User's Guide

Masimo W1™

Masimo

For general wellness and health applications including sports, fitness, and relaxation management.

These operating instructions provide the necessary information for proper operation of the Masimo W1 Health and Wellness. There may be information provided in this manual that is not relevant for your Masimo W1. It is recommended to read the instructions before operating Masimo W1.

See instructions for use for use information, including 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

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

Patents: ***www.masimo.com/patents.htm***

Contents

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.

Product Description and Features

Product Description

Masimo W1™ is a wearable device that continuously tracks health data to better understand your general state of health and promote healthier lifestyle decisions.

The Masimo W1 is compatible with the Masimo Health app where users can access, track and trend their health data.

Features

Key features of Masimo W1 include:

- Masimo SET+™ technology.
- Bluetooth® LE for the wireless communication.

The Masimo W1™ provides these measurement features:

Oxygen Level (SpO_2) *	Oxygen levels in your blood, which can change with heart and lung function, activity, and altitude.
Pulse Rate (PR)	How often the heart pushes blood through your body, which can change with general health, physical activity, and with your mental or emotional state (e.g., stress, anxiety).
Pulse Rate Variability (PRV)	The changes in your pulse rate that can show how consistently your blood is being pushed through your body even under exercise or stress.
Pleth Variability Index (PVi)	A calculation based on the changes in your perfusion index, which may be affected by your fluid volume during your respiration cycle and can increase with lower fluid levels.
Perfusion Index (Pi)	A calculation of the relative strength of your pulse, which changes based on your circulation. The changes in your pulse rate that can show how consistently your blood is being pushed through your body even under exercise or stress.
Heart Rate (HR)	The number of times the heart beats in a minute, based on electrical signals.
Heart Rate Variability (HRV)	Variations in the amount of time between heart beats, which may provide insight in how consistently your reacting to changes that affect your heart rate like exercise or stress.
Breaths Per Minute (RRp)	The number of breaths you take in a minute, based on the pleth; respiration rate can change with your general health condition, physical activity, or mental or emotional state

* *Arterial Oxygen Saturation*

General Warnings and Precautions

WARNING: Always consult your physician regarding clinical decisions. Do not rely on the readings as the only basis for medical decisions. Incorrect clinical decisions may result in harm. Before use, read the following carefully**.**

Safety Warnings

WARNING: Do not use if it appears damaged or if you think it is damaged. Damage to the device can result in exposed sharp edges that may cause harm.

WARNING: Do not adjust, repair, open, disassemble, or modify the Masimo W1. Damage to the device may result in degraded performance and/or injury.

WARNING: Do not use in areas filled with flammable gases: such as anesthetics, oxygen, oxygen-enriched environments, or nitrous oxide to prevent risk of fire.

WARNING: Keep Masimo W1 away from small children. Small items may become a choking hazard.

Note: Use and store as directed in the ***Specifications*** section in this manual.

Performance Warnings

WARNING: Do not self-diagnose or self-medicate based on the measurements. Always consult your doctor regarding clinical decisions.

WARNING: See ***Risk and Benefit*** Section for information on limitations and ways to get the most accurate readings.

WARNING: Do not use Masimo W1 as an apnea monitor. Oxygen changes may be delayed from when your breathing actually stops.

WARNING: The Masimo W1 may not fully charge if the room is too hot.

WARNING: Check the fit of the watchband periodically. Avoid wearing the Masimo W1 too loose or too tightly to avoid inaccurate readings or pressure injury.

WARNING: Keep electronics with communication capabilities greater than 30 cm (12 inches) to any part of the Masimo W1. Otherwise, degradation performance could result.

CAUTION: When using with a smart device, keep both devices within the recommended range of each other. See Specifications for details. Moving outside of this range may cause a loss in connection.

CAUTION: Do not place the Masimo W1 near electrical equipment that may affect the device, preventing it from working properly.

CAUTION: Failure to charge Masimo W1 promptly after a Low Battery notification message may result in the device shutting down.

CAUTION: To establish and maintain the minimum Quality of Service of the Masimo W1, the keep the Masimo W1 within ~7 m (~23 ft.) line of sight to the smart device App.

