

# MightySat Fingertip Pulse Oximeter

## Operator's Manual

### Not for Sale in the USA - For Export Only

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.

Cleared Use Only: The device and related accessories have obtained CE Mark for noninvasive user 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.

## About this Manual

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

Always use the MightySat 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 Fingertip Pulse Oximeter is a noninvasive device that measures and displays arterial oxygen saturation (SpO<sub>2</sub>), Pulse Rate (PR), Perfusion Index (PI), and Pleth Variability Index (PVI®).

The MightySat Fingertip Pulse Oximeter is available in the following models:

Model	Product	Features
9701	MightySat	Measures and displays arterial oxygen saturation (SpO <sub>2</sub> ), Pulse Rate (PR), and Perfusion Index (PI).
9801	MightySat, Bluetooth	Measures and displays arterial oxygen saturation (SpO <sub>2</sub> ), Pulse Rate (PR), and Perfusion Index (PI). Bluetooth LE radio for transfer of parameter data to a compatible smart device.
9901	MightySat, Bluetooth and PVI	Measures and displays arterial oxygen saturation (SpO <sub>2</sub> ), Pulse Rate (PR), Perfusion Index (PI), and Pleth Variability Index (PVI). Bluetooth radio for transfer of parameter data to a smart device.

### Indications for Use

The MightySat Fingertip Pulse Oximeter is indicated for noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), Pulse Rate (PR), and Perfusion Index (PI).

The MightySat Fingertip Pulse Oximeter is intended for spot-checking on people > 30 kg (66 lbs) during no motion and motion conditions, and for people who are well or poorly perfused. This device is suitable for use in hospitals, hospital-type facilities, mobile, and home environments.

## Safety Information, Warnings, and Cautions

### Safety Warnings and Cautions

- Warning:** Do not use MightySat if it appears or is suspected to be damaged.
- Warning:** Do not repair, open, or modify MightySat. Injury or equipment damage could occur.
- Warning:** Do not use MightySat during magnetic resonance imaging (MRI) or in an MRI environment.
- Warning:** Do not expose MightySat components to excessive moisture such as direct exposure to rain. Excessive moisture can cause the components to perform inaccurately or fail.
- Warning:** Do not place MightySat or accessories in any position that might cause it to fall on the user.
- Warning:** Electric Shock Hazard: Do not use MightySat during defibrillation.
- Warning:** Do not use device during electrosurgery.
- Warning:** Do not use MightySat in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Warning:** Do not use tape to secure MightySat to the site; this can restrict blood flow and cause inaccurate readings. Use of tape can cause skin damage, and/or pressure necrosis or damage the sensor.
- Warning:** Keep the oximeter away from young children. Small items such as the battery door and battery may become choking hazards.
- Warning:** When MightySat is applied for extended periods of time, the sensor site must be checked frequently to ensure adequate circulation, skin integrity, and correct optical alignment.
- Warning:** If MightySat is applied too tightly or becomes tight due to edema it will cause inaccurate readings and can cause pressure necrosis.
- Warning:** Do not use the lanyard with MightySat during activities where a risk of strangulation may exist (i.e. sleeping).
- Caution:** Do not attempt to reprocess, recondition or recycle MightySat as these processes may damage the electrical components, potentially leading to user harm.
- Caution:** Before changing batteries, make sure the device is off and is not applied to a finger.
- Caution:** MightySat contains a magnet which may interfere with other devices, including pacemakers.
- Note:** The maximum skin surface temperature is measured to be less than 41°C (106°F) in a minimum 35°C (95°F) environment. This was verified by measuring the skin interface temperature with MightySat operating under reasonable worst-case conditions.

### Performance Warnings and Cautions

- Warning:** MightySat is not an apnea monitor and should not be used for arrhythmia analysis.
- Warning:** Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor.
- Warning:** MightySat does not include visual alerts or audible alarm features to support continuous monitoring. It is intended for spot-check use only.
- Warning:** SpO<sub>2</sub> is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Warning:** Inaccurate SpO<sub>2</sub> readings may be caused by:
  - Improper MightySat placement or alignment
  - Elevated levels of COHb and MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO<sub>2</sub>. 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
  - Avoid placing the MightySat sensor on any extremity with an arterial catheter or blood pressure cuff.
  - Elevated levels of bilirubin
  - Severe anemia
  - Venous congestion
  - Venous pulsation
  - Low arterial perfusion
  - Motion artifact
- Caution:** To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to MightySat.
- Caution:** High ambient light sources, fluorescent lights, infrared heating lamps and direct sunlight can interfere with the performance of MightySat.

