

# Masimo W1™





**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.

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


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Patents: [www.masimo.com/patents.htm](http://www.masimo.com/patents.htm)

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## 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, Features and Indications for Use

### Product Description

The Masimo W1™ is a watch that provides spot-check ECG measurements and continuous measurements of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), 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

### Features

Key features of Masimo W1 include:

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

The Masimo W1™ provides these measurement features:

<b>Heart Rate (HR)</b>	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.
<b>Functional Oxygen Saturation of Arterial Hemoglobin (SpO<sub>2</sub>)</b>	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.
<b>Pulse Rate (PR)</b>	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 <sub>2</sub> .

<b>Respiration Rate from Pleth (RRp)</b>	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).
<b>Atrial Fibrillation (AFib)</b>	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.
<b>Sinus Rhythm</b>	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.
<b>Perfusion (Pi)</b>	Calculation of the relative strength of the pulsatile signal used for the SpO <sub>2</sub> and Pulse Rate. The Pi increases with better blood circulation. Your SpO <sub>2</sub> 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.
<b>Pleth Variability Index (PVI)</b>	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.
<b>Pulse Rate Variability (PRV)</b>	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).

## 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 (SpO<sub>2</sub>), pulse rate (PR), and respiration rate from the pleth (RRp) on adults.

## Safety Information, Warnings and Cautions

**CAUTION:** Read the manual, all precautionary information, and specifications before use.

Failure to follow these instructions may increase the potential residual risk of the following:

- Possible wrong or delayed treatment decision due to overreliance.
- Electrical, Fire, or Mechanical Injury.
- Skin irritation due to potential allergic reaction.

## Safety Warnings and Cautions

**WARNING:** Do not use the Masimo W1 if it appears or is suspected to be 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.

**WARNING:** Do not touch if defibrillation is required to prevent damage to the device.

**WARNING:** Do not use Masimo W1 during magnetic resonance imaging (MRI) or in an MRI environment.

- The device contains materials that can be attracted by the MR magnet core that can make it a risk of projectile injury.
- Metal components can heat up during MR scanning that can present thermal injury and burns.
- Artifacts can be created in the MR image.
- Strong magnetic fields may prevent the device from operating properly.

**Note:** Do not use on more than a single patient at a time with the Masimo W1.

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

## Performance Warnings and Cautions

**WARNING:** Masimo W1 should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

**WARNING:** Masimo W1 is not intended to be used as an apnea monitor. Do not rely on the Masimo W1 for detection of cessation of breathing.

**WARNING:** If any measurement seems questionable, first check the patient's vital signs by alternate means and then check that the Masimo W1 is functioning properly.

**WARNING:** Masimo W1 does not have alarms to support continuous monitoring.

**WARNING:** Masimo W1 may be used during defibrillation; however, the display may require up to 5 seconds to return to normal operation.

**WARNING:** Masimo W1 is not intended for use during electrocautery.

**WARNING:** Masimo W1 may not fully charge in a high ambient temperature environment.

**WARNING:** Displayed parameter(s) may not be accurate when the SIQ is low. Additional information to supplement values should be used to completely understand the patient's condition.

**WARNING:** Check the watchband periodically to ensure adequate securement, circulation, and skin integrity. Watchbands applied too tightly or that become tight due to edema can cause inaccurate readings and/or pressure injury.

**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Masimo W1. Otherwise, degradation of the performance of this equipment 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:** The RRp value may be inaccurate under conditions where the pulse rate is less than two times the respiration rate. The following conditions may include, but it's not limited to patients with high respiration rate and low heart rate, or patients with specific medical conditions such as sick sinus syndrome, bradycardia due to any primary cardiac conditions as well as secondary condition from beta blockers, digoxin, etc.

**CAUTION:** Respiration rate provides an indicator of central ventilatory drive and not a direct indication that air is moving through the upper airway.

**CAUTION:** If using Masimo W1 during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate, or the device might read zero for the duration of the active irradiation period.

**CAUTION:** When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

**CAUTION:** High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance.

**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 alarm may result in the device shutting down.

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

**CAUTION:** The wireless quality of services may be influenced by the presence of other devices that may create radio frequency interference (RFI). Some RFI devices to consider are as follows: electrocautery equipment, diathermy, cellular telephones, wireless PC and tablets, pagers, RFID, MRI, electrically powered wheelchair, etc. When used in the presence of potential RFI devices, consideration should be taken to maximize separation distances and to observe for any potential signs of interference such as loss of communication or reduced Wi-Fi signal strength.

**Note:** Always charge Masimo W1 when it is not in use to ensure that the Masimo W1 battery is fully charged before use.

**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.

## ECG 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:** For paced patients who exhibit only intrinsic rhythm, the monitor can erroneously count pace pulses as QRS complexes. Do not rely on the Masimo W1 for ECG monitoring of cardiac patients with pacemakers.

**WARNING:** ECG signal detection and HR reading can be affected by the following:

- Poor electrode contact
- Conditions that may increase skin impedance (e.g., dry skin).
- Weak heart (ECG) 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

## Pulse Oximetry Performance

**WARNING:** If SpO<sub>2</sub> values indicate hypoxemia, do not self-diagnose. Confirmation by a medical professional is required.

**WARNING:** SpO<sub>2</sub> is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

**WARNING:** Optical, pleth-based measurements (e.g., SpO<sub>2</sub>, PR, and RRp) can be affected by the following:

- Incorrect watch placement or securement (e.g., too loose, too tight).
- Blood pressure cuff inflated or constricting the same arm.
- Intravascular dyes such as indocyanine green or methylene blue.
- Arterial catheter
- Venous congestion
- Abnormal venous pulsations (e.g., tricuspid valve regurgitation, Trendelenburg position).
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g., cardiac arrhythmias, intra-aortic balloon, etc.).
- Moisture, birthmarks, skin discoloration, tattoos, henna, or foreign objects in the light path.
- Elevated levels of bilirubin
- Physiological conditions that can significantly shift the oxygen dissociation curve.
- A physiological condition that may affect vasomotor tone or changes in vasomotor tone.
- Loss of pulsatile signal

**WARNING:** No or inaccurate SpO<sub>2</sub> readings may additionally be caused by:

- Elevated levels of COHb and/or MetHb. Note: High levels of COHb or MetHb may occur with a seemingly normal SpO<sub>2</sub>.
- Severe anemia.
- Very low arterial perfusion.
- Hypocapnic or Hypercapnic conditions.
- Excessive motion.
- Vasospastic disease such as Raynaud's.
- Hemoglobinopathies and synthesis disorders (e.g., thalassemias, Hb s, Hb c, sickle cell).
- Peripheral vascular disease.
- EMI radiation interference.

**WARNING:** Inaccurate RRp readings may additionally be caused by:

- Low arterial perfusion.
- Motion induced artifact.
- Severe anemia
- Arrhythmia

## Cleaning and Service Warnings and Cautions

**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 patient harm.

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

**CAUTION:** Do not touch, press, or rub the watch face with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the display.

**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.

**CAUTION:** Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the Masimo W1. These substances affect the device's materials and device failure can result.

**CAUTION:** Do not submerge Masimo W1 in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage Masimo W1.

## Compliance Warnings and Cautions

**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 wirelessly connect Masimo W1 with software not authorized for use by Masimo.
- Check the paired connection is made with the correct device.
- Connect the Masimo W1 to a Masimo smart device application so that data can be stored and kept.
- Reset the Masimo W1 to factory default if you are no longer using or sending the watch out for service.

**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 for medical devices according to the 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:** Users are advised that high-power radars are allocated as primary users (i.e., priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN 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.

## Chapter 1: Description

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

### General 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](http://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 10.

**4 Top ECG Electrode**

- ECG electrode provided on the bottom bezel to be contacted with the finger 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.

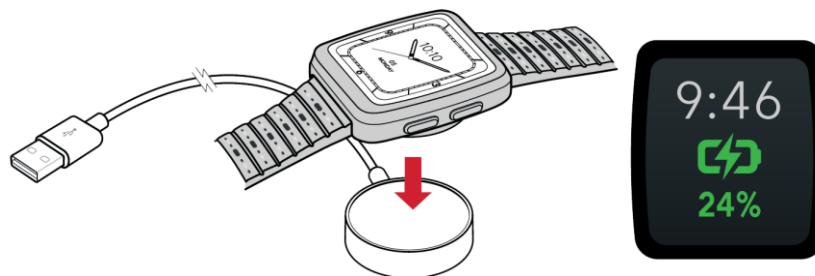
**3 Wrist M-band release button**

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

## Chapter 2: 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 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 Personal 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. Masimo Personal Health or Masimo SafetyNet are required to support software updates to the Masimo W1 watch. This prevents unauthorized upgrades to the Masimo W1.

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



## Pair Masimo W1 to Masimo App

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



**Note:** Masimo Personal Health App is shown in the example.

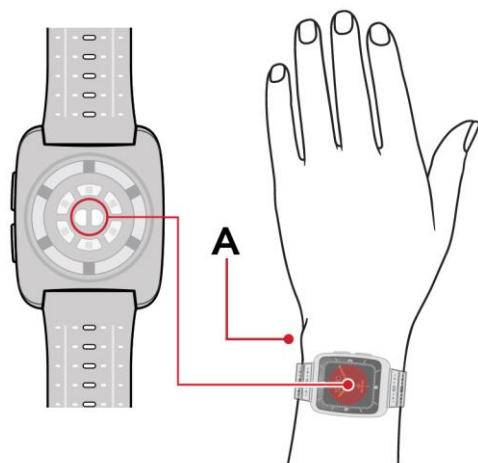
To pair the watch to the Masimo Personal Health App, from the *Devices* screen on the App, choose **Add Device**.

To pair the watch to the Masimo SafetyNet App, from the *My Devices* screen on the App, choose “+” to add a 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 wrist M-band is too loose. See **Watch Status Screen** on page 12 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.

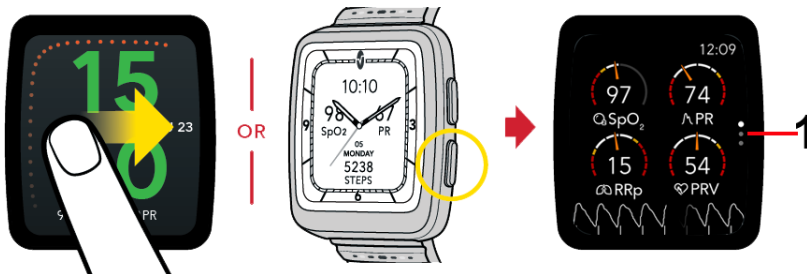


**Swipe** - Touch and move one finger on the screen left, right, up or down.

## 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 12 or *Watch Status Screen* on page 12.

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 no 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 (1) using one finger to navigate the *Live Health Data* screen and view all available health data.

See *Live Health Data (Vitals) Screen* on page 13 for complete information about the *Live Health Data* 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* on page 12. Ensure the Masimo W1 is on the wrist identified in the *Orientation* settings to ensure a proper ECG measurement. See *Changing Settings Options* on page 14.

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. 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 ECG measurement. The measurement will take approximately 30s.

## Understanding the ECG Results Screen

Screen Message	Explanation
<b>Sinus Rhythm</b>	Displays when you have a normal heart rhythm. Sinus rhythm is the name typically given to normal heart rhythms where the electrical pulse travels through the heart muscle correctly from the sinus node.
<b>Atrial Fibrillation (AFib)</b>	Displays when you have an irregular heartbeat. AFib is an irregular heartbeat that occurs in the atria. The atria are the two upper parts of the heart. Do not attempt to self-diagnose. Contact your healthcare provider if you have concerns or questions.
<b>Inconclusive</b>	Displays when the confidence of the ECG waveform is low. Follow the on-screen instructions to help improve the measurement confidence.

<b>Abnormal</b>	Displays when the HR is high (> 100 BPM) or low (< 50 BPM). Do not attempt to self-diagnose. Contact your healthcare provider if you have concerns or questions
<b>Noise</b>	Displays when the ECG waveform is being distorted by external signal interference.

## Chapter 3: 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 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 11.



**ECG Measurement** - Feature to perform an ECG spot check. See **Take an ECG Heart Rate Measurement** on page 11.



**Watch Face Settings** - Feature to change watch face. See **Change Watch Face** on page 13.



**Settings Menu** - Access additional watch settings. See **Changing Settings Options** on page 14.



**Watch Information** - Displays software and regulatory information about watch. Serial number and compliance information are also located behind recess for the wrist M-band.

\* 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.

	<b>Battery Level</b>	Battery level in percentage displays on the <i>Watch Status</i> screen. When battery charge is low, a notification displays.
	<b>Bluetooth Status</b>	Off, On, Connected
	<b>Vibration Mode</b>	Touch the icon to display the <i>Vibration</i> screen. This feature can be turned on or off from the <i>Vibration</i> screen.
	<b>Bedtime Setting</b>	Touch the icon to display the <i>Bedtime</i> screen and change the settings. See <b>Changing Settings Options</b> on page 14 for complete information.

 **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 11.

---

 **Wrist 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** on page 13 to display a different face design.

\* Displays when *Vitals* is enabled. See **Activate Continuous Health Data** on page 11.

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

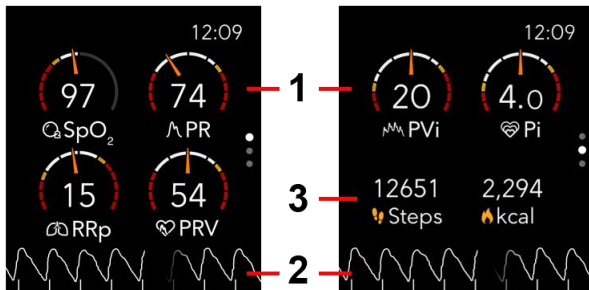
## Change Watch Face

To change the Masimo W1 face, open the *Main Menu*. See **Main Menu** on page 12.

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 11.

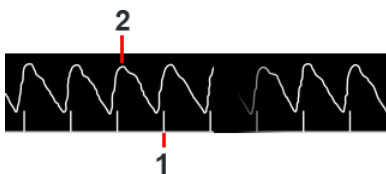
### 2 Waveform and Signal Quality Indicators

See **Waveform and Signal Quality Indicators** on page 13 for information.

### 3 Daily Step and Calorie Count

Shows how many steps have been taken and calories burned 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 SpO2 measurement displayed.

## Changing Settings Options

The following settings are available through the *Main Menu*.

<b>Brightness</b>	Screen brightness can be adjusted from the <i>Brightness</i> screen. Default brightness is 7. Touch to select a brightness level from 1 (dim) to 10 (most bright). <b>Note:</b> A high brightness setting may reduce battery life.
<b>Always On</b>	<i>Always On</i> 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 <i>Always On</i> screen. <b>Note:</b> When this feature is enabled, battery life may be reduced.
<b>Raise to Wake</b>	The <i>Raise to Wake</i> feature is turned on or off from the <i>Raise to Wake</i> screen. <ul style="list-style-type: none"> <li>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 <b>Orientation</b>.</li> <li>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.</li> </ul> <b>Note:</b> Turning this feature off may extend battery life.
<b>Bluetooth</b>	Bluetooth is turned "On" or "Off" from the <i>Bluetooth</i> screen. Bluetooth is On by default. When Bluetooth is off, Masimo W1 will not communicate with the Masimo App to share Health Data.
<b>Vibration</b>	Vibration is turned on or off from the <i>Vibration</i> screen. When on, a vibration is felt when notifications are displayed on the Masimo W1.
<b>Bedtime</b>	The <i>Bedtime</i> 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.
<b>Set Time and Date</b>	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 <b>Edit Time</b> or <b>Edit Date</b> tile to manually set the time or date.
<b>Orientation</b>	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 <b>Right</b> from the options available on the <i>Orientation</i> screen. <b>Note:</b> Orientation setting can affect the <i>Raise to Wake</i> feature operation.

