Operator's Manual

MightySat™ Rx Fingertip Pulse Oximeter

MASIMO

For Sale in the USA

These operating instructions provide the necessary information for proper operation of all models of the MightySat™ Rx Fingertip Pulse Oximeter. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of MightySat Rx are prerequisites for its proper use. Do not operate MightySat Rx without completely reading and understanding these instructions.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) for noninvasive patient monitoring and may not be used for any processes, procedures, experiments or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

For professional use. See directions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

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MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005, CAN/CSA C22.2 No. 60601-1:2008, and applicable Particular, (ISO 80601-2-61:2011) and related Collateral (IEC 60601-1-11:2010) Standards for which the product has been found to comply by Intertek.

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

Contents

About this Manual

Do not operate the MightySat™ Rx Fingertip Pulse Oximeter without completely reading and understanding the instructions.

Always use the MightySat Rx precisely in accordance with the directions in this manual, including site selection and sensor placement. Failure to follow all of the directions in this manual could lead to inaccurate measurements.

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 to the patient or user (for example, injury, serious adverse effect, or death).

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 instrument, or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description and Indications

Product Description

The MightySat™ Rx Fingertip Pulse Oximeter is intended as a noninvasive device that measures and displays arterial oxygen saturation (SpO_2), Pulse Rate (PR), Perfusion Index (Pi), and optional Pleth Variability Index (PVi®) and Pleth Respiration Rate (RRp).

The following key features are available for the MightySat Rx:

- Masimo SET® technology for SpO_2 and pulse rate monitoring in motion and low perfusion environments.
- Optional Bluetooth® LE wireless technology for the wireless transfer of patient data to smart devices.

The MightySat™ Rx Fingertip Pulse Oximeter is available in the following versions:

Product Versions	**Features**
MightySat Rx	Intended to measure and display arterial oxygen saturation (SpO_2), Pulse Rate (PR), and Perfusion Index (Pi).
MightySat Rx, Bluetooth LE	Intended to measure and display arterial oxygen saturation (SpO_2), Pulse Rate (PR), and Perfusion Index (Pi). Bluetooth LE radio is intended to transfer of parameter data to a compatible smart device.
MightySat Rx, Bluetooth LE, PVi and RRp	Intended to measure and display arterial oxygen saturation (SpO_2), Pulse Rate (PR), Perfusion Index (Pi), and Pleth Variability Index (PVi) and Pleth Respiration Rate (RRp). Bluetooth LE radio is intended for transfer of parameter data to a compatible smart device.

Indications for Use

The Masimo MightySat™ Rx Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments, and transport.

The Masimo MightySat™ Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

The Masimo MightySat™ Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients.

Safety Information, Warnings, and Cautions

Safety Warnings and Cautions

- **WARNING:** Do not use MightySat Rx during magnetic resonance imaging (MRI) or in an MRI environment.
- **WARNING:** Do not place MightySat Rx or accessories in any position that might cause it to fall on the patient.
- **WARNING:** Do not use MightySat Rx during defibrillation.
- **WARNING:** Do not use MightySat Rx during electrosurgery.
- **WARNING:** Do not use MightySat Rx in the presence of flammable anesthetics or other flammable substances, oxygen-enriched environments, or nitrous oxide to avoid the risk of explosion.
- **WARNING:** Only use the MightySat Rx to secure it to the finger. Excessive pressure to a finger can cause skin damage.
- **WARNING:** Check the sensor site every hour to ensure adequate circulation, skin integrity, and sensor alignment. Skin damage, pressure necrosis, or inaccurate readings may result.
- **WARNING:** Do not leave the MightySat Rx unattended around children. Small items such as the battery door, battery, and lanyard may become choking hazards.
- **WARNING:** Do not use the lanyard during activities where it may become wrapped around the neck. Strangulation may occur.
- **CAUTION:** Do not use the MightySat Rx near devices that are sensitive to magnets. The magnet provided with the MightySat Rx could interfere with the proper operation of the device.
- **Note**: The maximum skin surface temperature is measured to be less than 41°C (106°F) in a 35°C (95°F) environment. This was verified by measuring the skin interface temperature with MightySat Rx operating under reasonable worst-case conditions.

Performance Warnings and Cautions

- **WARNING**: MightySat Rx is not an apnea monitor and should not be used for arrhythmia analysis.
- **WARNING:** MightySat Rx should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- **WARNING:** Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor.
- **WARNING:** Do not use MightySat Rx for continuous monitoring. It is intended for spot-check use only. No alarms are provided to support continuous monitoring.
- **WARNING:** Do not use MightySat Rx if it appears or is suspected to be damaged. Damage to internal parts can result in no or inaccurate readings.

