

MightySat[®] Medical

Pulse Oximeter




Read these instructions before use. If you have a serious problem, please contact your competent authority and Masimo.

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MEDICAL ELECTRICAL EQUIPMENT
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Glossary

Apnea: Describes a condition where breathing has stopped.

Hemoglobin: The protein in red blood cells that moves 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 provides oxygen saturation and pulse rate based how light passes through the body.

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

Device Description

Description of the MightySat

The MightySat® Medical Pulse Oximeter is for self-monitoring of SpO₂ and pulse rate by individuals 18 years and older.

Key features available:

- Masimo SET® technology for SpO₂ and pulse rate in no motion and low perfusion.
- Bluetooth® LE for the wireless connection to smart devices.

Understanding Health Data Parameters

The following information describes the measurement feature data collected.

Feature	Explanation
Oxygen Level (SpO₂)	Percentage of usable oxygen in your blood. Low oxygen (< 90%) can be a sign of a problem that may be related to your breathing or blood circulation.
Pulse Rate (PR)	A measure of the number of times your heart beats per minute. The average pulse rate is typically 65 to 100 beats per minute.
Perfusion Index (Pi)	Feature that reflects the relative strength of the signal used for the SpO ₂ and Pulse Rate. The Pi will increase with better blood circulation. Your SpO ₂ values may be more reliable when your Pi value is higher. Pi values 0.25 or below are typically considered low. If your Pi is low, try warming your hands or using a different finger.

Who is MightySat for?

Feature (Use)	Who is it for?
General	Individuals 18 years and older
SpO₂	Individuals 18 years and older
Pulse Rate	Individuals 18 years and older

What does the MightySat do and Who is MightySat for (Intended Use and Indications for Use)

The Masimo MightySat® Medical Pulse Oximeter is intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR).

The Masimo MightySat® Medical Pulse Oximeter is indicated for use with individuals 18 years and older who are well or poorly perfused under no motion conditions.

The Masimo MightySat® Medical Pulse Oximeter is not intended for diagnosis or screening of lung disease and treatment decisions using the device should only be under the advice of a healthcare provider.

Self-Monitoring Do's and Do Not's

- **Do** self-monitor your oxygen and pulse rate as recommended by your healthcare provider. This does not mean diagnosing and treating.
- **Do** check your finger can cover the bottom pad of the MightySat and close comfortably.
- **Do** wait a few seconds for your oxygen and pulse rate values to become brightly display and steady for the most reliable values.
- **Do** familiarize yourself with your normal (baseline) SpO₂ levels. Focus on changes from your baseline over time and not solely on a single measurement at any given moment.
- **Do** seek medical attention if you are not feeling well even if your readings are normal.
- **Do** review the information on the limitations and way to improve the accuracy of the reading provided in this manual.
- **Do Not** self-diagnose and treat yourself. Your physician uses the measurements along with other symptoms and your medical history in their treatment decision. This cannot be replaced by a pulse oximeter.
- **Do Not** change your treatment plan on your own. Never alter oxygen delivery settings or medical treatment prescribed by your physician.
- **Do Not** rely only on the readings. Reading can provide a false sense of security to a lung or health condition that has not yet affected your blood oxygen.
- **Do Not** use as an apnea monitor. Oxygen changes may be delayed from when your breathing actually stops.
- **Do Not** use for continuous monitoring or for long periods. No alarms are provided and prolonged pressure on the finger can affect blood circulation.

General Warnings and Precautions

Before use, read the following carefully.

Safety Warnings

WARNING: Do not use if it appears damaged or if you think it is damaged. Exposed electrical circuits can lead to harm.

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

WARNING: Do not use in areas filled with flammable gases: such as anesthetics, oxygen, oxygen-enriched environments, or nitrous oxide to prevent risk of fire.

WARNING: Do not use MightySat during magnetic resonance imaging (MRI) or in an MRI environment.

- The device contains materials that can be attracted by the MR magnet core that can make it a risk of projectile injury.
- Metal components can heat up during MR scanning that can present thermal injury and burns.
- Artifacts can be created in the MR image.
- Strong magnetic fields may prevent the device from operating properly.

WARNING: Do not attempt to secure it to the finger using any external means (e.g., tapes or bands). Too much pressure to a finger can cause skin injury.

WARNING: Avoid using for long periods. Skin injury or placement changes may result in inaccurate readings.

WARNING: Keep small parts 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 if it can get wrapped around the neck. Strangulation may occur.

WARNING: The following can cause damage that can create a safety or performance issue with your MightySat:

- Do not set on a wet surface.
- Do not immerse it in liquid.
- Do not attempt to sanitize or sterilize using heat, steam, boiling or similar means.
- Clean only with the solutions listed in this manual.
- Do not clean while in use.

CAUTION: Do not use near devices that are sensitive to magnets (e.g., pace makers). The magnet provided with the MightySat could hinder proper operation of the device.

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

Performance Warnings

WARNING: Do not self-diagnose or self-medicate based on the measurements. Always consult your doctor.

WARNING: See Risk and Benefit section for information on limitations and ways to get the most accurate readings.

WARNING: MightySat is not intended to be used as an apnea monitor.

WARNING: If any measurement seems questionable, check your vital signs by alternate means and then check that the MightySat is functioning properly. Contact your doctor if you are still unsure about your measurements.

WARNING: MightySat is not designed to be used during medical procedures such as surgeries, Magnetic Resonance Imaging (MRI) sessions, and cardioversion/defibrillation procedures.

WARNING: MightySat is not intended for use during electrocautery.

CAUTION: The displayed parameter data may require additional time to stabilize in order to get the most accurate readings.

CAUTION: When using with a smart device, keep both devices within the recommended range of each other. See the Specifications section for details. Moving outside of this range may cause a loss in connection.

CAUTION: Move the devices away from sources that may interfere with Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI). This may result in loss of Quality of Service. Example devices that cause RFI are: other smart devices, devices with remote controls, and baby monitors.

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

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

Pulse Oximetry Performance

▲ WARNING: If SpO₂ values indicate hypoxemia, do not self-diagnose. Confirmation by a medical professional is required.

▲ WARNING: SpO₂ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

▲ CAUTION: Optical, pleth-based measurements (e.g., SpO₂ and PR) can be affected by the following:

- Incorrect placement or securement (e.g., too loose, too tight).
- Blood pressure cuff inflated or constricting the same arm.
- Intravascular dyes such as indocyanine green or methylene blue.
- Arterial catheter
- Venous congestion
- Abnormal venous pulsations (e.g., tricuspid valve regurgitation, Trendelenburg position).
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g., cardiac arrhythmias, intra-aortic balloon, etc.).
- Moisture, birthmarks, skin discoloration, tattoos, henna, or foreign objects in the light path.
- Elevated levels of bilirubin
- Physiological conditions that can significantly shift the oxygen disassociation curve.
- A physiological condition that may affect vasomotor tone or changes in vasomotor tone.
- Loss of pulsatile signal

▲ CAUTION: No or inaccurate SpO₂ readings may additionally be caused by:

- Elevated levels of COHb and/or MetHb. Note: High levels of COHb or MetHb may occur with a seemingly normal SpO₂.
- Severe anemia.
- Very low arterial perfusion.
- Hypocapnic or Hypercapnic conditions.
- Excessive motion.
- Vasospastic disease such as Raynaud's.
- Hemoglobinopathies and synthesis disorders (e.g., thalassemias, Hb s, Hb c, sickle cell).
- Peripheral vascular disease.
- EMI radiation interference.

Cleaning and Service Warnings

WARNING: To prevent damage:

- Remove batteries when not 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 laws.

Compliance Warnings

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.

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

WARNING: 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.

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

Note: When using 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: 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. 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

See the Benefits and Risks of the MightySat below.

Your Body and Oxygen

When we breathe, oxygen moves in our blood around our body. Pulse oximeters like the MightySat help to identify the oxygen level in the blood. A normal resting SpO₂ levels are typically 95% or greater. However, normal values can be lower for individuals with lung disease, advanced age, or those living at high altitude. A SpO₂ below 90% is typically considered low and outside the normal range, but it is important to not self-diagnose. Consult your healthcare provider.

Low SpO₂ Less than 90% of SpO₂

Additionally, if your oxygen level is trending lower, or you are not feeling well, seek the advice of your physician.

Risks of MightySat

- Inappropriate use or misuse of the device. You should follow the information provided in this manual and not self-diagnose or treat yourself. Always seek the advice of your physician if you are not feeling well.
- With electrical devices, there may be a risk of electrical hazards. These risks are reduced by the design and testing of MightySat.
- As with all devices with small parts, there is a risk of a child swallowing and choking. Keep small parts away from small children to prevent such hazards.
- As with all items applied directly to the skin, there is a risk of skin irritation and discomfort.

Benefits of MightySat

- MightySat is a portable medical device able to provide clinically validated oxygen saturation (SpO₂) and pulse rate (PR).
- MightySat wirelessly connects to a smart device for storage and review of data.

Use of Pulse Oximeters and their Limitations

Pulse oximeters provide blood oxygen levels, SpO₂, based on how light shines through the finger. Accuracy of your SpO₂ depends on how well the light through the finger is measured.

Limitations

Things that interfere with the light can affect your SpO₂ accuracy. Some things can be controlled, while others need awareness.

Controllable things:

- Choose a finger that completely covers the sensor.
- Not wearing nail polish.
- Keeping fingers dry and free of foreign objects.
- Not blocking the light through your finger.
- Avoiding direct exposure to bright lights, including direct sunlight.
- Keeping your finger still.
- Warming your hands to improve circulation.
- Avoid use on same arm with blood pressure cuff inflated.
- Keep away from other electrical equipment that may cause readings to be affected (e.g., microwaves, strong radio transmitters).

Other things that require awareness:

- Skin pigment or color.
- Skin or finger thickness.
- Health conditions affecting how oxygen is carried in your blood (e.g., sickle cell, severe anemia).
- Poor blood circulation.
- Presence of blood components not able to carry oxygen (e.g., elevated carbon monoxide levels in your blood, recent tobacco use).
- Age and medical history.

Description

Parts List

These items should be included with your MightySat:



Item	Description
1	MightySat
2	Batteries
3	Lanyard
4	Carrying Case

MightySat 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 SIQ line will be taller with greater confidence in the readings displayed. If your SIQ is low, try keeping your finger still. When the waveform option is turned off, the Pulse Bar displays the pulse rate. The taller the Pulse Bar the greater the confidence in the readings displayed. For more reliable SpO ₂ values, use a SpO ₂ value with a taller SIQ line and a higher Pi value that is above 0.25.
6	Touchpad	User interface for settings (see Using the Touchpad on page 13 in this manual).

Basic Setup and Use

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



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

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



1. Place the MightySat 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.

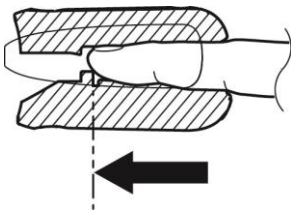


MightySat turns on when the device is opened to place on a finger.



1. To open the MightySat, 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.

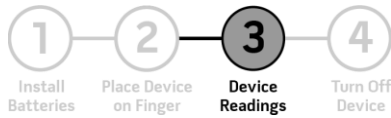


5. Check the fit on the finger by making sure the finger can cover the entire inside bottom pad. If your finger is too small, choose a different finger. If no finger is big enough, then the MightySat should not be used.

Note: The top half of MightySat should rest comfortably on the top of the finger. If MightySat feels tight and your finger feels uncomfortable, try a smaller finger as your finger may be too thick.

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

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



1. After correctly placing on the finger, readings will display.
2. If you are recording your SpO₂ and Pulse Rate values, wait a few seconds for the SpO₂ and Pulse Rate values to be brightly lit and steady before recording.

Note: The SpO₂ and Pulse Rate values will appear dim until reliable SpO₂ and Pulse Rate are available. If readings are not displayed, see **Troubleshooting** on page 15.

Your Readings

- Normal resting SpO₂ levels are typically 95% or greater. However, normal values can be lower for individuals with lung disease, advanced age, or those living in high altitude. Please consult your healthcare provider to define your normal values.
- Changes or trends in SpO₂ may be more meaningful than a single SpO₂ value.
- Pay attention to other signs or symptoms of low oxygen level, such as:
 - Bluish coloring in the face, lips, or nails
 - Shortness of breath, difficult breathing, or a cough that gets worse
 - Restlessness and discomfort
 - Chest pain or tightness
 - Fast or racing pulse rate




The MightySat turns off after removing it from the finger.

Advanced Setup and Use

Using the Touchpad

The multi-function Touchpad  on MightySat 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 settings. See <i>Main Menu Options</i> on page 13.
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 <i>Main Menu Options</i> on page 13.
Exit the Menu Screen.	Swipe right on the Touchpad to display arrow, then touch and release.	Returns to the Main Screen. See <i>Main Menu Options</i> on page 13.

* 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 13.

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 a feature available for use with compatible smart devices. For a full list of compatible smart devices, see www.masimo.com.

Bluetooth Connection

The MightySat provides a Bluetooth LE connection to a smart device. The Bluetooth connection is only available with the Masimo App. Bluetooth icon will appear when connected. MightySat connects to a single device at a time to reduce risk of unauthorized access.

Note: The MightySat requires the use of the Masimo App to connect to a smart device.

Pair MightySat 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” app.
4. Launch the Masimo App.
5. Turn the MightySat Bluetooth On. See **Main Menu Options** on page 13 of this manual for further instructions.
6. Follow the Masimo App on-screen instructions to pair a device.
7. When the Masimo App identifies the MightySat, press/select it to pair.
8. Once MightySat is connected to a smart device, the Masimo App returns to the Main screen.

Note: A connection icon will appear on the MightySat device when a Bluetooth connection has been established.

9. Place MightySat on the patient's finger. Confirm that readings on MightySat and readings displayed on the Masimo App are the same without a delay greater than 10 seconds.

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

Note: Turn off the Bluetooth on the MightySat to prevent unauthorized connections when not used.

CAUTION: When using Bluetooth, keep both devices within range of each other. See Specifications for details. Moving out of range may cause a loss in connection with the smart device.

CAUTION: When using Bluetooth, move the devices away from sources that may interfere with the connection. Interference may result in loss of Quality of Service. See **Specifications** on page 15 for details.

Verify Paired MightySat

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

Note: *Sensor Mode* is always *Bluetooth Sensor* when using MightySat with a smart device.
3. Compare the *Paired Device* information to the *BT SN* (Bluetooth Serial Number) displayed on the MightySat *About* screen, see **Main Menu Options** on page 13 for information on accessing the *About* screen.

Disconnect Paired MightySat

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

Appendix

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	<ul style="list-style-type: none"> • Incorrect finger placement • Incorrect battery orientation • No battery • Low battery • Environmental influences 	<ul style="list-style-type: none"> • Wait for measurement. • Reposition finger (see Using MightySat in this manual) • Re-orient batteries • Replace with new batteries • Relocate device • Contact Masimo Technical Services
Device display does not turn on	<ul style="list-style-type: none"> • No battery • Incorrect battery orientation • Device damaged 	<ul style="list-style-type: none"> • Replace with new batteries • Re-orient batteries • Contact Masimo Technical Services
Numbers appear dim	<ul style="list-style-type: none"> • Brightness set low • Exposed to bright lights or sunlight • Incorrect finger placement • Measurement site may be poorly perfused 	<ul style="list-style-type: none"> • Check brightness setting in menu • Relocate device so that it is not directly under bright lights • Reposition finger (See Using MightySat in this manual) • Contact Masimo Technical Services
Device keeps turning off while on the finger	<ul style="list-style-type: none"> • Incorrect finger placement • Environmental influences • Device damaged 	<ul style="list-style-type: none"> • Reposition finger (See Using MightySat 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	<ul style="list-style-type: none"> • Bluetooth LE not connected • Compatible app not installed on smart device • Device damaged • Smart device damaged 	<ul style="list-style-type: none"> • Confirm Bluetooth LE is on for the MightySat 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 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%

The MightySat includes LEDs that emit wavelengths range from 600 nm to 1000 nm with a peak optical power less than 15 mW that are used to estimate your oxygen saturation. This information about the wavelength range may be more useful for your healthcare professional.

Performance Specifications

Accuracy root mean squared, or A_{RMS} , is used to show how well a pulse oximeter provides SpO₂ compared to a blood sample, SaO₂. The A_{RMS} is the potential error that can be expected between the SpO₂ and SaO₂. The lower the A_{RMS} value the better the accuracy.

The A_{RMS} is based on clinical studies on healthy volunteers as their oxygen is lowered. The A_{RMS} is the value where at least 2/3 (67%) of the differences in SaO₂ to SpO₂ fell.

For the MightySat, the A_{RMS} testing was done under 2 different conditions; no motion and low perfusion.

Condition	Description
No Motion	Volunteers keep their fingers still during measurements.
Low Perfusion	Simulator used to simulate very low blood circulation during measurements and different skin tones.

Below is the A_{RMS} for the MightySat.

SpO ₂ Accuracy			
Condition	Range	Population	A _{RMS} *
No Motion [1]	70% to 100%	Adults, Pediatrics	1.5%
Low perfusion [2]	70% to 100%	Adults, Pediatrics	2%

See the **SpO₂ Performance Study Summary** on page 16 for additional SpO₂ accuracy information.

Pulse Rate (PR)			
Condition	Range	Population	A _{RMS} *
No Motion [3]	25 bpm to 240 bpm	Adults, Pediatrics	3 bpm
Low perfusion [3]	25 bpm to 240 bpm	Adults, Pediatrics	3 bpm

* 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 Study Summary

Table below shows the results from the SpO₂ clinical study. The study used 39 healthy volunteers (22 dark skin and 17 light skin). Data was collected on each volunteer while at different oxygen levels when their finger was still. The overall measured A_{RMS} value was within 1.5% under no motion.

Overall Measured A _{RMS} Value				
Range	Bias	Precision	A _{RMS}	LOA
70% – 100%	-0.02	1.26	1.26	[-2.50 2.45]

The following are the results for each 10% grouping.

Measured A _{RMS} Values		
Range	A _{RMS}	Npairs
90% – 100%	1.16 %	894
80% – 90%	1.19 %	646
70% – 80%	1.52 %	490

The Bland-Altman plot below shows the difference between SpO₂ and SaO₂ during the study. Between the two dotted lines is where 95% of the differences were found, or the limits of agreement. This is different from the A_{RMS} value which is set at about 67%. This generally means about 67% of SpO₂ values were within 1.26% of the blood sample values and about 95% of the SpO₂ values were within 2.48 to -2.60% of the blood sample values. For example, if the SpO₂ value reads 95%, then the true oxygen saturation in the blood can be generally thought to be between 92% to 98% based upon the limits of agreement and 93% to 97% based upon the A_{RMS}.

The dotted lines on the Bland-Altman plot also help to identify data points that are outside of the limits of agreement, or potential outliers. The upper dotted line at 2.48% and lower dotted line at -2.60% shows that during the study the SpO₂ value was about equally above and below the true oxygen saturation in the blood. In other words, there is an equal chance that the true oxygen saturation can be higher or lower than the SpO₂ value you see. The plot is provided to help you understand that just because you see one value on the MightySat that it will always match the value from a blood test.

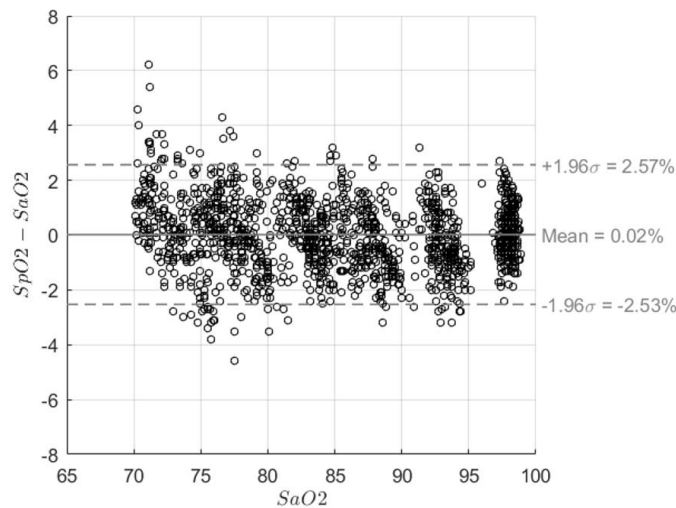


Figure 1 - MightySat® Medical Pulse Oximeter Pulse Oximeter (A_{RMS} 70-100%)

Specific SaO₂ Range of 85-95%

Bias, Precision, A_{RMS} , and LoA results were also computed for 85-95% SaO₂. The performance in this SpO₂ range may help understand how well a pulse oximeter can work when the blood oxygen is in the transition between normal to low oxygen levels.

Sat Level	Bias	Precision	A_{RMS}	LOA	Npairs
[85-95]	-0.35	1.17	1.22	[-2.63 1.94]	738

MightySat® Medical Pulse Oximeter Performance in the SaO₂ range of 85-95%.

Subgroup Analysis: By Pigment and Gender

The data from the study was also analyzed by gender and skin pigment. The skin pigments were grouped using the color-based Massey-Martin scale (1-10). The subjects with a score of 1-3 were grouped as "Light", and subjects with a score of 4-10 were categorized as "Dark". The performance by gender and skin pigment may help understand how well a pulse oximeter can work on different people. Comparing the ARMS and LoA shows that MightySat performed similarly on all groups.

Group	Bias	Precision	A_{RMS}	LOA	Npairs
Light Male	-0.13	1.26	1.27	[-2.61 2.35]	384
Dark Male	0.11	1.44	1.44	[-2.70 2.93]	612
Light Female	-0.06	1.11	1.11	[-2.11 2.23]	258
Dark Female	-0.18	1.30	1.32	[-2.73 2.38]	216

Figure 2 provides a scatter plot, which shows the relationship between the SpO₂ to the SaO₂ blood reference for different subgroups (i.e., Light Male, Dark Male, Light Female and Dark Female). The best result would be a diagonal line that passes through the same value for SpO₂ and SaO₂. For example, a line that passes through 90% SpO₂ and SaO₂, 80% SpO₂ and SaO₂, and 70% SpO₂ and SaO₂.

