Home Care 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.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked 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.

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

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***

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Glossary

Apnea: A sleep disorder in which breathing starts and stops.

Hemoglobin: The protein in red blood cells that transports oxygen from the lungs throughout the body and carbon dioxide from the tissues back to the lungs.

Necrosis: The death of most or all of the cells in a tissue due to disease, injury, or failure of the blood supply.

Oxygen Saturation: The percentage of hemoglobin in blood that is bound to oxygen.

Parameter: A parameter is an element of a system that is critical in evaluating the system's condition.

Perfusion: The bodily process of delivering blood to the capillary beds.

Pulse Oximeter: A medical device that uses a sensor to indirectly measure oxygen saturation of blood and pulse rate.

Quality of Service (QoS): Description or measurement of overall performance of the Bluetooth communication between MightySat Rx and the mobile device as seen by the user.

Device Description

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.

Purpose of the 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.

General Warnings and Precautions

The MightySat Rx should be used under the care of and following the instructions of your physician.

WARNING: Always consult your physician regarding clinical decisions. Do not rely on MightySat Rx as the only basis for medical decisions. Incorrect clinical decisions may result in harm.

Before using the MightySat Rx, read the following carefully.

Safety Warnings

WARNING: Follow the MightySat Rx instructions to prevent harm or damage to the device.

WARNING: Do not use MightySat Rx if the device enclosure appears damaged or if you suspect it has been damaged. Exposed electrical circuits can lead to harm.

WARNING: Do not adjust, repair, open, disassemble, or modify MightySat Rx. Such changes may cause MightySat Rx to malfunction and may lead to false readings.

WARNING: Do not use MightySat Rx near flammable gases such as anesthetics, oxygen, oxygen-enriched environments, or nitrous oxide to prevent risk of fire.

WARNING: Only use the MightySat Rx to the secure it to the finger. Too much pressure to a finger can cause skin damage.

WARNING: Check the sensor site every hour to ensure proper blood flow, skin quality, and sensor placement. Skin damage, pressure necrosis, or inaccurate readings may result.

WARNING: Only use Masimo-approved accessories and devices with MightySat Rx to prevent damage to the device and inaccurate readings.

WARNING: Keep MightySat Rx away from small children. Small items such as the battery door, battery, and lanyard may become a choking hazard.

WARNING: Do not use the lanyard during activities where it may become wrapped around the neck. Strangulation may occur.

WARNING: Do not touch MightySat Rx while defibrillating a patient to prevent damage to the device.

WARNING: To prevent harm to the patient and damage to MightySat Rx:

- Do not set MightySat Rx on a wet surface.
- Do not immerse it in liquid.
- Do not attempt to sterilize it.
- Clean only with the solutions listed in this manual.
- Do not clean MightySat Rx while it is connected to the patient.

CAUTION: Do not use the MightySat Rx near devices that are sensitive to magnets. The magnet provided with the MightySat Rx could hinder proper operation of the device.

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

Performance Warnings

WARNING: Do not use MightySat Rx as an apnea monitor. MightySat Rx does not have alarms to alert you when the patient's breathing is not normal or has stopped.

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.

WARNING: Check the following to prevent inaccurate (or no) readings:

- MightySat Rx is applied correctly.
- Blood pressure cuff is not applied to the same arm as a sensor site.
- Sensor site is free of nail polish, acrylic nails, glitter, etc.
- Sensor site is free of moisture, birthmarks, skin discoloration, and any foreign objects in the path of the sensor.
- MightySat Rx is placed where other devices may not interfere with its operation.
- The patient does not have any medical conditions that might interfere with readings.
- Contact your physician if you have concerns.

WARNING: Inaccurate respiration rate (RRp) measurements may be caused by:

- Low arterial perfusion
- Motion

CAUTION: Avoid using the MightySat Rx under bright light sources 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: 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: other cellular telephones, wireless PC and tablets, pagers, Bluetooth devices, devices with remote controls, and baby monitors.

Note: The MightySat Rx display may be difficult to view when exposed to direct sunlight or bright lights.

Note: The MightySat Rx display will shut off automatically if there are no readings.

Note: Please contact health professionals if Respiration Rate is <8 or >24 respirations per minute.

Cleaning and Service Warnings

WARNING: Do not re-manufacture, recondition or recycle MightySat Rx to prevent harm or damage to the device.