CAUTION: Move the devices away from sources that may interfere with Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI). This may result in loss of Quality of Service. Example devices that cause RFI are other smart devices, devices with remote controls, and baby monitors.

Note: All batteries lose capacity with age, thus the amount of run time at Low Battery will vary depending upon the age of the battery.

Note: A functional tester cannot be used to assess the accuracy of the Masimo W1.

HR Performance

WARNING: Make sure the Masimo W1 makes good contact with your wrist and your finger. Poor contact can result in no or incorrect readings.

WARNING: Avoid wearing watch over compromised skin, excessive hair, or scar tissue, as this may result in incorrect readings.

WARNING: Pacemakers that create fusion beats (pace pulse on top of the QRS complex) may not be detected by Masimo W1.

WARNING: HR reading can be affected by the following:

- Poor electrode contact.
- Conditions that may increase skin impedance (e.g., dry skin).
- Weak heart signals.
- Excessive movement.
- Electrode or electrodes placement over skin injuries or hair.
- Abnormal heart rhythms due to physiological conditions or induced through external factors (e.g., cardiac arrhythmias, ventricular tachycardia/fibrillation, seizures etc.).
- EMI radiation interference.
- Pacemakers

Cleaning and Service Warnings

WARNING: The following can cause damage that may impact the performance of your Masimo W1:

- Do not attempt to sanitize or sterilize using heat, steam, boiling or similar means.
- Clean only with the solutions listed in this manual.

WARNING: Do not attempt to remanufacture, recondition, or recycle the Masimo W1 as these processes may damage the electrical components, potentially leading to user harm.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the Masimo W1 for servicing.

CAUTION: To avoid permanent damage to the Masimo W1, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

Compliance Warnings

WARNING: Changes or modifications not expressly approved can void the user's authority to operate the equipment.

WARNING: The frequency bands of this device (2.4 GHz and 5.15 to 5.25 GHz) are only for indoor use, in accordance with international telecommunication requirements.

WARNING: Do not incinerate the Masimo W1. The device contains a battery that should be properly disposed according to local laws and regulations.

WARNING: To help mitigate cybersecurity concerns, consider the following:

- Deactivating the Masimo W1 Bluetooth when not compatible or uncertain of the security of the Bluetooth connection.
- Do not wireless connect Masimo W1 with software not authorized for use by Masimo.
- Check the paired connection is made with the correct decision.
- Connect the Masimo W1 to a Masimo smart device application so that data can be stored and kept.

CAUTION: Comply with local laws in the disposal of the device.

CAUTION: Keep Masimo W1 away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.

Note: This equipment has been tested and found to comply with the Class B limits in accordance with EN 60601-1-2: 2015. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

Note: 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.

Note: Masimo W1 and Masimo W1 Wireless Charger are exempt from FCC and IC RSS 102 RF radiation exposure testing requirements set forth for an uncontrolled environment.

Note: When using Masimo W1 and consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Note: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Risks and Benefits

See the Benefits and Risks of the Masimo W1 below.

Risks

- Inappropriate use or misuse of the device. You should follow the information provided in this manual and not self-diagnosis or treat yourself. Always seek the advice of your physician if you are not feeling well.
- With electrical devices, there may be a risk of electrical hazards. These risks are reduced by the design and testing of Masimo W1.
- As with all devices with small parts, there is a risk of a child swallowing and choking. Keep small parts away from small children to prevent such hazards.
- As with all items applied directly to the skin, there is a risk of skin irritation and discomfort.

Benefits

- Masimo W1 is a wearable device able to provide clinically validated continuous oxygen saturation (SpO_2), pulse rate (PR), and respiration rate (RRp).
- Masimo W1 can provide heart rate (HR) health data.
- Masimo W1 provides wireless communication capabilities to support storage and review of data from a connected smart device.

Description

This chapter contains the description of the Masimo W1 physical features.

General Description

The Masimo W1 includes the following:

- Masimo W1 Device
- Masimo W1 Wireless Charger

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

Features

Top

1 Main Menu/Back Button

- Press and hold to turn the watch On or Off.
- Press to cycle through menus from Home Screen OR use as a back button when in submenus.

2 Live Screen Button

- Press once to view health data (live screen). Screen returns to watch face after a few moments of inactivity.
- From the Watch Face, press once to turn off screen.

