Heart Rate (HR)

Pulse Rate (PR)

Sinus Rhythm

Perfusion (Pi)

Heart Rate Variability (HRV)

Arterial Hemoglobin (SpO2)

Functional Oxygen Saturation of

Respiration Rate from Pleth (RRp)

Atrial Fibrillation (AFib)

Pleth Variability Index (PVi)

Pule Rate Variability (PRV)

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 manufacture

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

Wireless Radio:

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

Manufacturer Masimo Corporation

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

Patents: www.masimo.com/patents



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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

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.

> 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.

Variations in the amount of time between heart beats, which may provide insight in how consistently you are reacting to changes

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.

Feature that reflects how often blood is being pushed through the body by the heart or pulse. Estimation of the number of times

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).

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.

A normal heartbeat classification made on the ECG waveform. The classification is made based on the detection of normal heart

Calculation of the relative strength of the pulsatile signal used for the SpO2 and Pulse Rate. The Pi increases with better blood

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.

circulation. Your SpO2 values may be more reliable when your Pi value is higher. Pi values 0.25 or below are typically considered

 $Calculation \ of \ the \ variation \ of \ the \ amount \ of \ time \ between \ pulses \ monitored \ during \ the \ pulse \ rate \ estimation. \ The \ calculation \ is$

made by analyzing the pulse rate and determining the difference in the amount of time between pulses in milliseconds (ms).

blood is pushed through the body by the heart per minute. The estimation is made from the pulsatile light absorption changes

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

EU authorized representative for Masimo Corporation:

that affect your heart rate like exercise or stress.

EC REP

MDSS GmbH

Schiffgraben 41 D-30175 Hannover, Germany

The Masimo W1® provides these measurement features:

Product Description, Features and Indications for Use

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

Key features of Masimo W1 include:

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

Intended Use

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

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

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.



* Press and hold both buttons

1 Main Menu/Back Button*

- Press and hold to turn the watch Off. When Off, press once to turn the watch On. • From the watch face, press once to view the Main Menu OR to navigate backwards
- From the watch face, press once to view the live health data screen. Screen returns to the watch face after a few moments of inactivity.
- From the watch face, press two times to turn off the screen.

when viewing setting menus and other screens.

- · Press once to return to the watch face when viewing setting menus and other
- 3 Touch Screen
 - Used to interact with the watch. See Using the Touch Screen section.
- - ECG electrodes provided on the top and bottom bezels to be contacted with the fingers during ECG measurements.



1 Bottom ECG Electrode

rhythms where the electrical pulse travels through the heart muscle correctly from the sinus node.

low. If your Pi is low, try warming your hands or using a different finger.

- ECG electrode on the bottom of the Masimo W1 that makes contact with the wrist.
- 2 Optical Pulse Oximeter Sensor
- Location of sensors for Vitals measurements.
- 3 Wrist M-band Release Button
 - Press inward to remove the wrist M-band (watchband). Serial number and compliance information are located in the recesses behind the wrist M-band.

Basic Setup and Use

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

Charge the Watch

Before using Masimo W1, fully charge the battery.

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



Turn the Watch On

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

Download the Masimo Health or Masimo SafetyNet App

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

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

Pair Masimo W1 to the Masimo App

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

Note: Masimo SafetyNet App is shown in the example. To pair the watch to the Masimo SafetyNet App, from the My

Devices screen on the App, choose "+" to add a device. To pair the watch to the Masimo Health App, from the Devices screen on the App, choose Add Device.

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

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

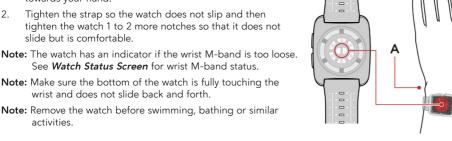
Put on the Watch

- 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
- tighten the watch 1 to 2 more notches so that it does not slide but is comfortable. Note: The watch has an indicator if the wrist M-band is too loose.

See Watch Status Screen for wrist M-band status.

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.







on the screen.

Touch and hold an item

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

Turn On Health Data

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

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

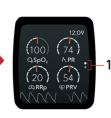
screen, swipe left or right across the watch face using one finger until the screen displays OR press the lower button on the side of the Masimo W1. Swipe up and down (1) using one finger to navigate the Live Health Data screen and view all available

Screen Message Explanation

To view the Live Health Data (Vitals)







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

Take an ECG Heart Rate Measurement

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

- Access the ECG measurement screen by touching the ECG icon from the Main Menu.
- Check that the electrode pad on the bottom of the watch makes good contact to the wrist.
- Place your thumb on the electrode pad on the lower bezel (below the lower portion of the watch screen) and index finger on the upper bezel (above the upper portion of the watch screen) until the results screen is displayed. Note: Do not move during the ECG measurement. The measurement will take approximately 30 seconds.