WARNING: To prevent damage to MightySat Rx:

- Remove batteries when the MightySat Rx will not be in use for more than 30 days
- Replace both batteries at the same time to avoid mixing fully and partially charged batteries.
- Use only AAA alkaline batteries.

WARNING: Dispose of battery according to local regulations.

CAUTION: Perform only the maintenance procedures specifically described in this manual to prevent damage to the device. For all other maintenance or repair, return MightySat Rx to Masimo for servicing.

CAUTION: Do not clean MightySat Rx with undiluted bleach, petroleum-based products, acetone, or other harsh solvents. Clean only with the solutions specified in this manual to prevent damage to the device.

CAUTION: Do not touch, press, or rub the display panels with anything that could scratch the display, such as abrasive cleaning compounds, instruments, brushes, or rough-surface materials. These can damage the device.

CAUTION: Do not submerge MightySat Rx in liquid or attempt to sterilize the MightySat Rx by any method to prevent damage to the device.

Compliance Warnings

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

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

CAUTION: Comply with local laws and regulations when disposing of MightySat Rx, its accessories, and its battery.

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.

Risks and Benefits

Before using any medical device, it is important to consult your physician and weigh the risks and benefits.

The following section describes the Benefits and Risks associated with using MightySat Rx.

Risks of MightySat Rx

- As with all medical electrical devices, there is always a risk of electrical, mechanical, and fire hazards. However, these risks have been mitigated through the design and testing of MightySat Rx.
- As with all devices with small parts, there is always a risk of a child's swallowing a component or choking. Keep small parts away from small children to prevent such hazards.
- As with all items applied directly to the skin, there is always a risk of skin irritation, pressure injury, and general discomfort while a sensor or cuff is applied to a patient. Periodically check the areas where the patient's skin makes contact with the sensor or blood pressure cuff to prevent potential issues.

Benefits of MightySat Rx

- MightySat Rx is a portable fingertip device able to provide pulse oximetry measurements including oxygen saturation (SpO_2), pulse rate (PR), perfusion index (Pi), Respiratory Rate (RRp), and pleth variability index (PVi) within a home environment.
- The MightySat Rx with optional Bluetooth can wirelessly transfer data to a compatible smart device for a larger display and/or storage of data.

Description

Parts List

MightySat Rx consists of the following items:

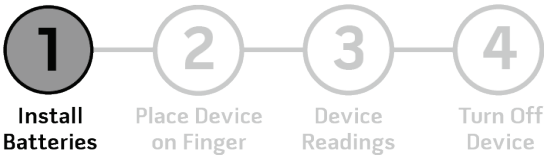
Item	Description
1	MightySat Rx
2	Batteries
3	Lanyard
4	Carrying Case

MightySat Rx Features

Item	Description	Function
1	Enclosure Clip	Attach lanyard to the clip.
2	Bluetooth Indicator (Optional)	Displays when Bluetooth is enabled on the device.
3	Battery Status Indicator	Displays remaining battery life.
4	Main Screen	Display for measurements and indicators. **Note:** Numbers are dim when confidence in the measurement is low.
5	Waveform and SIQ or Pulse Bar	When the waveform option is turned on, the Waveform and SIQ line display. The height of the SIQ line shows the confidence in the measurement displayed. When the waveform option is turned off, the Pulse Bar displays the pulse rate. The height of the Pulse Bar shows the confidence in the measurement displayed.
6	Touchpad	User interface for settings (see ***Using the Touchpad*** on page 21 in this manual).

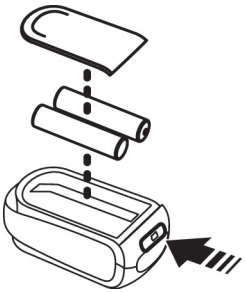
Basic Setup and Use

The following steps include basic setup and use for operating the MightySat Rx device.



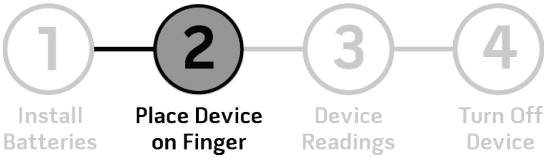
The MightySat Rx requires two alkaline AAA batteries to operate. To install batteries, follow the steps below:

Note: MightySat Rx will not work if the batteries are inserted backwards.