- **WARNING:** Do not repair, open, or modify MightySat Rx. Damage to internal parts can result in no or inaccurate readings.
- **WARNING:** Do not use the MightySat Rx if the internal parts have been exposed to liquids. Damage to the internal parts may result in no or inaccurate readings.
- **WARNING:** SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- **WARNING:** Optical, pleth-based measurements (e.g. SpO_2 and RRp) can be affected by the following:
    - Improper MightySat Rx placement or alignment
    - Intravascular dyes such as indocyanine green or methylene blue
    - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
    - Blood pressure cuff applied to the same arm as the sensor site
    - Placing the MightySat Rx sensor on any extremity with an arterial catheter
    - Elevated levels of bilirubin
    - Venous congestion
    - 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 balloon, etc.)
    - Physiological conditions that can significantly shift the oxygen disassociation curve
    - A physiological condition that may effect vasomotor tone or changes in vasomotor tone
- **WARNING:** Inaccurate SpO_2 readings may be caused by:
    - Elevated levels of COHb and/or MetHb
    - Severe anemia
    - Extremely low arterial perfusion
    - Excessive induced motion
    - Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (Quantitative defects such as Thalassemias).
- **WARNING**: Inaccurate respiration rate (RRp) measurements may be caused by:
    - Improper MightySat Rx placement or alignment
    - Low arterial perfusion
    - Excessive motion
    - Arrhythmia
- **CAUTION:** The RRp value may be inaccurate under rare conditions where the pulse rate is less than two times the respiration rate; conditions may include, but not limited to the following: 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:** The RRp value may be inaccurate when used on patients with respiration rates outside of the range of 4 to 70 respirations per minute.
- **CAUTION:** Respiration rate provides an indicator of central ventilatory drive and not a direct indication that air is moving through the upper airway.
- **CAUTION:** Properly apply and avoid using the MightySat Rx under high ambient light sources, fluorescent lights, infrared heating lamps and direct sunlight to minimize interference that may result in no or inaccurate readings.
- **CAUTION:** Keep the MightySat Rx away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.
- **CAUTION:** When using MightySat Rx 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 with the smart device.
- **CAUTION:** When using MightySat Rx with a smart device, relocate the devices away from sources that may interfere with the Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service (see Specifications for details) of the Bluetooth connection. Devices that may cause RFI include but are not limited to the following: electrocautery equipment, diathermy equipment, other cellular telephones, wireless PC and tablets, pagers, RFID devices, MRI, and electromagnetic security systems.
- **CAUTION:** Do not attempt to remanufacture, recondition, or recycle MightySat Rx as these processes may damage the internal parts. Damage to internal parts can result in no or inaccurate readings.
- **Note:** The MightySat Rx display may be difficult to view when exposed to direct sunlight or bright lights.
- **Note:** Do not assess the accuracy of the MightySat Rx using a functional tester. A functional tester should only be used to check if a unit is working properly.
- **Note:** The MightySat Rx display will shut off automatically if there are no readings.
- **Note:** The MightySat Rx display may be difficult to view when exposed to direct sunlight or bright lights.

Cleaning, Disinfecting, Service Warnings and Cautions

- **WARNING:** Properly use and dispose of Alkaline batteries or they may leak or explode.
- **WARNING:** Remove alkaline batteries when the MightySat Rx will not be in use for more than 30 days to avoid damage to the device due to batteries that may leak.
- **WARNING:** Replace both batteries at the same time to avoid mixing fully and partially charged batteries. These actions may cause the batteries to leak; resulting in possible damage to the device.

- **CAUTION:** Use only AAA alkaline batteries. Use of non-alkaline batteries may affect the accuracy of the battery status indicator.
- **CAUTION:** Only perform maintenance procedures specifically described in the manual; otherwise, return MightySat Rx for servicing. Improper maintenance may result in damage to the internal parts. Damage to internal parts may result in no or inaccurate readings.
- **CAUTION:** Thoroughly clean and low level disinfect the MightySat Rx before applying it to on a new patient.
- **CAUTION:** Do not clean MightySat Rx with any chemical other than those specified in ***Cleaning, Disinfecting, and Service*** on page 25. These substances may affect the device's materials and damage internal parts.
- **CAUTION:** Do not submerge MightySat Rx in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.
- **CAUTION:** Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in ***Cleaning, Disinfecting, and Service*** on page 25 of this manual. Permanent damage to MightySat Rx may occur if other unspecified solutions are used.
- **CAUTION:** Never submerge MightySat Rx in water or any other liquid solution this may cause permanent damage to the MightySat Rx.

Compliance Warnings and Cautions

- **WARNING:** Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.
- **CAUTION:** Comply with local laws in the disposal of the MightySat Rx, including batteries.
- **CAUTION:** This device has not been evaluated for use in aircrafts.
- **Note:** When using MightySat Rx with a device with wireless features, consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.
- **Note:** In accordance with international telecommunication requirements, the frequency band of 2.4 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.
- **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:** 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.
- Consult the dealer or an experienced radio/TV technician for help.

- **Note**: This equipment has been tested and found to comply with the Class B limits for medical devices according to the IEC 60601-1-2: 2007, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.
- **Note**: This Class B digital apparatus complies with Canadian ICES-003.

Technology Overview

The following chapter contains general descriptions about parameters, measurements, and the technology used by Masimo products.

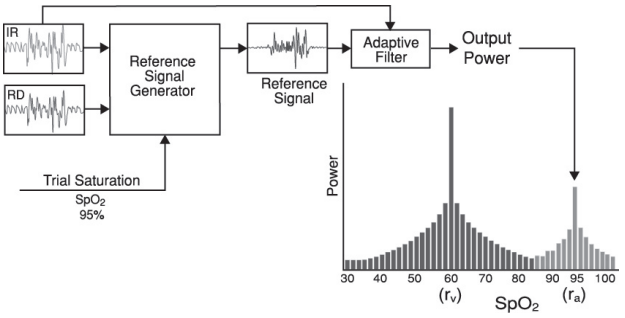
Signal Extraction Technology® (SET®)

Masimo Signal Extraction Technology's signal processing differs from that of conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise).

Masimo SET® pulse oximetry utilizes parallel engines and adaptive filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET® signal processing algorithm, Discrete Saturation Transform® (DST®), in parallel with Fast Saturation Transform (FST®), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO2)

Pulse oximetry is governed by the following principles:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
- The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Successful Monitoring for SpO2, PR and Pi

Stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each.

The stability of the readings over time is affected by the averaging time being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO_2 and pulse rate.

Functional Oxygen Saturation (SpO2)

The MightySat Rx is calibrated to measure and display functional oxygen saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.

Note: Dyshemoglobins are not capable of transporting oxygen, but are recognized as oxygenated hemoglobins by conventional pulse oximetry.

General Description for Perfusion Index (Pi)

The Perfusion Index (Pi) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. PI thus represents a noninvasive measure of peripheral perfusion that can be and noninvasively obtained from a pulse oximeter.

General Description for Pulse Rate (PR)

Pulse rate (PR), measured in beats per minute (BPM) is based on the optical detection of peripheral flow pulse.

General Description for Pleth Variability Index (PVi)

The Pleth Variability Index (PVi) is a measure of the dynamic changes in the Perfusion Index (Pi) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. PVi is displayed as a percentage (0-100%).