3 Touch Screen

- Used to interact with the watch. See ***Using the Touch Screen*** on page 9.

4 Top Electrode

- Electrode provided on the bottom bezel to be contacted with the finger during HR health data measurements.

Bottom

1 Bottom Electrode

- Electrode on the bottom of the Masimo W1 that contacts the wrist for HR health data measurements.

2 Optical Sensor

- Location of sensors for Vitals measurements.

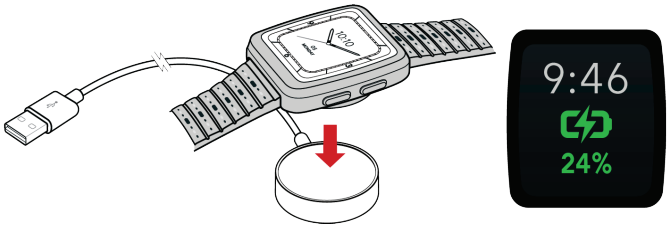
3 Watchband release button

- Press inward to remove the watchband. Serial number and compliance information are in recess behind watchbands.

Basic Setup and Use

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

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 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.

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 App

The Masimo Health App collects and displays health data from the Masimo W1 and other paired devices.

Download the Masimo Health App directly from the Google Play or Apple App Store and follow the setup instructions.

Masimo Health is required to support software updates to the Masimo W1 watch. This prevents unauthorized upgrades to the Masimo W1.

GET IT ON Google Play

Download on the App Store

Pair Masimo W1 to Masimo Health App

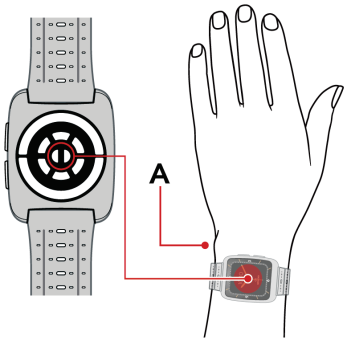
Pair Masimo W1 to the mobile device to view data from the watch on the Masimo Health App.

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

Click on Masimo W1 under the *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 wristband is too loose. See ***Watch Status Screen*** on page 11 for wristband 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.

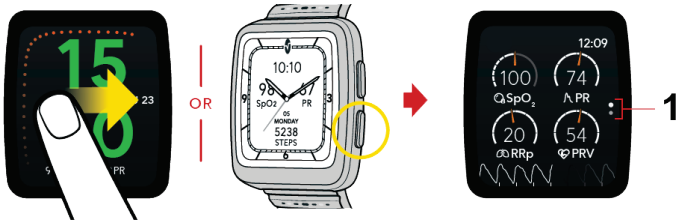
Touch and Hold- Touch and hold an item on the screen.

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

Activate Continuous Health Data

The continuous health data can be activated 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*** on page 10 or ***Watch Status Screen*** on page 11.

1. Select the *Vitals* icon to activate the Continuous Health Data.
2. Check the bottom of the watch makes good contact with the top of your wrist.
3. Check the watch is secured comfortably to prevent it from slipping (1 or 2 notches tighter after it longer slides on the wrist).



To view the *Live Health Data* screen, swipe right across the watch face using one finger or press the lower button on the side of the Masimo W1.

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

See ***Live Health Data (Vitals) Screen*** on page 11 for complete information about the *Live Health Data* screen.

How to Take a Heart Rate Measurement

The Heart Rate Measurement can be accessed by touching the Heart Rate icon from the *Main Menu* and following the steps below. See ***Main Menu*** on page 10. Ensure the Masimo W1 is on the wrist identified in the *Orientation* settings to ensure a proper heart rate measurement. See ***Changing Settings Options*** on page 12.