- Caution:** To prevent interference from ambient light, ensure that MightySat is properly applied. Failure to take this precaution in high ambient light conditions may result in inaccurate or no measurements.
- Caution:** If no measurements are displayed, find a better perfused monitoring site.
- Caution:** When using MightySat Model 9801 or Model 9901 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 missing, lost, and/or inaccurate data to display on the smart device.
- Note:** The MightySat display may be difficult to view when exposed to direct sunlight or bright lights.
- Note:** A functional tester cannot be used to assess accuracy of MightySat.
- Note:** The MightySat display will shut off automatically if there are no readings.

### Cleaning and Service Warnings and Cautions

- Warning:** Changes or modifications not expressly approved by Masimo shall void the warranty for this equipment.
- Warning:** Use only AAA alkaline batteries.
- Warning:** Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for more than 30 days.
- Warning:** Do not mix fully charged and partially charged batteries at the same time. These actions may cause the batteries to leak.
- Caution:** A user may only perform maintenance procedures specifically described in the manual; otherwise, return MightySat for servicing.
- Caution:** Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean MightySat. These substances affect the device's materials and instrument failure can result.
- Caution:** Do not submerge MightySat 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 here because permanent damage to MightySat may occur.
- Caution:** Never immerse MightySat in water or any other liquid solution.

### Compliance Warnings and Cautions

- Caution:** Disposal of Product: Comply with local laws in the disposal of the instrument and/or its accessories, including batteries.
- Note:** When using MightySat 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.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  - Consult the dealer or an experienced radio/TV technician for help.
- Note:** This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 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.

## The Masimo Difference

From the leader in hospital pulse oximetry comes a complete pulse oximeter that is compact and portable to help you measure blood oxygen saturation through motion and low perfusion. The MightySat Fingertip Pulse Oximeter allows you to noninvasively track oxygen saturation (SpO<sub>2</sub>), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI). The MightySat features Masimo® Signal Extraction Technology® (SET®) technology, proven to provide accurate pulse oximetry measurements during motion and low perfusion.

For more than 20 years, Masimo has been focused on a singular mission—to take noninvasive patient monitoring to new sites and applications. Visit [www.Masimo.com](http://www.Masimo.com) to learn why clinicians worldwide know and trust Masimo for patient care.

## About the MightySat Technology

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).

Display Parameter	Description
Functional oxygen saturation (SpO <sub>2</sub> )	Functional oxygen saturation (SpO <sub>2</sub> ) is the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.
Pulse Rate (PR)	Pulse rate (PR), measured in beats per minute (BPM), is based on the optical detection of peripheral flow pulse.
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 continuously and noninvasively obtained from a pulse oximeter.
Pleth Variability Index (PVI) (Model 9901 only)	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%). The utility of PVI is unknown at this time and requires further clinical studies. Technical factors that may affect PVI include malposition and patient motion.
Plethysmograph Waveform (Pleth)	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. Clinicians have attempted to utilize this waveform and its variation for assigning signal integrity, physiological and artifactual changes such as perfusion changes, dysrhythmia, motion artifact, and electrical interference. For this reason, accurate and reliable presentation of the plethysmograph waveform is of importance.
Signal I.Q. Indicators (SIQ)	The Signal I.Q.® (SIQ) provides an indicator of the assessment of the confidence in the displayed SpO <sub>2</sub> value. The height of the vertical line of the SpO <sub>2</sub> SIQ provides an assessment of the confidence in the measurement displayed. A high vertical line indicates higher confidence in the measurement. A small vertical line indicates lower confidence in the displayed measurement.

## MightySat Fingertip Pulse Oximeter

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# Getting Started with MightySat

## Compatibility

**Note:** Compatibility is limited to Models 9801 and 9901 only.



For select Android®-powered devices.



For select Apple® devices.

## Operation

### MightySat Features



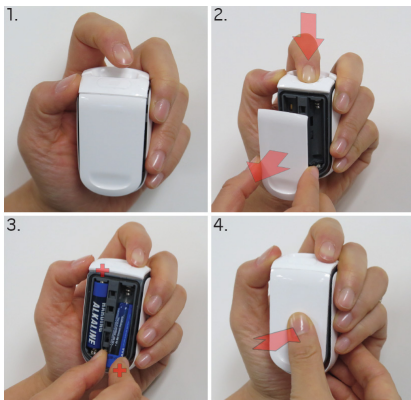
ID	Description	Function
1	Enclosure Clip	Clip provided for ease of lanyard attachment.
2	Bluetooth Indicator (For Models 9801 and 9901)	Indicates when Bluetooth is enabled on the device.
3	Battery Status Indicator	Indicates the remaining relative life of the battery.
4	Display Screen	Display for measurements and indicators. <b>Note:</b> Numbers will dim when confidence in the value is low.
5	Waveform and SIQ	Display of the pleth waveform and the SIQ provides an indicator of the relative signal strength.
6	Touchpad	User interface to allow for change of settings (see <b>Using the Touchpad</b> section in this manual).