PVi may show changes that reflect physiological factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

The utility of PVi has been evaluated in clinical studies [1-11]. Technical and clinical factors that may affect PVi include probe malposition, probe site, patient motion, skin incision, spontaneous breathing activity, lung compliance, open pericardium, use of vasopressors or vasodilators, low perfusion index, subject age, arrhythmias, left or right heart failure, and tidal volume [12-14].

Citations for Pleth Variability Index (PVi)

1. *Cannesson M., Desebbe O., Rosamel P., Delannoy B., Robin J., Bastien O., Lehot J.J. Pleth Variability Index to Monitor the Respiratory Variations in the Pulse Oximeter Plethysmographic Waveform Amplitude and Predict Fluid Responsiveness in the Operating Theatre. Br J Anaesth. 2008 Aug; 101(2):200-6.*
2. *Forget P, Lois F, de Kock M. Goal-Directed Fluid Management Based on the Pulse Oximeter-Derived Pleth Variability Index Reduces Lactate Levels and Improves Fluid Management. Anesth Analg. 2010 Oct; 111(4):910-4.*
3. *Zimmermann M., Feibicke T., Keyl C., Prasser C., Moritz S., Graf B.M., Wiesenack C. Accuracy of Stroke Volume Variation Compared with Pleth Variability Index to Predict Fluid Responsiveness in Mechanically Ventilated Patients Undergoing Major Surgery. Eur J Anaesthesiol. 2010 Jun; 27(6):555-61.*
4. *Desebbe O, Boucau C, Farhat F, Bastien O, Lehot JJ, Cannesson M. Anesth Analg. The Ability of Pleth Variability Index to Predict the Hemodynamic Effects of Positive End-Expiratory Pressure in Mechanically Ventilated Patients under General Anesthesia. 2010 Mar 1; 110(3):792-8.*
5. *Tsuchiya M., Yamada T., Asada A. Pleth Variability Index Predicts Hypotension During Anesthesia Induction. Acta Anesthesiol Scand. 2010 May; 54(5):596-602.*
6. *Loupec T., Nanadoumgar H., Frasca D., Petitpas F., Laksiri L., Baudouin D., Debaene B., Dahyot-Fizelier C., Mimoz O. Pleth Variability Index Predicts Fluid Responsiveness in Critically Ill Patients. Crit Care Med. 2011 Feb; 39(2):294-9.*
7. *Fu Q., Mi W.D., Zhang H. Stroke Volume Variation and Pleth Variability Index to Predict Fluid Responsiveness during Resection of Primary Retroperitoneal Tumors in Hans Chinese. Biosci Trends. 2012 Feb; 6(1):38-43.*
8. *Haas S., Trepte C., Hinteregger M., Fahje R., Sill B., Herich L., Reuter D.A. J. Prediction of Volume Responsiveness using Pleth Variability Index in Patients Undergoing Cardiac Surgery after Cardiopulmonary Bypass. Anesth. 2012 Oct; 26(5):696-701.*
9. *Byon H.J., Lim C.W., Lee J.H., Park Y. H., Kim H.S., Kim C.S., Kim J.T. Br. J. Prediction of fluid Responsiveness in Mechanically Ventilated Children Undergoing Neurosurgery. Anaesth 2013 Apr; 110(4):586-91.*
10. *Feissel M., Kalakhy R., Banwarth P., Badie J., Pavon A., Faller J.P., Quenot JP. Plethysmographic Variation Index Predicts Fluid Responsiveness in Ventilated Patients in the Early Phase of Septic Shock in the Emergency Department: A Pilot Study. J Crit Care. 2013 Oct; 28(5):634-9.*
11. *Yu Y., Dong J., Xu Z., Shen H., Zheng J. Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia. J Clin Monit Comput. 2014 Feb 21.*
12. *Desgranges F.P., Desebbe O., Ghazouani A., Gilbert K., Keller G., Chiari P., Robin J.,Bastien O., Lehot J.J., Cannesson M. Br. J. Anaesth 2011 Sep; 107(3):329-35.*
13. *Cannesson M. Arterial pressure variation and goal-directed fluid therapy. J Cardiothorac Vasc Anesth. 2010 Jun; 24(3):487-97.*
14. *Takeyama M, Matsunaga A, Kakihana Y, Masuda M, Kuniyoshi T, Kanmura Y. Impact of Skin Incision on the Pleth Variability Index. J Clin Monit Comput 2011 Aug; 25(4):215-21.*

General Description for Respiration Rate (RRp)

Respiration rate can be determined by the plethysmographic waveform (RRp). This method measures respirations per minute (rpm) based on plethysmographic amplitude changes that correspond to the respiratory cycle.

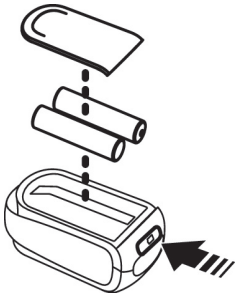
Operation

MightySat Rx Features

ID	Description	Function
1	Enclosure Clip	Clip provided for ease of lanyard attachment.
2	Bluetooth Indicator (Optional)	Indicates when Bluetooth LE is enabled on the device.
3	Battery Status Indicator	Indicates the remaining relative life of the battery.
4	Display Screen	Display for measurements and indicators. **Note:** Numbers will dim when confidence in the value is low.
5	Waveform and SIQ or Pulse Bar	When the waveform option is turned on, the plethysmographic waveform and SIQ line display. The height of the SIQ line provides an assessment of the confidence in the measurement displayed. When the waveform option is turned off, the pulse bar displays as a visual indicator with blinking that corresponds to the pulse rate. The height of the pulse bar provides an assessment of the confidence in the measurement displayed.
6	Touchpad	User interface to allow for change of settings (see ***Using the Touchpad*** on page 21 in this manual).