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

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

Advanced Use

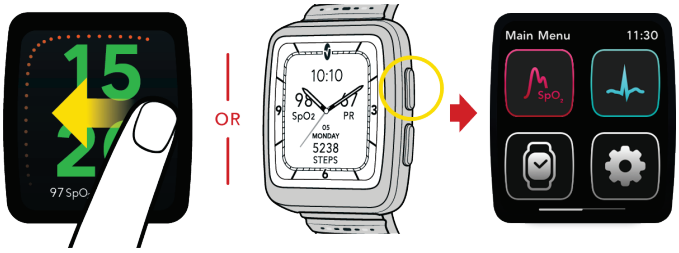
The following information are for the additional features available that go beyond the basic set up and use

User Interface (Display)

Main Menu

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

- To open the *Main Menu*, swipe left across the watch face using one finger or press the upper button on the side of the Masimo W1.
- Swipe left and right using one finger to navigate the *Main Menu* and view all available Apps.
- Open an app by tapping on its icon.



Vitals Measurement * - Feature to start or stop health data measurements. See ***Activate Continuous Health Data*** on page 9.

Heart Rate Measurement - Feature to perform a heart rate spot check. See ***How to Take a Heart Rate Measurement*** on page 10.

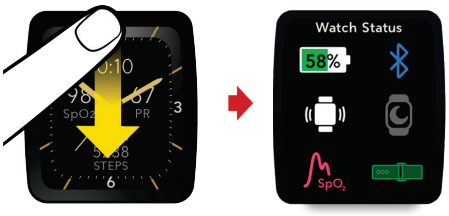
Watch Face Settings - Feature to change watch face. See ***Change Watch Face*** on page 11.

Settings Menu - Access additional watch settings. See ***Changing Settings Options*** on page 12.

Watch Information - Displays software and regulatory information about watch. Serial number and compliance information are also located behind recess for watchbands.

* 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.

58%	**Battery Level**	Battery level in percentage displays on the *Watch Status* screen. When battery charge is low, a notification displays.		
	Bluetooth Status	Off	On	Connected
	Vibration Mode	Touch the icon to display the *Vibration* screen. This feature can be turned on or off from the *Vibration* screen.		
	Bedtime Setting	Touch the icon to display the *Bedtime* screen and change the settings. See ***Changing Settings Options*** on page 12 for complete information.		
SpO2	**Health Data**	Touch the icon to display the *Vitals* screen. Vitals can be started and stopped from this screen. See ***Activate Continuous Health Data*** on page 9.		
	Watchband Tightness	Undetermined	OK Correct	Too Loose / Too Tight

Watch Face

The *Watch Face* displays Date, Time, Daily Step Count, and *Health Data (Blood Oxygen Content (SpO_2/%), Pulse Rate (PR/bpm), and Respiration Rate (RRp/rpm)).

See ***Change Watch Face*** on page 11 to display a different face design.

* Displays when *Vitals* is enabled. See ***Activate Continuous Health Data*** on page 9.

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

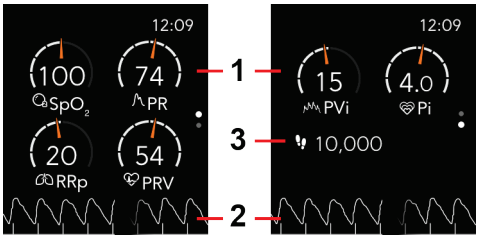
Change Watch Face

To change the Masimo W1 face, open the *Main Menu*. See ***Main Menu*** on page 10.

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

Live Health Data (Vitals) Screen

The *Live Health Data* (Vitals) screen contains the following information:



1 Health Data (Vitals)

When Vitals are enabled, Health Data displays. If Vitals are not enabled, the options to **Start** Vitals displays. See ***Activate Continuous Health Data*** on page 9.

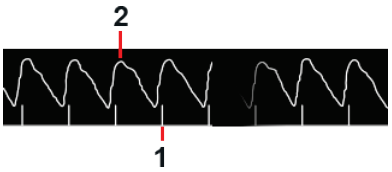
2 Waveform and Signal Quality Indicators

See ***Waveform and Signal Quality Indicators*** on page 12 for information.

3 Daily Step Count

Shows how many steps have been taken on this date. This count resets daily.

Waveform and Signal Quality Indicators



Signal IQ (SIQ) indicators are displayed as vertical bars within the Pleth Waveform for each individual pulsation. The height of the bar provides an assessment of the confidence in the SpO_2 measurement displayed.

Changing Settings Options

The following setting 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.
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. **Note:** When this feature is enabled, battery life my be reduced.
Raise to Wake	The *Raise to Wake* feature is turned on or off from the *Raise to Wake* screen. • 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:** Turning this feature off may extend battery life.
Bluetooth	Bluetooth is turned "On" or "Off" from the *Bluetooth* screen. Bluetooth is On by default. When Bluetooth is off, Masimo W1 will not communicate with the Masimo Health App to share Health Data.
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.
Bedtime	The *Bedtime* screen is used to Turn Bedtime "On" or "Off" and set the Bedtime START and Bedtime END. This silences notifications from the Masimo W1 during the set time.
Set Time and Date	When connected to the Masimo Health 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.
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, selection **Right** from the options available on the *Orientation* screen. **Note:** Orientation setting can affect the *Raise to Wake* feature operation.

Appendix

Troubleshooting Masimo W1

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

Error	Possible Causes	Recommended Solutions
Masimo W1 does not turn on	• Low battery • Masimo W1 internal error.	• Charge the battery. See ***Charge the Watch*** on page 8. • If problems persist, contact Masimo Support. See ***Contacting Masimo*** on page 18.
Masimo W1 does not charge.	The charger is not properly connected.	• 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.
	Poor connection between Masimo W1 and the charger.	• Ensure no objects or foreign material is between the Masimo W1 and the charger. • Ensure the back of the Masimo W1 is clean.

Error	Possible Causes	Recommended Solutions
	Masimo W1 internal error.	• Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds. • If problems persist, contact Masimo Support. See ***Contacting Masimo*** on page 18.
Masimo W1 is not connected to the app on the smart device.	App is incompatible with smart device.	• Ensure the correct app is being used. • Ensure the latest version of the app is installed.
	Connection issues between Masimo W1 and smart device.	• 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 Masimo Health App*** on page 8. • Unpair and pair the Masimo W1 to the smart device again using the App. See ***Pair Masimo W1 to Masimo Health App*** on page 8. • 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 Masimo Health App*** on page 8.
	Masimo W1 may be too far away from the smart device.	Move the Masimo W1 closer to the smart device and recheck connection.
	Masimo W1 internal error.	• 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 Masimo Health App*** on page 8. • If problems persist, contact Masimo Support. See ***Contacting Masimo*** on page 18.
Vitals measurements display as dashes "--".	• Readings may not have stabilized. • Masimo W1 may not be worn properly.	• 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*** on page 11.
Cannot perform Heart Rate measurement	• Masimo W1 may not be worn properly. • Excessive movement during measurement. • Finger is placed incorrectly on the top electrode pad. • Finger not held on the top electrode long enough.	• Ensure Masimo W1 is worn properly on the wrist. See ***Put on the Watch*** on page 9. • Ensure the finger makes good contact with the bottom side of the bezel of the Masimo W1. See ***How to Take a Heart Rate Measurement*** on page 10. • Hold finger steady for 30 seconds to process the 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.	• 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. See ***Contacting Masimo*** on page 18.
Something went wrong. Contact Masimo for further assistance.	Internal error.	• Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds. • If problems persist, contact Masimo Support. See ***Contacting Masimo*** on page 18.

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

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.

Oxygen Level Accuracy (ARMS*)

Parameter	Specification
SpO_2 (No Motion) [1] (Low Perfusion) [2]	2% A_{RMS}, over the range 70% to 100% for Adults
Pulse Rate (No Motion)	3 bpm A_{RMS}, over the range of 25 bpm to 240 bpm for Adults
Respiration Rate by Pleth (No Motion) [3]	3 rpm A_{RMS}, over the range 4 RPM - 70 RPM, for Adults

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

HR Accuracy (ARMS)*

Heart Rate (HR)	
Range of 25 bpm to 240 bpm	≤ 5 bpm

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

Physical Characteristics

Physical Characteristics	
Watch Face Size	40mm (1.57")
Weight with Watchband	54 g (1.9 oz.)
Display Type	16 bits color display with brightness adjustment
Expected Service Life	3 Years
Protection against harm from solid and liquid ingress	IP24, Protected from objects greater than 12 millimeters and water spray from any direction.