## Installing the AAA Batteries

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

**Warning:** Before changing batteries, make sure the device is off and is not applied to a finger.

- Orient the MightySat so that the display screen is facing downwards. Locate the battery button on the front of the sensor pad.



- Push lightly on the battery button to release the battery cover and then remove the battery cover.
- Locate the battery orientation labels (+ and -) provided inside the battery compartment. Insert two new AAA alkaline batteries and carefully match the orientation labels (+ and -).
- Caution:** MightySat will not work if the batteries are inserted in the incorrect orientation.
- Once the batteries are correctly inserted, carefully snap the battery door back onto the device.  
**Warning:** Ensure that the battery door is intact before use.  
**Note:** MightySat will automatically activate when the device is opened so that the sensor pads are exposed as shown in the image below.

## Using MightySat

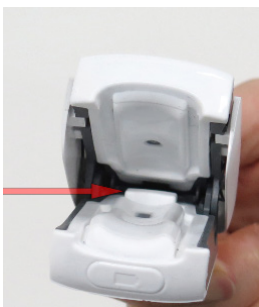
To take readings with the MightySat, follow the instruction below:

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

- MightySat will automatically activate when the device is opened so that the sensor pads are exposed.



- To open the MightySat squeeze the back portion of the device as shown in the image above.
- 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 should be facing upwards as depicted in the image above.
- Position the finger so that the tip of the finger touches the backstop provided at the end of the sensor pad as shown in the image below.

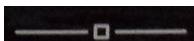


- Once the finger is correctly positioned, gently close the MightySat by releasing the pressure on the back of the device.  
**Note:** Ensure the finger is correctly positioned for accurate measurements.
- Once the MightySat is correctly closed on the finger, the MightySat will display readings.  
**Note:** 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 to the finger using external pressure. The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.

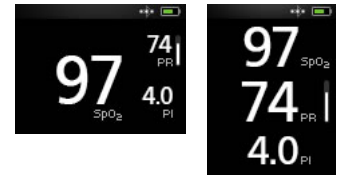
## Turning off MightySat

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

## Using the Touchpad

The Touchpad  on MightySat device is located below the display screen.  
**Note:** The display is not a touch screen.

Action	Description	Function
Touch	Tap and release. Action will be performed once finger is released.	Select a menu item or action Touch rotates the display clockwise
Press and Hold	Press and hold. Release finger once action has been performed.	Enter and Exit the Main Screen
Swipe	Touch and slide (left, and right) and release.	Scroll through all selectable menu options.



## Navigating the Menu

From the Main Screen, press and hold the Touchpad to access the Main Menu.

Use the Touchpad *Swipe* gesture to scroll through the Main Menu Options. Use the *Touch* gesture to select the Main Menu Option. Use the same gestures to adjust settings.

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.	On	On or Off
Brightness		Change the brightness of the display screen.	100%	25%, 50%, 75% and 100%
About		Hardware and software information about the device including serial number, software version, and Bluetooth LE Mac Address.	N/A	N/A
Bluetooth (Models 9801 and 9901 only)		Allows the user to connect to a smart device via Bluetooth LE.	On	On or Off

## Cleaning and Service

### Cleaning MightySat

**Warning:** Before cleaning, read **Cleaning 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.

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

To clean the MightySat, follow the instructions below:

- The outer surfaces can be cleaned either with a soft cloth dampened with a mild detergent and warm water solution or they can be wiped down with the following cleaning solutions:
- Cidex Plus (3.4% glutaraldehyde)
- 10% bleach solution
- 70% isopropyl alcohol solution
- Allow the MightySat to dry thoroughly before using again.

**Caution:** To avoid permanent damage to the MightySat, 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 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** section in this manual.

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

## Troubleshooting

Error or Error Message	Possible Causes	Recommended Solutions
A red battery symbol displays on display screen.	Low battery	Replace low batteries as soon as possible. (see <b>Installing the AAA Batteries</b> 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 <b>Using MightySat</b> 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	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 no directly under bright lights Reposition finger (See <b>Using MightySat</b> section in this manual) Choose different finger Contact Masimo Technical Services
Device keeps turning off while on the finger	Incorrect finger placement Environmental influences Device damaged	Reposition finger (See <b>Using MightySat</b> section in this manual) Relocate device Contact Masimo Technical Services
Measurement does not display on the smart device	Bluetooth not connected Compatible App not installed on smart device Device damaged Smart device damaged	Confirm Bluetooth is on for the MightySat and the smart device Confirm the Masimo app is installed on the smart device Close and re-launch Masimo app Check that MightySat is paired to the correct smart device Contact Masimo Technical Services

## Product Support

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

## Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product MightySat 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 24 months and any Masimo-branded batteries, if supplied by Masimo with the product, for six (6) 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

### Measurement Ranges

Parameter	Display Ranges
SpO <sub>2</sub> (Oxygen Saturation)	0% to 100%
PR (Pulse Rate)	25 bpm to 240 bpm
PI (Perfusion Index)	0.02% to 20%
Pleth Variability Index (PVI)	0 to 100

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.

Parameter	$\bar{A}_{rms}$
SpO <sub>2</sub> (no motion)	± 2% (From 70%-100% SaO <sub>2</sub> ) [1]
SpO <sub>2</sub> (motion)	± 3% (From 70%-100% SaO <sub>2</sub> ) [2]
SpO <sub>2</sub> (low perfusion)	± 2% (From 70%-100% SaO <sub>2</sub> ) [3]
Pulse Rate (no motion)	± 3 bpm [4]
Pulse Rate (motion)	± 5 bpm [4]

### Battery Life

Item	Description
Operating	1.5 Volt AAA Battery
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 1.2" (7.4 cm x 4.1 cm x 3.0 cm)
Weight without Battery	0.11lbs. (51g)
Weight with Battery*	0.16 lbs. (73g)

\*Note: Weight is dependent on batteries used

### Bluetooth LE Wireless Technology Information

Bluetooth Wireless Technology Information	
Modulation Type	GFSK
Max. Output Power	-1 dBm
Frequency Range	2402-2480 MHz
Antenna Peak Gain	-7 dBi
Recommended Range	~10 feet (~3 meters) line-of-sight

Radio Compliance	
Radio Modes	Bluetooth LE
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

### 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 to 1060 mBar

## Compliance

Safety Compliance
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

EMC Compliance
EN 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
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 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 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.*
2. *The Masimo SET Technology used in the MightySat 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.*
3. *The Masimo SET Technology used in the MightySat 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 a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.*
4. *The Masimo SET Technology used in the MightySat 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. This variation equals plus or minus one standard deviation which encompasses 68% of the population.*

## Symbols

The following symbols may be found on the product or packaging.

Symbol	Definition
	Follow Instructions for Use
	Consult Instructions for Use
	Manufacturer
	Date of Manufacture
	Not for Continuous Monitoring (No Alarm for SpO2)
	Type BF Applied Part
<b>IP23</b>	Protection from ingress of particulates > than 12.5 mm and ingress from spraying water
	ETL Intertek certification. Conforms to ANSI/AAMI ES 60601-1 and certified to CAN/CSA STD C22.2 No. 60601-1
	Mark of Conformity to European Medical Device Directive 93/42/EEC
	Wireless features can be used in member states with the restriction of indoor use in France
	Not made with natural rubber latex
	Polypropylene
	Separate collection for electrical and electronic equipment (WEEE)
	Storage/transport temperature and air pressure range
	Non-Sterile
	Body Weight
	Federal Communications Commission (FCC) licensing
FCC ID, IC, IC Model	Identifies unit has been registered as a radio device



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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.

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## 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	Suitable for use in all establishments, including domestic environments.

## 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%.
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.
Radiated RF IEC 61000-4-3 ISO 80601-2-61, Clause 202	20 V/m 80 MHz to 2.5 GHz	20 V/m	Recommended separation distance $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$ 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, should be less than the compliance level in each frequency range <sup>b</sup> . Interference may occur in the vicinity of equipment marked with the following symbol: 
<b>Note 1:</b> At 80 MHz and 800 MHz, the higher frequency range applies. <b>Note 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
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.			
<sup>b</sup> 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 $d = 1.17 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 0.18 \cdot \sqrt{P}$	800 MHz to 2.5GHz $d = 0.35 \cdot \sqrt{P}$
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.			
<b>Note 1:</b> At 80 MHz and 800 MHz, the higher frequency range applies. <b>Note 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			