## Chapter 4: Troubleshooting

### Troubleshooting Masimo W1

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

Error	Possible Causes	Recommended Solutions
<i>Masimo W1 does not turn on</i>	<ul style="list-style-type: none"> <li>Low battery</li> <li>Masimo W1 internal error.</li> </ul>	<ul style="list-style-type: none"> <li>Charge the battery. See <b>Charge the Watch</b> on page 9.</li> <li>If problems persist, contact Masimo Support. See <b>Contacting Masimo</b> on page 20.</li> </ul>
<i>Masimo W1 does not charge.</i>	The charger is not properly connected.	<ul style="list-style-type: none"> <li>Check that the charger cable is properly connected to the USB Power Adapter.</li> <li>Check that the USB Power Adapter is plugged into the power outlet completely.</li> </ul>
	Poor connection between Masimo W1 and the charger.	<ul style="list-style-type: none"> <li>Ensure no objects or foreign material is between the Masimo W1 and the charger.</li> <li>Ensure the back of the Masimo W1 is clean.</li> </ul>
	Masimo W1 internal error.	<ul style="list-style-type: none"> <li>Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds.</li> <li>If problems persist, contact Masimo Support. See <b>Contacting Masimo</b> on page 20.</li> </ul>
<i>Masimo W1 is not connected to the app on the smart device.</i>	App is incompatible with smart device.	<ul style="list-style-type: none"> <li>Ensure the correct app is being used.</li> <li>Ensure the latest version of the app is installed.</li> </ul>
	Connection issues between Masimo W1 and smart device.	<ul style="list-style-type: none"> <li>Check that Masimo W1 Bluetooth is on.</li> <li>Check that Masimo W1 has been paired through the App and not just the smart device Bluetooth settings. See <b>Pair Masimo W1 to Masimo App</b> on page 10.</li> <li>Unpair and pair the Masimo W1 to the smart device again using the App. See <b>Pair Masimo W1 to Masimo App</b> on page 10.</li> <li>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 <b>Pair Masimo W1 to Masimo App</b> on page 10.</li> </ul>
	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.	<ul style="list-style-type: none"> <li>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 <b>Pair Masimo W1 to Masimo App</b> on page 10.</li> <li>If problems persist, contact Masimo Support. See <b>Contacting Masimo</b> on page 20.</li> </ul>
<i>Vitals measurements display as dashes "--".</i>	<ul style="list-style-type: none"> <li>Readings may not have stabilized.</li> <li>Masimo W1 may not be worn properly.</li> </ul>	<ul style="list-style-type: none"> <li>Allow time for readings to stabilize.</li> <li>Check if blood flow to the arm/wrist is restricted.</li> <li>Check that Masimo W1 is worn properly and that the watchband is tight. See <b>Watch Status Screen</b> on page 12.</li> </ul>

Error	Possible Causes	Recommended Solutions
Cannot perform ECG measurement	<ul style="list-style-type: none"> <li>Masimo W1 may not be worn properly.</li> <li>Excessive movement during ECG measurement.</li> <li>Finger is placed incorrectly on the top electrode pad.</li> <li>Finger not held on the top electrode long enough.</li> </ul>	<ul style="list-style-type: none"> <li>Ensure Masimo W1 is worn properly on the wrist. See <b>Put on the Watch</b> on page 10.</li> <li>Ensure the finger makes good contact with the bottom side of the bezel of the Masimo W1. See <b>Take an ECG Heart Rate Measurement</b> on page 11.</li> <li>Hold finger steady for 30 seconds to process ECG measurement.</li> </ul>

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"> <li>Remove from charger.</li> <li>Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds.</li> <li>If problems persist, contact Masimo Support. See <b>Contacting Masimo</b> on page 20.</li> </ul>
Something went wrong. Contact Masimo for further assistance.	Internal error.	<ul style="list-style-type: none"> <li>Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds.</li> <li>If problems persist, contact Masimo Support. See <b>Contacting Masimo</b> on page 20.</li> </ul>

## Chapter 5: Specifications

### Display Range and Resolution

Measurement	Display Range	Resolution
Oxygen Level (SpO <sub>2</sub> )	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
ECG Waveforms	≥ 10 mV	≤ 1 $\mu$ V