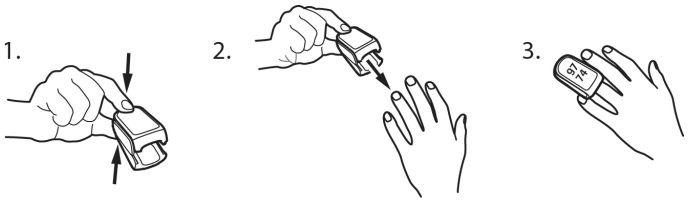


1. Place the MightySat Rx with the display screen facing down.
2. Push lightly on the battery button (identified by the arrow) to release and remove the battery cover.
3. Insert two new AAA alkaline batteries to match the labels (+ and -) inside of the battery case.
4. Snap the battery door back onto the device.

   CAUTION: Ensure that the battery door is installed before use.

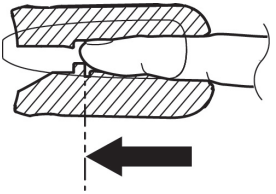


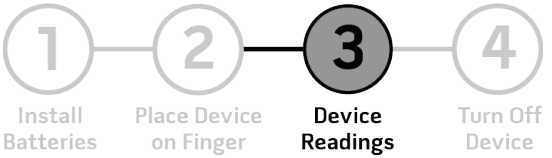
MightySat Rx turns on when the device is opened to place on a finger.



1. To open the MightySat Rx, squeeze the back of the device **(1)**.
2. Insert the ring finger with the display facing up **(2)**. For a right-handed person, this would be the left hand ring finger, for a left-handed person, this would be the right hand ring finger.
3. Once the device is correctly placed on the finger, release the device to close. The display should be facing up **(3)**.
4. The tip of the finger should touch the finger stop as shown in the image below.

   Note: Ensure the finger is correctly positioned.



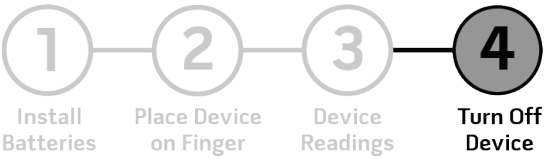


After the MightySat Rx is correctly placed on the finger, readings display.

Note: If readings are not displayed, see ***Troubleshooting*** on page 25.

CAUTION: Do not press the top of the device while on the finger.

WARNING: Do not attempt to secure the MightySat Rx to the finger using additional pressure.



The MightySat Rx turns off after removing it from the finger.

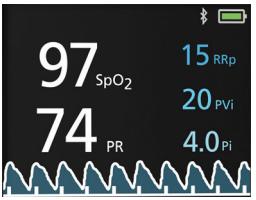
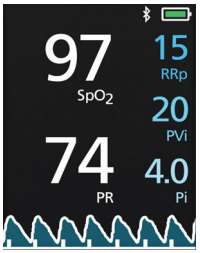
Notes:

Advanced Setup and Use

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.
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 26 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 26 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.

Notes:

Appendix

Troubleshooting

Troubleshooting

Error or Error Message	Possible Causes	Recommended Solutions
A red battery symbol displays on Main Screen	Low battery	Replace low batteries as soon as possible. (see Installing the AAA Batteries 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 ***Basic Setup and Use*** **on page 17** in this manual) • Re-orient batteries • Replace with new batteries • Relocate device • Contact Masimo Technical Services
Device display does not turn on	• No battery • Incorrect battery orientation • Device damaged	• Replace with new batteries • Re-orient batteries • Contact Masimo Technical Services
Numbers appear dim	• Brightness set low • Exposed to bright lights or sunlight • Incorrect finger placement • Measurement site may be poorly perfused	• Check brightness setting in menu • Relocate device so that it is not directly under bright lights • Reposition finger (See ***Basic Setup and Use*** on page 17 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 ***Basic Setup and Use*** on page 17 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

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 28 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
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.