Understanding the ECG Results Screen.

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

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

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

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

Operation

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

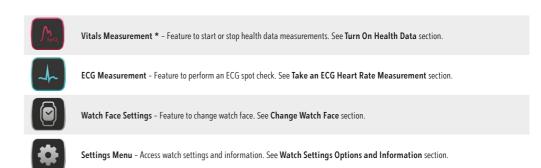
User Interface (Display)

Main Menu

The Main Menu displays a list of available apps.

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



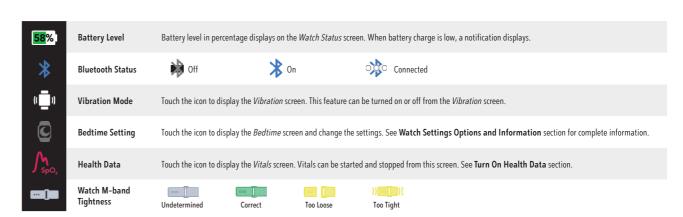


* The *Vitals* icon background color changes when active

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.



Watch Face



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

* Displays when *Vitals* is enabled. See **Turn On Health Data** section. **Note:** The watch face may be difficult to view when in direct sunlight.

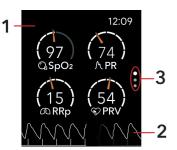
Change Watch Face

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

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



This screen contains the following information:

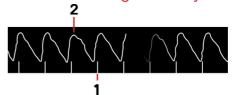
- Health Data (Vitals)
- When Vitals are enabled, Health Data displays*. If Vitals are not enabled, the options to **Start** Vitals displays. See **Turn On Health Data** section.
- Waveform and Signal Quality Indicators
 See Waveform and Signal Quality Indicators section for information.
- 3. View Additional Screens
 - Swipe up/down to view additional screens that display more vitals measurements as well as activity data (daily step count, calories burned, and miles walked on this date). Activity data resets daily.
- * Touch a Vitals measurement to show information about that measurement. Press the top button on the side of the Masimo W1 to return to the screen.

Software Updates

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

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

Waveform and Signal Quality Indicators



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

Low Confidence Indicator



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

Watch Settings Options and Information

The following settings are available through the Main Menu.

Brightness	Screen brightness can be adjusted from the Brightness screen. Default brightness is 7. Touch to select a brightness level from 1 (dim) to 10 (most bright).
	Note: A high brightness setting may reduce battery life.
Always On	Always On displays the screen even when your wrist is down. When your wrist is raised, all functions of the Masimo W1 are available. This feature is turned On or Off from the Always On screen. Default setting is Off.
	Note: When this feature is On, battery life may be reduced.
Raise to Wake	The Raise to Wake feature sensitivity can be set to Low, Medium or High (On), or turned Off. Default setting is Medium.
	 When On, the screen turns on when your wrist is raised. When your wrist is lowered, the screen turns off. If the Masimo W1 does not wake when raised, check that the correct wrist orientation is selected. See Orientation.
	When Off, to view you must touch the screen or press one of the buttons on the Masimo W1. If the Masimo W1 does not wake when the screen is touched or buttons are pressed, the battery may need to be charged
	Note: A High sensitivity may shorten battery life. A low sensitivity or turning this feature Off may extend battery life.
	Note: This feature is disabled during the set hours when Bedtime is enabled.
Vibration	Vibration is turned On or Off from the Vibration screen. When On, a vibration is felt when notifications are displayed on the Masimo W1. Default setting is On.

Bedtime	The Bedtime screen is used to Turn Bedtime On or Off and set the Bedtime START and Bedtime END. This disables the Raise to Wake feature of the Masimo W1 during the set time.	
Set Time and Date When connected to the Masimo App, the time and date for Masimo W1 are automatically so date can also be set manually. Touch the Edit Time or Edit Date tile to manually set the		
Orientation	By default, the Masimo W1 is set to be worn on the left wrist. To set the watch to be worn on the right wrist, select Right from the options available on the Orientation screen.	
	Note: Correctly setting the orientation is necessary for accurate ECG waveforms and Raise to Wake feature operation.	
Step Sensitivity	Step sensitivity for the step counter can be set to Low, Medium or High. Default setting is Low. Note: A High step sensitivity may shorten battery life.	
Bluetooth	Bluetooth is turned On or Off from the Bluetooth screen. Default setting is On. When Bluetooth is Off, Masimo W1 will not communicate with the Masimo App to share Health Data.	
Line Frequency	Line frequency for the ECG measurement can be set to 50Hz or 60Hz. Default setting is 60Hz.	
About	Displays software and regulatory information about watch. Serial number and compliance information are also located behind recess for the wrist M-band.	

Troubleshooting

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

Error	Possible Causes	Recommended Solutions
Masimo W1 does not turn on	Low battery. Masimo W1 internal error.	 Charge the battery. See Charge the Watch section. If problems persist, contact Masimo Support.
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.
	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.
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 the Masimo App section. Unpair and pair the Masimo W1 to the smart device again using the App. See Pair Masimo W1 to the Masimo App section. Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds and retry the pairing procedure on the App. See Pair Masimo W1 to the Masimo App section.
	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 the Masimo App section. If problems persist, contact Masimo Support.
Vitals measureaments 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 section.
Cannot perform ECG measurement	Masimo W1 may not be worn properly. Excessive movement during ECG measurement. Finger is placed incorrectly on the top electrode pad. Finger not held on the top electrode long enough.	 Ensure Masimo W1 is worn properly on the wrist. See Put on the Watch section. Ensure the finger makes good contact with the bottom side of the bezel of the Masimo W1. See Take an ECG Heart Rate Measurement section. Hold finger steady for 30 seconds to process ECG measurement.

The following messages may appear on Masimo W1.

Message	Possible Causes	Recommended Solutions
Device Overheated, Watch needs to cool down before using	Internal temperature safety limit reached.	 Remove from charger. Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds. If problems persist, contact Masimo Support.
Something went wrong. Contact Masimo for further assistance	Internal error.	 Restart the Masimo W1 by pressing and holding both side buttons for at least 15 seconds. If problems persist, contact Masimo Support.

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

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

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

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 cautions: 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

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 SpO2 values indicate hypoxemia, do not self-diagnose. Confirmation by a medical professional is required WARNING: Sp02 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin

(MetHb).

WARNING: Optical, pleth-based measurements (e.g., SpO2, 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
- balloon, etc.).
- Abnormal venous pulsations (e.g., tricuspid value regurgitation, Trendelenburg position). Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g., cardiac arrhythmias, intra-aortic
- . 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 disassociation curve.
- A physiological condition that may affect vasomotor tone or changes in vasomotor tone. Loss of pulsatile signal.
- Elevated levels of COHb and/or MetHb. Note: High levels of COHb or MetHb may occur with a seemingly normal Sp02.
 - Very low arterial perfusion
 - Hypocapnic or Hypercapnic conditions
 - 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.

Symbols

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.

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.

- Do not wirelessly connect Masimo W1 with software not authorized for use by Masim

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

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.

Compliance Warnings and Cautions

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

Service and Maintenance

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:

- 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
- 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
- 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.
- 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
- When using CaviWipes, use a 4" x 4" gauze pad saturated with DI water to wipe the surface once.

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 below.
- **Masimo Corporation**

52 Discovery, Irvine, California 92618 Tel:+1 949 297 7000 Fax:+1 949 297 7001

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 purchase

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. 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, promothy return the entire Product, including all acrossories in their

original packages, with your sales receipt to Masimo for a full refund

*

Bluetooth

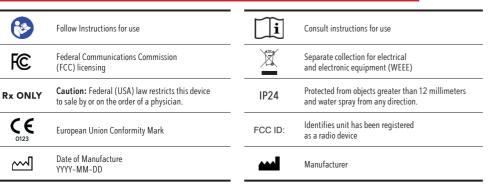
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- 3. Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation 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 computers of tware 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

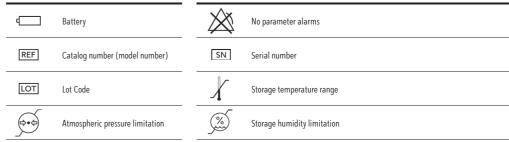
Cybersecurity Information

To help prevent cybersecurity issues, consider the following:

- Don't provide your personal information unless it is protected by a login and password.
- Don't share password information.
- Avoid using the same password for multiple apps.
- Turn off the Bluetooth connection when not in use to avoid unwanted connections.
- · Look for signs that your account has been compromised (e.g., settings that changed, slow or delayed communication with an app). • Disconnect and stop using an app if that appears to be compromised.
- Reset the Masimo W1 to factory default if that appears to be compromised

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





Instructions/Directions for Use/Manuals are available in electronic format

@http://www.Masimo.com/TechDocs Note: eIFU is not available in all countries.

Specifications

Display Range and Resolution

Measurement	Display Range	Resolution
Oxygen Level (SpO2)	0% to 100%	1%
Pulse Rate (PR)	25 bpm to 240 bpm	1 bpm
Pi (Perfusion Index)	0.02 to 0.99	0.01
	1.0 to 9.9	0.1
	10 to 20	1
PVi (Pleth Variability Index)	0 to 100	1
RRp (Respiration Rate)	4 rpm to 70 rpm	1 rpm
Pulse Rate Variability (PRV)	0 ms to 150 ms	1 ms
HR (Heart Rate)	25 bpm to 240 bpm	1 bpm
HRV (Heart Rate Variability)*	0 ms to 150 ms	1 ms
ECG Waveforms	≥ 10 mV	≤1 uV

^{*} HRV is only available when ECG is classified as "Normal Sinus Rhythm"

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

Pulse-Oximetry Performance

•	
Parameter	Specification*
SpO2 (No Motion) [1]	2% Arms, over the range 70% to 100% for Adults
SpO2 (Low Perfusion) [2]	2% Arms, over the range 70% to 100% for Adults
Pulse Rate (No Motion)	3 bpm ARMS, over the range of 25 bpm to 240 bpm for Adults
Respiration Rate by Pleth (No Motion) [3]	3 rpm ARMS, over the range 4 RPM - 70 RPM, for Adults

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

ECG Performance

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

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

Physical Characteristics

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

Electrical

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

Environmental

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

Compliance

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

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

Wireless Specifications

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

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

Citations

- ¹¹¹SpO2 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.
- ¹²¹SpO2 performance has been validated under low perfusion (≤ 0.3 perfusion index) accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70%–100% against a laboratory co-oximeter.
- [3] RRp performance has been validated for no motion accuracy on healthy male and female volunteers against manual clinician-scored capnograms. RRp performance was validated across the entire range of 4 to 70 RPM through bench testing.
- (4) This represents approximate run time with Screen on-time: 0%, Bluetooth connection On, Active Measurement, SpO2 and Heart Rate (Continuous Vitals On), ECG (10 Spot-Check measurements), using a fully charged battery.
- [3] The battery shall charge to 80% of battery capacity in no longer than 3 hours at ambient temperature and might not charge completely under playated ambient temperature
- under elevated ambient temperature.

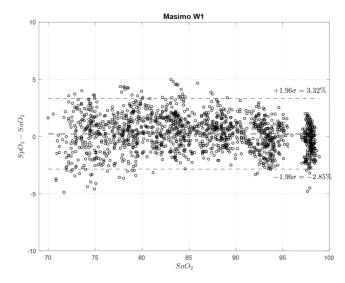
 [6] If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20°C to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

Oxygen Level (SpO₂) ARMS Performance Specifications

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

Measurement ARMS Values for Masimo W1			
SpO2 Accuracy Range (%)	Arms (%)		
90-100	1.35		
80-90	1.58		
70-80	1.87		
70-100	1.59		

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



Guidance and Manufacturer's Declaration

Electromagnetic Emissions				
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.				
Emission Test	Compliance	Electromagnetic Environment - Guidance		
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
RF Emissions CISPR 11	Class B	ME Equipment suitable for use in all establishments including domestic establishments.		

Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Masimo W1, including cables, than the recommendation separation distance calculated from the equation applicable to the frequency of the transmitter.

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 ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment.

Test Specifications for Enclosure Port Immunity to RF Wireless Communication Equipment

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-395	TETRA 400	Pulse modulation (b) 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM (c) +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710						
745	704-787	LTE Band 13, 17	Pulse modulation (b) 217 Hz	0.2	0.3	9
780						
810		GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation (b) 18 Hz	2	0.3	28
870	800-960					
930		33.11.1000, 212.34.14.0				
1720			Pulse modulation (b) 217 Hz	2	0.3	28
1845	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3. 4. 35: UMTS				
1970		223,7212 34114 1,701 11 001 011110				
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						
5500	5100-5800	WLAN 802.11 a/n	Pulse modulation (b) 217 Hz	0.2	0.3	9
5785	1					

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- (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.		
	Separation distance according to frequency of transmitter [m]	
Rated maximum output power of transmitter [W]	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.