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 <sub>2</sub> (No Motion) [1]	2% <i>A</i> <sub>RMS</sub> , over the range 70% to 100% for Adults
SpO <sub>2</sub> (Low Perfusion) [2]	2% <i>A</i> <sub>RMS</sub> , over the range 70% to 100% for Adults
Pulse Rate (No Motion)	3 bpm <i>A</i> <sub>RMS</sub> , over the range of 25 bpm to 240 bpm for Adults
Respiration Rate by Pleth (No Motion) [3]	3 rpm <i>A</i> <sub>RMS</sub> , over the range 4 RPM - 70 RPM, for Adults

\* *A*<sub>RMS</sub> accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- *A*<sub>RMS</sub> of the reference measurements in a controlled study.

## Oxygen Level (SpO<sub>2</sub>) ARMS Performance Specifications

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

Measurement $A_{RMS}$ Values for Masimo W1	
SpO <sub>2</sub> 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  $(SpO_2 + SaO_2)/2$  versus  $(SpO_2 - SaO_2)$  under no motion with an upper 95% and lower 95% limits of agreement.

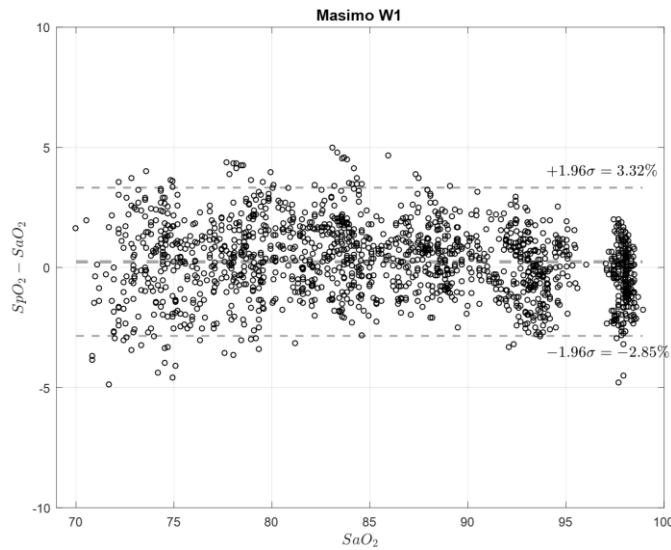


Figure 1: Masimo W1 Bland-Altman

## ECG Performance

Parameter	Specification*
Heart Rate (HR)	≤ 5 bpm over the range of 25 bpm to 240 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  $\pm A_{RMS}$  of the reference measurements in a controlled study.

## Physical Characteristics

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. 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

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 operation
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

## 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><b>Note 1:</b> At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p><b>Note 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <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.</p>			

### 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><b>Note:</b> 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.

## 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)
<b>Rx ONLY</b>	<b>Caution:</b> Federal (USA) law restricts this device to sale by or on the order of a physician.	<b>IP24</b>	Protected from objects greater than 12 millimeters and water spray from any direction.
	European Union Conformity Mark	<b>FCC ID:</b>	Identifies unit has been registered as a radio device
	Date of Manufacture YYYY-MM-DD		Manufacturer
	Battery		No parameter alarms
	Catalog number (model number)		Serial number
	Lot Code		Storage temperature range
	Atmospheric pressure limitation		Storage humidity limitation
	Bluetooth	-	--
	Instructions/Directions for Use/Manuals are available in electronic format @ <a href="http://www.Masimo.com/TechDocs">http://www.Masimo.com/TechDocs</a> <b>Note:</b> eIFU is not available in all countries.		

## Citations

[1] SpO<sub>2</sub> 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<sub>2</sub> performance has been validated under low perfusion ( $\leq 0.3$  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<sub>2</sub> 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.

## Chapter 6: Service and Maintenance

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The following chapter contains information about cleaning, 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 20 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.

## End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

## Restrictions

1. **Copyright Restrictions:** The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C. §117.
2. **Use Restrictions:** Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other instrument. Purchaser may not disclose, publish, translate, release, distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.
3. **Transfer Restrictions:** In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.
4. **U.S. Government Rights:** If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.







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