Installing the AAA Batteries

The MightySat Rx requires two alkaline AAA batteries to operate. To install batteries, follow the instructions below:



1. Place the MightySat Rx so that the display screen is facing downwards.
2. Find the battery button on the front of the sensor pad.
3. Push lightly on the battery button to release the battery cover and then remove the battery cover.
4. Insert two new AAA alkaline batteries and match the orientation labels (+ and -).

   Note: MightySat Rx will not work if the batteries are inserted in the incorrect orientation.
5. Once the batteries are correctly inserted, snap the battery door back onto the device.

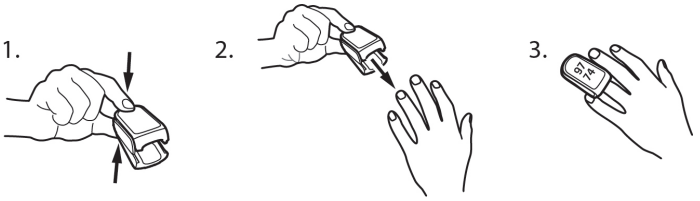
   WARNING: Ensure that the battery door is intact before use.

   Note: MightySat Rx will turn on automatically when the device is opened so that the sensor pads are exposed as shown in the image below.

Using MightySat Rx

To take readings with the MightySat Rx, follow the instruction below:

Note: Before use, ensure batteries are correctly installed in the MightySat Rx.

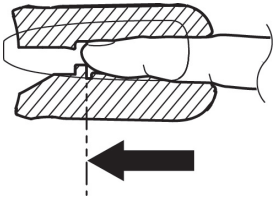


1. To open the MightySat Rx, squeeze the back portion of the device as shown in the image above.
2. Once the sensor pads are exposed, insert a finger (non-dominant, ring finger) so the sensor LED is above the fingernail.

   Note: The display screen of the MightySat Rx should be facing upwards as depicted in the image above.
3. Once the finger is correctly positioned, gently close the MightySat Rx by releasing the pressure on the back of the device.

   Note: Ensure the finger is correctly positioned for accurate measurements.

4. The tip of the finger should touch the finger stop as shown in the image below.



5. Once the MightySat Rx is correctly closed on the finger, the MightySat Rx will display readings.

   Note: If no readings are displayed, see ***Troubleshooting*** on page 26 in this manual.

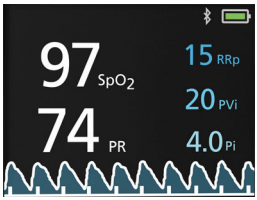
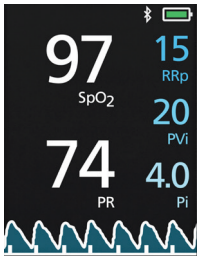
   WARNING: While on the finger, do not press the top of the device against any surface.

   WARNING: Do not attempt to secure the MightySat Rx to the finger using external pressure. The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.

Using the Touchpad

The multi-function Touchpad  on MightySat Rx is located below the display screen.

Note: The display is not a touch screen.

Desired Function	Required Action	Description
Rotate Main Screen for better view while on finger.*	Tap and release the Touchpad to rotate once in a clockwise direction.	The Main Screen can be rotated for best viewing angle.  
Enter the Menu Screen.	Press and hold the Touchpad.	The menu allows changes to MightySat Rx settings. See ***Main Menu Options*** on page 22.
Navigate the Menu Screen.	Swipe left or right on the Touchpad.	Switches between menu items on the Menu Screen.

Desired Function	Required Action	Description
Select a menu item.	Touch and release the Touchpad.	Select an item on the Menu Screen to switch between options or enable/disable that option. See ***Main Menu Options*** on page 22.
Exit the Menu Screen.	Swipe right on the Touchpad to display arrow, then touch and release.	Returns to the Main Screen. See ***Main Menu Options*** on page 22.

* This function does not rotate the Menu Screen.

Main Menu Options

Use the Touchpad to navigate the Menu Options. See ***Using the Touchpad*** on page 21.

The Menu options are:

Menu Icon	Menu Option	Description	Default Setting	Options
	Back	Return to Main Screen.	N/A	N/A
	Waveform	Allows the user to choose to display the waveform on the screen.	On	On or Off *
	Brightness	Change the brightness of the display.	100%	25%, 50%, 75%, and 100%
	Bluetooth (Optional)	For connection with a smart device. Enables or disables Bluetooth LE.	On	On or Off *
	About	Hardware and software information about the device. Serial number; software version; Bluetooth LE Mac Address	N/A	N/A

* When On, the icon is white, when Off, the icon is gray (dimmed).

Connecting to a Smart Device via Bluetooth (Optional)

Note: Bluetooth LE is an optional feature available on specific versions of MightySat Rx for use with compatible smart devices. For a full list of compatible smart devices, see www.masimoprofessionalhealth.com.

Bluetooth Connection

The MightySat Rx provides a Bluetooth LE wireless option to allow connection to a compatible smart device. The Bluetooth communication is only available to smart devices using the Masimo Professional Health App. When a Bluetooth connection is established the Bluetooth connected icon will appear. MightySat Rx can only communicate to a single smart device at one time to minimize the risk of unauthorized access.

Note: The MightySat Rx requires the use of the Masimo Professional Health app to communicate to a compatible smart device.

Pair MightySat Rx to Smart Device

1. Ensure the Bluetooth is enabled on the smart device through the device settings.
2. From your compatible smart device, perform one of the following:
   - For Android™-powered devices, go to the Google Play™ store.
   - For Apple® devices, go to the App Store℠.
3. Search and download the "Masimo Professional Health" app.
4. Launch the Masimo Professional Health app.
5. Turn the MightySat Rx Bluetooth On. See ***Main Menu Options*** on page 22 of this manual for further instructions.
6. Follow the Masimo Professional Health app on-screen instructions to pair a device.
7. When the Masimo Professional Health app identifies the MightySat Rx, press/select it to pair.
8. Once MightySat Rx is connected to a smart device, the Masimo Professional Health app returns to the Main screen.