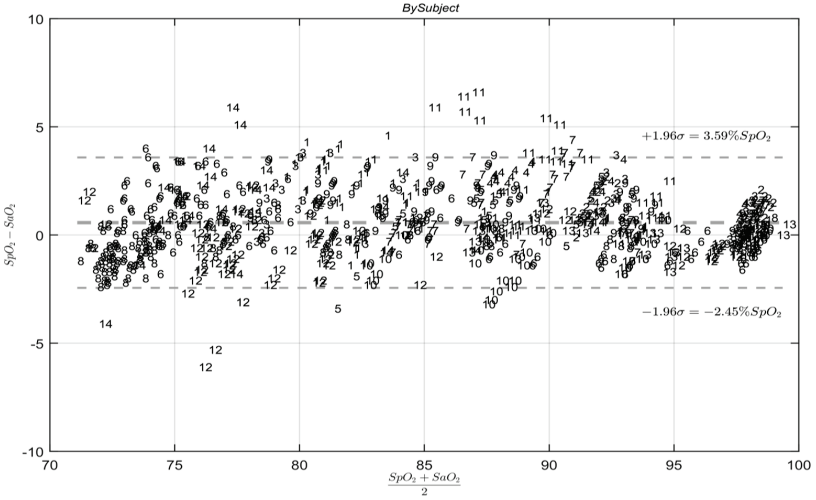


Figure 1: MightySat™ Rx Fingertip Pulse Oximeter (A_{RMS} 70-100%)

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.

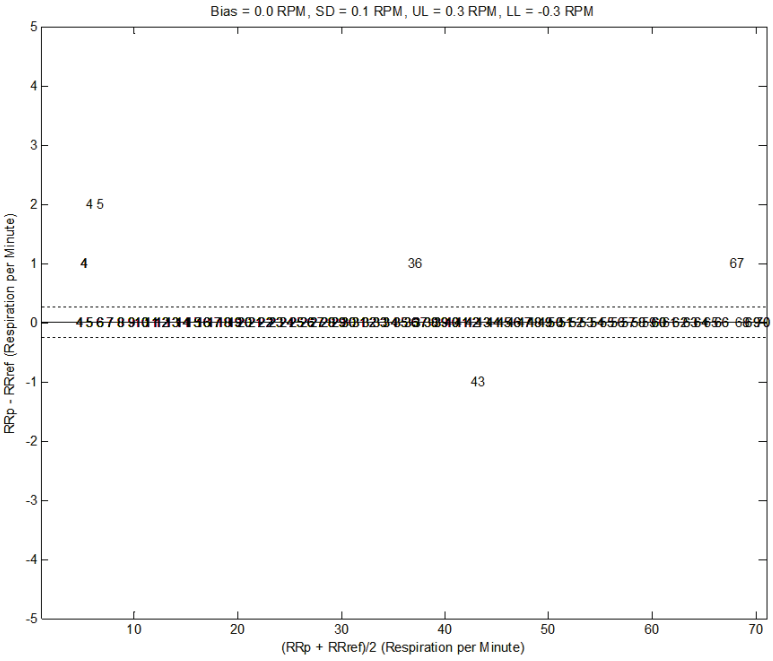


Figure 2: Bland-Altman plot of the RRp measurement with respect to the respiration rate value on a simulator (RRref)

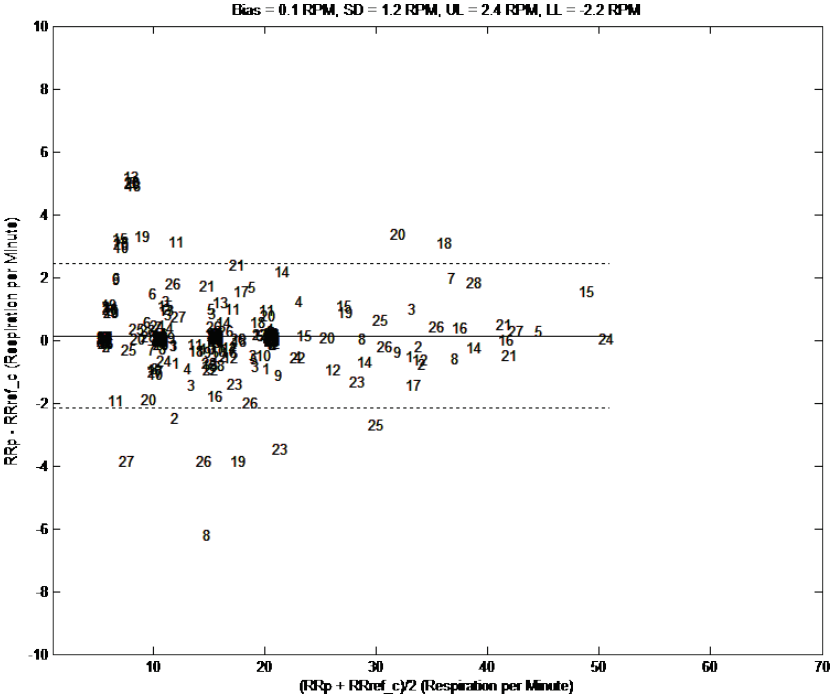


Figure 3: Subject by subject Bland-Altman plot of the RRp measurement with respect to the respiration rate determined by clinician-scored capnograms (RRref_c) from a clinical study of healthy volunteers

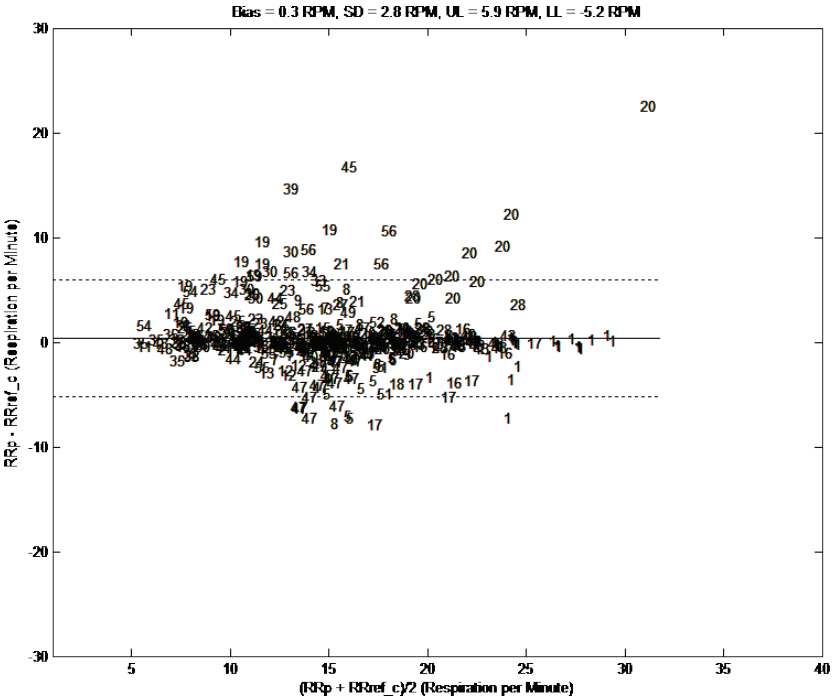


Figure 4: Subject by subject Bland-Altman plot of the RRp measurement with respect to the respiration rate determined by clinician-scored capnograms (RRref_c) from a clinical study of hospitalized patients

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
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

Musculoskeletal and Connective Tissue	
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	

Rectocele	1
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

Asthma	2
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)
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

Radio Compliance	
USA	FCC ID: VKF-MSAT01A FCC parts 15.207 and 15.247
Canada	IC-7362A-MSAT01A RSS-210
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 is not intended to be operated in the home environment. 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	3 V/m 150 kHz to 80MHz	3 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
ISO 80601-2-61, Clause 202	20 V/m 80 MHz to 2.5 GHz	20 V/m	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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		Mark of conformity to European medical device directive 93/42/EEC
IP23	Protection from ingress of particulates > than 12.5 mm and ingress from spraying water		Federal Communications Commission (FCC) Licensing
	No parameter alarms		Type BF applied part
	Non-Sterile		Polypropylene
	Separate collection for electrical and electronic equipment (WEEE)		Caution
	Body weight		Not made with natural rubber latex
	Storage temperature range		Storage humidity limitation

Symbol	Description	Symbol	Description
	Wireless features can be used in member states with the restriction of indoor use in France - Class 2 wireless device		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.

Cleaning, Disinfecting, and Service

Cleaning and Disinfecting MightySat Rx

WARNING: Before cleaning, read ***Cleaning and Service Warnings*** on page 11.

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 the outer surfaces using a dampened soft cloth twice with one of the recommended cleaning solutions listed below, 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 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.

The surfaces of the MightySat Rx may be cleaned with the following:

- 70% Isopropyl Alcohol
- Cidex Plus (3.4% glutaraldehyde)
- 10% (1:10) chlorine bleach to water solution

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 25 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.

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.

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