Electrical

Battery	
Type	Internal Li-ion rechargeable
Capacity	Approx. 26 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	
IEC60601-1	IEC 60601-1-2
EN ISO 80601-2-61	IEC 60601-1-11

Wireless Specifications

Communication (Bluetooth)	
Type	BLE
Frequency	2402-2480 MHz

Communication (Bluetooth)	
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

Guidance and Manufacturer's Declaration

Electromagnetic Emissions		
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	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	Equipment suitable for use in all establishments including domestic establishments.

Electromagnetic Immunity			
Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the 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.
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
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 Equipment is used exceeds the applicable RF compliance level above, the 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 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						

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
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						

(a) For some services, only the uplink frequencies are included.
(b) The carrier shall be modulated use a 50% duty cycle square wave signal.
(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.

Recommended Separation Distances

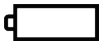
Recommended separation distances between portable and mobile RF communications equipment and the Masimo W1.	
Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**
	80 MHz to 2.7 GHz $d = 0.6\sqrt{P}$
0.01	0.06
0.1	0.19
1	0.6
10	1.9
100	6

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.

Symbols

The following symbols may be found on the Masimo W1, or packaging and are defined below.

Symbols	Definition	Symbols	Definition
	Follow Instructions for use		Consult instructions for use
	Federal Communications Commission (FCC) licensing		Separate collection for electrical and electronic equipment (WEEE)
FCC ID:	Identifies unit has been registered as a radio device	IP24	Protected from objects greater than 12 millimeters and water spray from any direction.
	Date of Manufacture YYYY-MM-DD		Manufacturer
REF	Catalog number (model number)	SN	Serial number
LOT	Lot Code		Storage temperature range
	Atmospheric pressure limitation		Storage humidity limitation

Symbols	Definition	Symbols	Definition
	No parameter alarms		Bluetooth
	Battery	-	--
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

[1] SpO_2 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] SpO_2 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, SpO_2 and Heart Rate (Continuous Vitals On), Heart Rate (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.

Cleaning, Disinfecting and Service

The following chapter contains information about cleaning, battery operation, performance verification, service, repair, and warranty.

Cleaning Masimo W1 and Charger

CAUTION: Do not immerse Masimo W1 in any liquid.

The surfaces of Masimo W1 have been tested to be chemically resistant to the following disinfectants/solutions:

- 70% Isopropyl Alcohol
- CaviWipes™

To clean Masimo W1, follow the instructions below:

1. Use a soft-bristle, nylon brush wet with DI water and gently brush along the grooves and crevices of the body to loosen debris before cleaning.
2. Use one CaviWipe or a 4” x 4” gauze pad saturated with 70% IPA to wipe the surfaces twice or until the surfaces are free of any visible residue.
3. Use a second soft-bristle, nylon brush with thin brush head wet with 70% IPA and gently brush along the grooves and crevices of the body at least twice.
4. Use a second CaviWipe or a second 4” x 4” gauze pad saturated with 70% IPA to wipe the surfaces twice or until the surfaces are free of any visible residue.
5. When using CaviWipes, use a 4” x 4” gauze pad saturated with DI water to wipe the surface once.
6. Allow the Masimo W1 device to dry thoroughly before using again.

CAUTION: Never saturate Masimo W1 completely with any disinfection solution.

Service and Return Procedure

Contact Masimo for product support. If needed, an RMA will be provided for repair or replacement. Masimo can be reached at 800-326-4890. For customers outside the United States, local contact information can be found at http://service.masimo.com.

Clean contaminated/dirty equipment before returning per Maintenance and Cleaning instructions. Make sure the equipment is fully dry before packing. Package the device securely, in the original shipping box if possible, and enclose the following information and items:

- Include the RMA form provided, or a letter describing in detail any difficulties experienced with Masimo W1. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included. Purchase Order number to cover repair if the device is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information. Person (name, telephone/Telex/fax number and country) to contact for any questions about the repairs.
- A certificate stating that the device has been decontaminated for bloodborne pathogens.
- Return the device to Masimo at the address listed in ***Contacting Masimo*** on page 18 below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product Masimo W1 and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 36 months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and Masimo does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product. Additionally, Masimo will not be liable for any incidental, indirect, special, or consequential loss, damage, or expense arising from the use or loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

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