   Note: A connection icon will appear on the MightySat Rx device when a Bluetooth connection has been established.
9. Place MightySat Rx on the patient's finger. Confirm that readings on MightySat Rx and readings displayed on the Masimo Professional Health app are the same without a delay greater than 10 seconds.

   Note: If the delay is greater than 10 seconds, move the MightySat Rx closer to the smart device and repeat the connection process.

   Note: To prevent unauthorized connection to the MightySat Rx, turn off the optional Bluetooth LE feature on the MightySat Rx when a connection is not required.

   CAUTION: When using MightySat Rx (optional Bluetooth version) with a smart device, keep both devices within range of each other (see ***Specifications*** on page 31 for details); moving out of range may cause a loss in connection with the smart device.

CAUTION: When using MightySat Rx (optional Bluetooth version) with a smart device, relocate the devices away from sources that may interfere with the Bluetooth connection. Interference may result in loss of Quality of Service (see ***Specifications*** on page 31 for details) of the Bluetooth connection.

Verify Paired MightySat Rx

1. On the smart device, access the Masimo Professional Health app *Options*.
2. Locate *Paired Device*.

   Note: *Sensor Mode* is always *Bluetooth Sensor* when using MightySat Rx with a smart device.
3. Compare the *Paired Device* information to the *BT SN* (Bluetooth Serial Number) displayed on the MightySat Rx *About* screen, see ***Main Menu Options*** on page 22 for information on accessing the About screen.

Disconnect Paired MightySat Rx

1. On the smart device, access the Masimo Professional Health app *Options*.
2. Press/select the *Paired Device* information.
3. Select *Forget this Device*. MightySat Rx will be disconnected from the smart device. MightySat Rx will need to be paired if it is to be used with this smart device again.

Turning off MightySat Rx

The MightySat Rx turns off automatically after removing the finger from the device in the absence of device interaction or connection to a smart device.

Cleaning, Disinfecting, and Service

Cleaning and Disinfecting MightySat Rx

WARNING: Before cleaning, read ***Cleaning, Disinfecting, Service Warnings and Cautions*** on page 11 in this manual.

WARNING: Before cleaning, make sure the device is off and is not applied to a finger.

CAUTION: Thoroughly clean and low level disinfect the MightySat Rx before applying it to on a new patient.

Note: Before cleaning, remove the batteries and make sure the battery cover is re-attached correctly.

To clean the MightySat Rx, follow the instructions below:

- Wipe each of the sensor pads and outer surfaces using a CaviWipes™ wipe twice or until the surfaces are free of any visible residue.

  Note: Pay particular attention to cracks, crevices, and hard to reach areas of the device.
- Repeat the above cleaning step using a fresh wipe.
- Allow the MightySat Rx to dry thoroughly before using again.

To conduct low level surface disinfection of the MightySat Rx, follow the instructions below:

Note: Follow cleaning instructions prior to disinfecting the device.

- Visibly wet the sensor pads and outer surfaces using a soft cloth dampened with a 10% (1:10) chlorine bleach to water solution.
- Allow the solution to sit for 10 minutes on the sensor pads before wiping them with a dry soft cloth.
- Allow the MightySat Rx to dry thoroughly before using again.

Alternatively, the MightySat Rx can be disinfected using the same instructions above, except with CaviWipes with a 5 minute exposure time.

The surfaces of the MightySat Rx have been tested to be chemically resistant to following solution(s):

- 70% Isopropyl Alcohol
- Cidex Plus (3.4% glutaraldehyde)
- 10% (1:10) chlorine bleach to water solution
- Quaternary ammonium chloride solution wipe (CaviWipes™)

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

Service

WARNING: Do not attempt to repair the MightySat Rx as this may cause damage to the device and prevent it from operating properly.

If the device does not appear to be operating correctly, see ***Troubleshooting*** on page 26 section in this manual.

Note: To maintain the proper functionality of the battery compartment and avoid possible damage from alkaline batteries that may leak, remove batteries from the device when not in use for long periods of time.

Troubleshooting

Error or Error Message	Possible Causes	Recommended Solutions
A red battery symbol displays on display screen	Low battery	Replace low batteries as soon as possible. (see ***Installing the AAA Batteries*** **on page 20** in this manual)
Device does not display readings	Incorrect finger placement Incorrect battery orientation No battery Low battery Environmental influences	Wait for measurement (Optional PVI may take a maximum of 5 minutes before initial measurement) Reposition finger (see ***Using MightySat Rx*** **on page 20** in this manual) Re-orient batteries Replace with new batteries Relocate device Contact Masimo Technical Services
Device display does not turn on	No battery Device damaged Batteries may be magnetic	Replace with new batteries Contact Masimo Technical Services
Numbers appear dim	Low battery Brightness set low Exposed to bright lights or sunlight Incorrect finger placement Measurement site may be poorly perfused	Check battery status indicator and replace batteries if necessary Check brightness setting in menu Relocate device so that it is not directly under bright lights Reposition finger (See ***Using MightySat Rx*** on page 20 in this manual) Contact Masimo Technical Services

Error or Error Message	Possible Causes	Recommended Solutions
Device keeps turning off while on the finger	Incorrect finger placement Environmental influences Device damaged	Reposition finger (See ***Using MightySat Rx*** on page 20 in this manual) Relocate device Replace with new batteries Contact Masimo Technical Services
Measurement does not display on the smart device using optional Bluetooth LE	Bluetooth LE not connected Compatible app not installed on smart device Device damaged Smart device damaged	Confirm Bluetooth LE is on for the MightySat Rx and the smart device Confirm a compatible app is installed on the smart device Close and re-launch the compatible app on the smart device Check that MightySat Rx is connected to the correct smart device Contact Masimo Technical Services

Product Support

For additional help, contact Masimo Technical Services at (949) 297-7498. Local contact information can be found at http://service.masimo.com.

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product MightySat™ Rx Fingertip Pulse Oximeter 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 48 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.

The above described warranty is in addition to any statutory rights provided to Purchaser under applicable laws and regulations of the region in which the product was sold to the extent that those rights cannot be disclaimed and are superseded by the above described warranty to the extent permitted under applicable laws and regulations of the region in which the product was sold.

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.

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Specifications

Display Ranges

Parameter	Display Ranges
SpO_2 (Oxygen Saturation)	0% to 100%
PR (Pulse Rate)	25 bpm to 240 bpm
Pi (Perfusion Index)	0.02% to 20%
PVi (Pleth Variability Index)	0% to 100%
RRp (Respiration Rate)	4 rpm to 70 rpm

The emitted wavelengths range from 600 nm to 1000 nm and the peak optical power is less than 15 mW. Information about the wavelength range can be especially useful to clinicians.

Performance Specifications

SpO2 Accuracy			
Condition	**Range**	**Population**	**A_{RMS}***
No Motion [1]	70% to 100%	Adults, Pediatrics	2%
Motion [2]	70% to 100%	Adults, Pediatrics	3%
Low perfusion [3]	70% to 100%	Adults, Pediatrics	2%

See the ***SpO2 Performance Specifications*** on page 32 for additional SpO2 accuracy information.

Pulse Rate (PR)			
Condition	**Range**	**Population**	**A_{RMS}***
No Motion [4]	25 bpm to 240 bpm	Adults, Pediatrics	3 bpm
Motion [4]	25 bpm to 240 bpm	Adults, Pediatrics	5 bpm

Pulse Rate (PR)			
Low perfusion [4]	25 bpm to 240 bpm	Adults, Pediatrics	3 bpm

Respiration Rate (RRp) [5]	
Range	**Accuracy**
4 rpm to 70 rpm	3 rpm A_{RMS}* ±1 rpm mean error

See RRp Performance Specifications for additional RRp accuracy information.

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

SpO2 Performance Specifications

Table below provides A_{RMS} (Accuracy Root Mean Square) values measured using the MightySat Rx with Masimo SET® Oximetry Technology in a clinical study under no motion conditions.

Measured A_{RMS} Values	
Range	A_{RMS}
90% – 100%	1.08%
80% – 90%	1.95%
70% – 80%	1.79%

Overall Claimed Accuracy Value	
Range	A_{RMS}
70% – 100%	2%

The below Bland-Altman plot represents the correlation of (SpO_2 - SaO_2) versus (SpO_2 + SaO_2)/2 under no motion with an upper 95% and lower 95% limits of agreement.

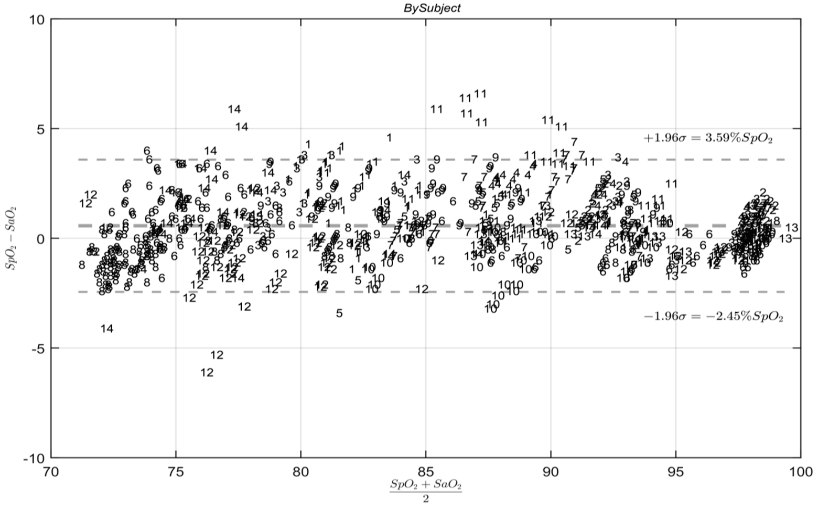


Figure 1: MightySat™ Rx Fingertip Pulse Oximeter (A_{RMS} 70-100%)

RRp Performance Specifications

The below Bland Altman plots represent the correlation of RRp and the reference respiration rate in three different studies, each with upper 95% and lower 95% limits of agreement.

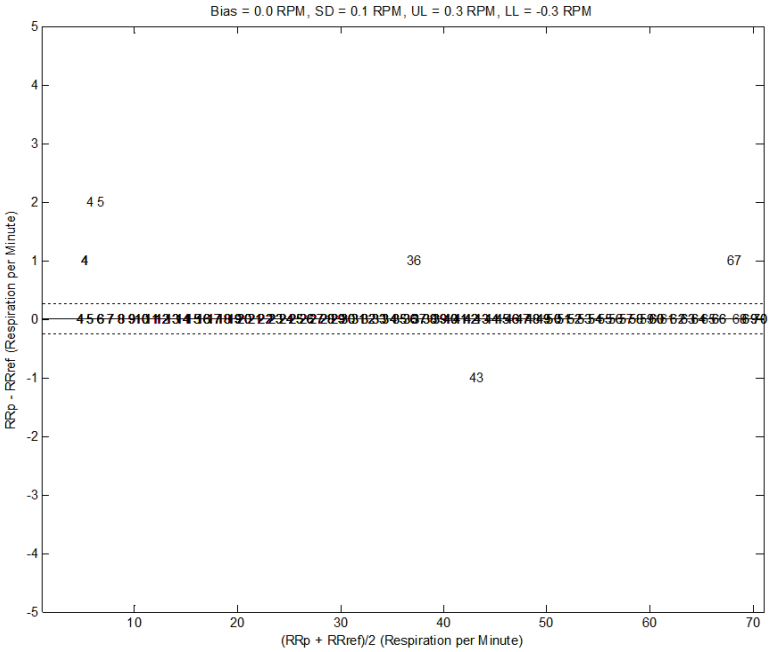


Figure 2: Bland-Altman plot of the RRp measurement with respect to the respiration rate value on a simulator (RRref)

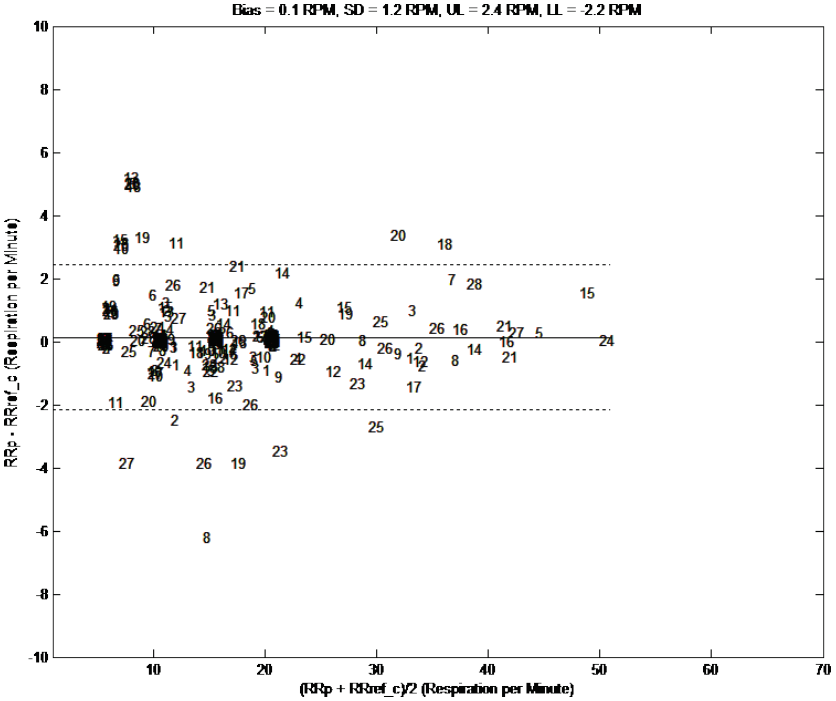


Figure 3: Subject by subject Bland-Altman plot of the RRp measurement with respect to the respiration rate determined by clinician-scored capnograms (RRref_c) from a clinical study of healthy volunteers

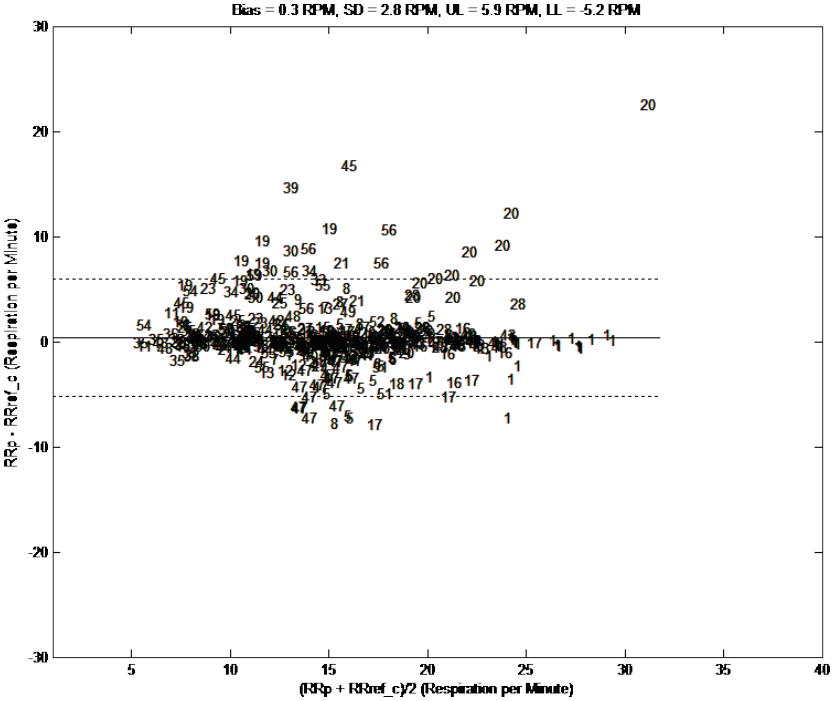


Figure 4: Subject by subject Bland-Altman plot of the RRp measurement with respect to the respiration rate determined by clinician-scored capnograms (RRref_c) from a clinical study of hospitalized patients

Medical Conditions

Medical Conditions from clinical study of hospitalized patients

	N		N
Autoimmune		**Infections**	
Psoriasis	1	Cellulitis	1
Cardiovascular		**Muscular**	
Atrial Septal Defect	1	Ventral Hernia	2
Coronary Disease	1	**Musculoskeletal and Connective Tissue**	

Hypertension	20
Endocrine/Metabolic	
Diabetes (Type I or II)	2
Hyperlipidemia	8
Hypomagnesemia	1
Hypothyroidism	2
Morbid Obesity	6
Gastrointestinal	
Acid Reflux	1
Crohn's Disease	1
Emesis	1
GERD	3
Hiatal Hernia	1
Reflux Disease	1
Genitourinary	
Bladder Cancer	1
Breast Cancer/Breast Cancer History	2
Cervical Cancer	1
Endometrial Cancer	1
Fibroid Uterus	1
Rectocele	1

Degenerative Joint Disease	1
Dupuytrens Contracture (Right Hand)	1
Osteoarthritis	4
Neoplasm	
Lipoma	1
Malignant Tumor	1
Neurological	
Bilateral Hand Tremors	1
Neuropathy	1
Restless Leg Syndrome	1
Ophthalmology	
Glaucoma	2
Other	
Lethargy	1
Subdural Hematoma	1
Renal	
Kidney Disease	2
Kidney Failure	1
Kidney Stones	1
Respiratory	
Asthma	2

