---------------------------------------|----------|
| SpO ₂ Accuracy Range (%) | ARMS (%) |
| 90-100 | 1.35 |
| 80-90 | 1.58 |
| 70-80 | 1.87 |
| 70-100 | 1.59 |

The below Bland-Altman plot represents the correlation of the (SpO₂ + SaO₂)/2 versus (SpO₂ - SaO₂) under no motion with an upper 95% and lower 95% limits of agreement.



Guidance and Manufacturer's Declaration

| Electromagnetic Emissions | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment. | | |
| Emission Test | Compliance | Electromagnetic Environment - Guidance |
| RF Emissions CISPR 11 | Group 1 | ME Equipment 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. |
| RF Emissions CISPR 11 | Class B | ME Equipment suitable for use in all establishments including domestic establishments. |

| Electromagnetic Immunity | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment. | | | |
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | +6 kV contact +8 kV air | +6 kV contact +8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment. |
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz to 2.7 GHz | 10 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Masimo W1, including cables, than the recommendation separation distance calculated from the equation applicable to the frequency of the transmitter. |
| <p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |
| Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment. | | | |

Test Specifications for Enclosure Port Immunity to RF Wireless Communication Equipment

| Test Frequency (MHz) | Band (a) (MHz) | Service (a) | Modulation (b) | Maximum Power (W) | Distance (m) | Immunity Test Level (V/m) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------------------------------------------------------------|---------------------------------------|-------------------|--------------|---------------------------|
| 385 | 380-395 | TETRA 400 | Pulse modulation (b) 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430-470 | GMRS 460, FRS 460 | FM (c) +/- 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | 704-787 | LTE Band 13, 17 | Pulse modulation (b) 217 Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800-960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation (b) 18 Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700-1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 35; UMTS | Pulse modulation (b) 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400-2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation (b) 217 Hz | 2 | 0.3 | 28 |
| 5240 | 5100-5800 | WLAN 802.11 a/n | Pulse modulation (b) 217 Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |
| <p>Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.</p> <p>(a) For some services, only the uplink frequencies are included.</p> <p>(b) The carrier shall be modulated use a 50% duty cycle square wave signal.</p> <p>(c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p> | | | | | | |

Recommended Separation Distances

| Recommended separation distances between portable and mobile RF communications equipment and the Masimo W1. | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| Rated maximum output power of transmitter [W] | Separation distance according to frequency of transmitter [m] |
| | |
| 0.01 | 0.06 |
| 0.1 | 0.19 |
| 1 | 0.6 |
| 10 | 1.9 |
| 100 | 6 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. | |
| Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | |