MightySat® Rx
Fingertip Pulse Oximeter

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DIRECTIONS FOR USE

These 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 to your device model. 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: Use of this device must follow the order of a physician.

Note: Cleared Use Only: The device and related accessories have obtained CE Mark 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 instructions for use or labeling.

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

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 functional oxygen saturation (SpO_2), Pulse Rate (PR), Perfusion Index (PI), Pleth Variability Index (PVi®), and Respiration Rate from the Pleth (RRp®). MightySat Rx is available for people who weigh more than 30 kg (66 lbs).

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.
- 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	FEATURES
MightySat Rx, Bluetooth LE, PVi, and RRp	Intended to measure and display functional oxygen saturation (SpO_2), Pulse Rate (PR), Perfusion Index (PI), Pleth Variability Index (PVi), and Respiration Rate from the Pleth (RRp). Bluetooth LE radio is intended for transfer of parameter data to a compatible smart device.

Indications for Use

The MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and respiration rate from the pleth (RRp). The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

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 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:** Avoid the following conditions to minimize the risk of inaccurate SpO_2 readings:
  - Improper MightySat Rx placement or alignment
  - Elevated levels of COHb and MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Intravascular dyes such as indocyanine green or methylene blue
  - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
  - Patients attached to a high pressure cuff
  - Placing the MightySat Rx sensor on any extremity with an arterial catheter or blood pressure cuff
  - Elevated levels of bilirubin
  - Severe anemia
  - Venous congestion
  - Venous pulsation
  - Extremely low arterial perfusion
  - Excessive motion
- **WARNING:** Inaccurate Respiration Rate (RRp) measurements may be caused by: improper MightySat Rx placement or alignment, low arterial perfusion, excessive motion, or during arrhythmia.
- **WARNING:** Only use Masimo authorized devices with MightySat. Using unauthorized devices with MightySat may result in damage to the device and/or patient 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 MightySat, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- **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.
- **CAUTION:** Do not place the MightySat near electrical equipment that may affect the device, preventing it from working properly.
- **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:** RF Radiation Exposure Statement: This equipment has been exempted from FCC RF radiation exposure testing and IC RSS 102 RF radiation exposure limits set forth for an uncontrolled environment.
- **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.

Cleaning, Disinfecting, and 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:** Do not clean MightySat Rx with any chemical other than those specified in the Cleaning, Disinfecting, and Service section. 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 the Cleaning, Disinfecting, and Service section 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.
- **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 and Industry Canada's license-exempt RSS standards. 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: 2014 +A1: 2020, 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.

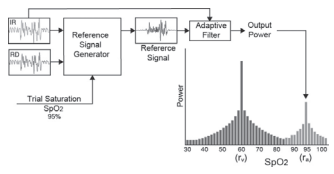
Signal Extraction Technology® (SET®)

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 (SpO_2)

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 SpO_2, 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 (SpO_2)

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 that 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%).

Pleth Variability Index (PVi) may show changes that reflect physiologic 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.

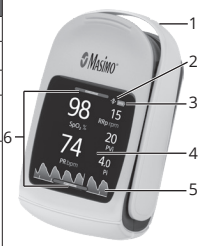
General Description for Respiration Rate (RRp)

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

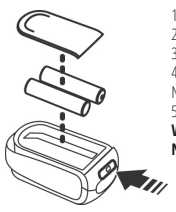
MightySat Rx Features

ID	DESCRIPTION	FUNCTION
1	Enclosure Clip	Clip provided for ease of lanyard attachment.
2	Bluetooth Indicator	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 the SIQ provide an indicator of the relative signal strength. When the waveform option is turned off, the pulse bar provides a blinking graphical indicator which corresponds to the pulse rate. Additionally, the relative signal strength is depicted by the height of the pulse bar.
6	Menu Indicators	Navigation elements that indicate access to different menus (see **Using the Touchscreen** section 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.

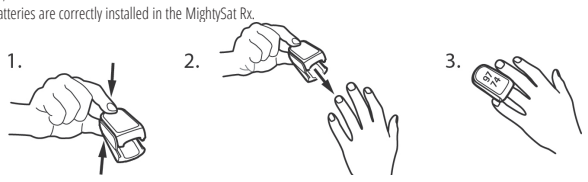
Warning: Ensure that the battery door is intact before use.

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.

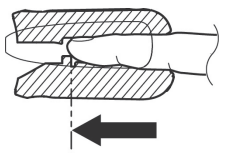
Using MightySat Rx

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 section 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.

MightySat® Rx
Fingertip Pulse Oximeter

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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.

Using the Touchscreen

Monitoring Screen


Main Menu Screen


Quick Access Menu

ACTION	DESCRIPTION	FUNCTION
Touch/Tap	Momentarily touch and release one finger on the Monitoring Screen.	Enables the option to swipe up or swipe down. See functions under Swipe for details.
	Momentarily touch and release one finger on the Main Menu or Quick Access Menu screen.	Selects a menu item or action from the Main Menu or Quick Access Menu. In the Quick Access Menu, rotate the display left or right, or access the Main Menu by tapping the gear icon.
Touch and Hold	Touch and hold anywhere on the monitoring screen.	Access the Main Menu Screen.
Swipe	Touch and slide down from the top when on the Monitoring Screen.	Access the Quick Access Menu.
	Touch and slide up from the bottom when on the Monitoring Screen.	Access the Main Menu Screen.
	Touch and slide up from the bottom when on the Quick Access Menu screen.	Go back to the Monitoring Screen.
	Touch and slide left or right when on the Main menu Screen.	Scroll through all selectable menu options.
	Touch and slide left or right when on the Monitoring Screen.	Sliding left rotates the Monitoring Screen counterclockwise. Sliding right rotates the Monitoring Screen clockwise.

Note: The direction of top, bottom, up, down, left, and right is with respect to the current screen orientation.

Navigating the Main Menu

Touch and hold anywhere on the monitoring screen to access the Main Menu.

Touch and slide left or right on the Main Menu screen to scroll through the Main Menu options. Momentarily touch and release one finger on the Main Menu Screen to select a menu item or action.

The Menu options are:

MAIN MENU OPTIONS	DISPLAY BUTTON	DESCRIPTION	DEFAULT	OPTIONS
Back		Return to Main screen	N/A	N/A
Waveform		Allows the user to choose if the waveform will be displayed on the screen. This menu tile will display its off state when waveform is toggled off.	On	On or Off*
Brightness		Change the brightness of the display screen.	100%	25%, 50%, 75% and 100%*
Bluetooth		Allows the user to connect to a smart device via Bluetooth LE. This menu tile will display its off state when Bluetooth is toggled off.	On	On or Off*
About		Hardware and software information about the device including serial number, software version, and Bluetooth LE Mac Address.	N/A	N/A

* Change option settings by tapping the display button, then swiping or tapping the toggle button on or off (for Brightness, select the appropriate brightness level percentage). The ✓ button engages after the option is changed. Tap the ✕ or ✓ button to return to the main screen.

Bluetooth Connection Overview

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 Personal 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.

1. Turn on Bluetooth on MightySat Rx. See Navigating the Main Menu of this manual for further instructions.
2. Ensure the Bluetooth is enabled on the smart device.
3. From your compatible smart device, do one of the following:
   - For Android™-powered devices, go to the Google Play™ store.
   - For Apple® devices, go to the App Store℠.
4. Search and download the "Masimo Personal Health" app.
5. Launch the Masimo Personal Health app to connect the MightySat Rx with a compatible smart device.
   Note: The MightySat Rx requires the use of the Masimo Personal Health app to communicate to a compatible smart device.
6. Confirm the correct connection by viewing the appropriate "Serial" number is displayed on the smart device. The Serial number can be found on the About screen, see Navigating the Menu of this manual for information on accessing the About screen.
7. Once MightySat Rx is connected to a smart device, confirm the readings on the MightySat Rx to the readings displayed on the Masimo Personal Health app are synchronized without a delay greater than 10 seconds.
   Note: A connection icon will appear on the MightySat Rx device when a Bluetooth connection has been established.
   Note: If the delay is greater than 10 seconds, move the MightySat Rx in closer proximity to the smart device or attempt to repeat the connection process.
   Note: To prevent unauthorized connection to the MightySat Rx, turn off the Bluetooth LE feature on the MightySat Rx.
   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. Interference may result in loss of Quality of Service (see Specifications for details) of the Bluetooth connection.