Hematology	
Acute Blood Loss Anemia	1
Anemia	1
Blood Clotting Disorder/Unspecified	1
Leukocytosis	1
Sickle Cell Disease	1
Hepatobiliary	
Cholelithiasis	2
Chronic Cholecystitis	1
Gall Stones	2
Liver Cyst	1
Pneumonia	2
Risk of Sleep Apnea	3
Sleep Apnea	13
Vascular	
Raynaud Phenomenon	1

Battery Life

Item	Description
Operating	1.5 Volt AAA Battery (2)
Battery Life	≥15 hours (screen brightness at 50%)

Environment

Item	Description
Operating Temperature	5°C to 40°C (41°F to 104°F)
Storage Temperature	-40°C to 70°C (-40°F to 158°F)

Item	Description
Operating Humidity	10% to 95% non-condensing
Storage Humidity	10% to 95% non-condensing
Atmospheric pressure	540 mBar to 1060 mBar

Physical Characteristics

Item	Description
Dimensions	3" x 1.7" x 1.3" (7.6 cm x 4.3 cm x 3.3 cm)
Weight without Battery	0.2 lbs. (90g)

Compliance

Safety Compliance
ANSI/AAMI ES60601-1
CSA C22.2 No. 60601-1
IEC/EN 60601-1
IEC 60601-1-6
IEC 60601-1-11
ISO 80601-2-61

EMC Compliance
IEC 60601-1-2, Class B
ISO 80601-2-61: Clause 202, 20 V/m radiated immunity

Equipment Classifications per IEC 60601-1	
Degree of Protection against electric shock	Type BF applied part
Mode of Operation	Continuous Operation
Degree of Protection from Liquid Ingress	IP23, Protection from ingress of particulates > than 12.5 mm and ingress from spraying water.
Environment	Not for use in the presence of flammable anesthetics

Bluetooth LE Wireless Technology Information

Bluetooth LE Wireless Technology Information	
Modulation Type	GFSK
Max. Output Power	-1 dBm
Frequency Range	2402 MHz - 2480 MHz
Antenna Peak Gain	-7 dBi
Recommended Range	˜10 feet (˜3 meters) line-of-sight
Quality of Service (QoS)	Delay <10 seconds
Security	Proprietary binary protocol

Radio Compliance	
Radio Modes	Bluetooth LE
USA	FCC ID: VKF-MSAT01A FCC parts 15.207 and 15.247
Canada	IC-7362A-MSAT01A RSS-210

Radio Compliance	
Europe	EN 300 328 EN 301 489-17

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Guidance and Manufacturer's Declarations - 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	This device has not been evaluated for use in aircrafts.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration - 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%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-3	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3 ISO 80601-2-61, Clause 202	3 V/m 150 kHz to 80MHz 20 V/m 80 MHz to 2.5 GHz	3 V/m 20 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
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.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
(a) 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. **(b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment

The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.018	0.035
0.1	0.37	0.057	0.11
1	1.17	0.18	0.35
10	3.7	0.57	1.1
100	11.7	1.8	3.5

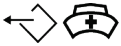
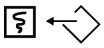
Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 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.

Symbols

The following symbols may appear on the product or product labeling:

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		ETL Intertek certification See ***Declarations on Page 1*** for certifications
IP23	Protection from ingress of particulates > than 12.5 mm and ingress from spraying water		Type BF applied part
	Non-Sterile		Polypropylene
	Separate collection for electrical and electronic equipment (WEEE)		Recyclable
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.	EC REP	Authorized representative in the European community

Symbol	Description	Symbol	Description
	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
	Non-ionizing electromagnetic radiation	IC Model:	Innovation, Science and Economic Development Canada (ISED)
	Warning, electricity		Biohazardous Waste
	Electrostatic	 SpO_2	Not for continuous monitoring (No alarm for SpO_2)
	No parameter alarms		Product contains no PVC (polyvinyl chloride) material
	Caution		Not made with natural rubber latex
	Manufacturer	REF	Catalog number (model number)
	Date of manufacture YYYY-MM-DD	####	Masimo reference number
	Storage temperature range	SN	Serial number
	Keep dry		Fragile, handle with care
	Storage humidity limitation		Do not use if package is damaged

Symbol	Description	Symbol	Description
	Atmospheric pressure limitation		Equipotential Ground Terminal
	AC current		Nurse Call Interface
	Fuse		SatShare Interface
	Stand-By		Wireless Symbol level
	RS-232 Interface		Wireless features can be used in member states with the restriction of indoor use in France - Class 2 wireless device
	Analog Out Interface		Iris Connection
	USB port		Ethernet
	Less than		Greater than
	China Restriction of Hazardous Substances		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual.
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

[1] The Masimo SET® Technology used in the MightySat™ Rx Fingertip Pulse Oximeter 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% to 100% SpO2 against a laboratory co-oximeter.

[2] The Masimo SET® Technology used in the MightySat™ Rx Fingertip Pulse Oximeter has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies while performing rubbing and tapping motions, at 2 Hz to 4 Hz at an amplitude of 1 cm to 2 cm and a non-repetitive motion between 1 Hz to 5 Hz at an amplitude of 2 cm to 3 cm in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory co-oximeter.

[3] The Masimo SET® Technology used in the MightySat™ Rx Fingertip Pulse Oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%.

[4] The Masimo SET® Technology used in the MightySat™ Rx Fingertip Pulse Oximeter has been validated for pulse rate accuracy for the range of 25 bpm to 240 bpm in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%. Pulse rate accuracy under motion was verified by bench top testing in the range of 55 bpm to 180 bpm against a Biotek simulator using the motion preset setting.

[5] RRp performance has been clinically validated on 28 healthy, adult volunteers and 59 hospitalized adult patients. The clinical testing included non-randomized studies comparing RRp measurements against manual, clinician-scored capnograms. The clinical testing on hospitalized adult patients was conducted using convenience sampling and did not necessarily include all patient conditions found in hospitals and hospital-type settings. The clinical testing results may not be generalized to all patient conditions. RRp performance was validated across the entire range of 4-70 RPM through bench testing.

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