CLEANING, DISINFECTING, AND SERVICE

Cleaning and Disinfecting MightySat Rx

WARNING: Before cleaning, read **Cleaning, Disinfecting, and Service Warnings and Cautions** section in this manual.
WARNING: Before cleaning, make sure the device is off and is not applied to a finger.
CAUTION: Thoroughly clean the MightySat Rx before applying it to on a new user or 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, and 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 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** section in this manual)
Device does not display readings	Incorrect finger placement Incorrect battery orientation No battery Low battery Environmental influences	Wait for measurement (PVi may take up to 2 minutes before initial measurement) Reposition finger (see **Using MightySat Rx** section 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** in this manual) Contact Masimo Technical Services
Device keeps turning off while on the finger	Incorrect finger placement Environmental influences Device damaged	Reposition finger (See **Using MightySat Rx** in this manual) Relocate device Replace with new batteries Contact Masimo Technical Services
Measurement does not display on the smart device using 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 the Masimo app is installed on the smart device Close and re-launch the compatible app on the smart device Check that MightySat Rx is paired to the correct smart device Contact Masimo Technical Services

PRODUCT SUPPORT

For additional help, contact Masimo Technical Services. Local contact information can be found at:

http://service.masimo.com.

If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

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

Performance Specifications

FUNCTIONAL OXYGEN SATURATION (SpO_2) ACCURACY‡		
Condition	**Range**	**Arms***
No Motion [1]	70% to 100%	2%
Motion [2]	70% to 100%	3%
Low perfusion [3]	70% to 100%	2%
‡See the SpO_2 Performance Specifications section for additional SpO_2 accuracy information.		

PULSE RATE (PR)		
Condition	**Range**	**Arms***
No Motion [4]	25 bpm to 240 bpm	3 bpm
Motion [4]	25 bpm to 240 bpm	5 bpm
Low perfusion [4]	25 bpm to 240 bpm	3 bpm

RESPIRATION RATE (RRp)		
Condition	**Range**	**Arms***
No Motion [5]	4 rpm to 70 rpm	1 rpm

* 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.

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

Resolution

PARAMETER	RESOLUTION
$\%SpO_2$	1%
Pulse Rate	1 bpm
Respiration Rate	1 rpm

SpO_2 Performance Specifications

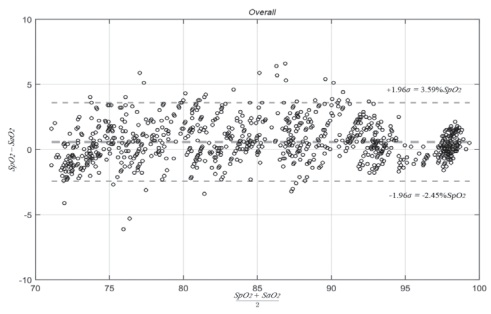
Table below provides Arms (Accuracy Root Mean Square) values measured using the MightySat Rx with Masimo SET® Oximetry Technology in a clinical study under no motion conditions.

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

MEASURED Arms VALUES	
RANGE	**Arms**
90% – 100%	1.08%
80% – 90%	1.95%
70% – 80%	1.79%

OVERALL CLAIMED ACCURACY VALUE	
RANGE	**Arms**
70% – 100%	2%

Battery Life



ITEM	DESCRIPTION
Operating	1.5 Volt AAA Battery (2)
Battery Life	*Approximately 1800 spot checks
***Note:** Based upon 15 hours of operation with screen brightness set to 50% a spot check of 30 seconds.	

Physical Characteristics

ITEM	DESCRIPTION
Dimensions	2.9" x 1.6 " x 1.3" (7.4 cm x 4.1 cm x 3.3 cm)
Weight without Battery	0.11 lbs. (50.4g)
Weight with Battery*	0.16 lbs. (72.4g)
***Note:** Weight is dependent on batteries used.	

Bluetooth LE Wireless Technology Information

BLUETOOTH LE WIRELESS TECHNOLOGY INFORMATION	
Modulation Type	GFSK
Max. Output Power	Typical: 6.89 dBm Tune-up tolerance: 1 dBm
Frequency Range	2402 MHz - 2480 MHz
Antenna Peak Gain	0.79 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-MSAT02A , FCC part 15.247
Canada	IC-7362A-MSAT02A, RSS-247
Europe	EN 300 328 , EN 302 489-17

Environment

ITEM	DESCRIPTION
Operating Temperature Range	5°C to 40°C
Operating Humidity	10% to 95% RH
Storage/Transport Temperature	-40°C to 70°C
Atmospheric pressure	540 mBar to 1060 mBar

Compliance

SAFETY COMPLIANCE	EMC COMPLIANCE	EQUIPMENT CLASSIFICATIONS PER IEC 60601-1	
ANSI/AAMI 60601-1 CSA C22.2 No. 60601-1 IEC 60601-1 EN 60601-1 IEC 60601-1-6 IEC 60601-1-11 ISO 80601-2-61	IEC 60601-1-2, Class B ISO 80601-2-61: Clause 202, 20 V/m radiated immunity	Degree of Protection against electric shock	Type BF applied part
		Mode of Operation	Continuous
		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

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%-100% SpO_2 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 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70%-100% SpO_2 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 25-240 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 55-180 bpm against a Biotek simulator using the motion preset setting.*
5. *The Masimo RRp (Respiration Rate from Pleth) spot-check technology used in the MightySat Rx Fingertip Pulse Oximeter has been bench tested for respiration rate accuracy in the range 4–70 rpm.*

SYMBOLS

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

SYMBOL	DEFINITION	SYMBOL	DEFINITION
(blue background)	Follow instructions for use		ETL Intertek certification. Conforms to ANSI/AAMI ES 1-60601 and certified to CAN/CSA STD C22.2 No. 1-60601
	Consult instructions for use		Wireless features can be used in member states with the restriction of indoor use in France - Class 2 wireless device
	Manufacturer		Not made with natural rubber latex
	Date of manufacture YYYY-MM-DD	5 PP	Polypropylene
SpO_2	Not for Continuous Monitoring (No Alarm for SpO_2)		Storage temperature range
	Type BF applied part		Storage humidity limitation
	Body weight	FCC ID:	Identifies unit has been registered as a radio device
NON STERILE	Non-Sterile		Federal Communications Commission (FCC) licensing
IP23	Protection from ingress of particulates > than 12.5 mm and ingress from spraying water	CE 0123	European Union Conformity Mark
IC Model:	Industry Canada Identification	EC REP	Authorized representative in the European community
	Do not discard	CH REP	Indicates the authorized representative in Switzerland
	Separate collection for electrical and electronic equipment (WEEE).		Atmospheric pressure limitation
LOT	Lot code		Fragile, handle with care
REF	Catalogue number (model number)		Caution
####	Masimo reference number		Do not use if package is damaged and consult instructions for use
	Importer	MD	Medical device
	Distributor	UDI	Unique device identifier
eIFU indication	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note: eIFU is not available in all countries.**		

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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.

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	Suitable for use in all establishments, including domestic environments.
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

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.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 ISO 80601-2-61, Clause 202	3 Vrms 150 kHz to 80 MHz 3 V/m 150 kHz to 80MHz 20 V/m 80 MHz to 2.5 GHz	N/A 3 V/m 20 V/m	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. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 kHz to 80 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 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.

[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 K Hz 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
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.			