While the Bland Altman plot (*Figure 1*) shows the difference between the SpO₂ and SaO₂ values, the scatter plot (*Figure 2*) shows the relationship between the SpO₂ and SaO₂ values. Using both plots can be helpful to understand the SpO₂ performance on different people. For example, from the Bland Altman plot (*Figure 1*), you see that your SpO₂ value can be about +/- 2.5% different from the SaO₂ value based upon the limits of agreement. While the scatter plots help to see if your SpO₂ is more likely to be higher or lower than the SaO₂ based upon your gender and skin pigment group and your SpO₂ value. For example, if you are a male with dark skin pigment (Massey Martin score 4 or greater) and your SpO₂ value is 95% you might expect your SaO₂ value to be between 92-98%. This is because the scatterplot shows at 95% SpO₂, SaO₂ values are between 98-92% as part of the study. However, at a SpO₂ value of 75%, you might expect your SaO₂ value to be around 70-75%. This is because the scatterplot at 75% SpO₂ shows more SaO₂ values between 75-70%. Fortunately, the performance of the MightySat is similar for all subgroups.

Bias, Precision, A_{RMS}, and LOA by four Pigment-Gender subgroups

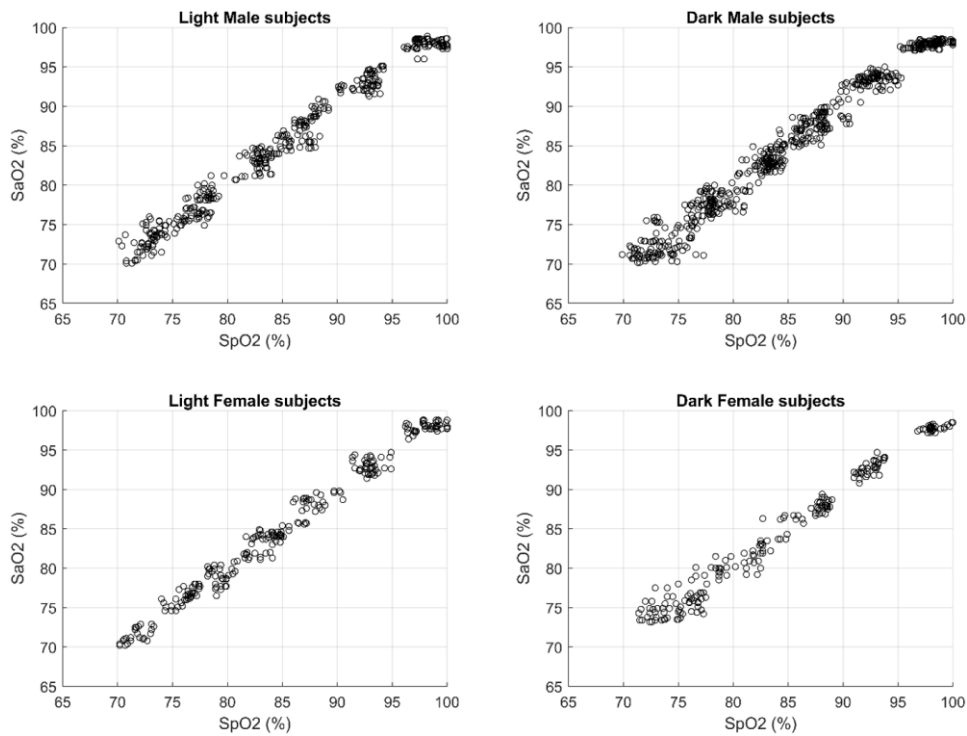


Figure 2 - Scatter plot of SaO₂ vs SpO₂ for each of the four Pigment-Gender subgroups

Battery Life

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

Expected Service (Useful) Life

Item	Description
Expected Service (Useful) Life	2 Years

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
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.

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
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.
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 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	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ 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: 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>(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</p>			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
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
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 be found on the MightySat, or packaging and are defined below.

Symbols	Definition	Symbols	Definition
	Follow Instructions for use		Consult instructions for use
	Federal Communications Commission (FCC) licensing		Separate collection for electrical and electronic equipment (WEEE)
	Wireless features can be used in member states with the restriction of indoor use in France - Class 2 wireless device		Protection from ingress of particulates > than 12.5 mm and ingress from spraying water
	Date of Manufacture YYYY-MM-DD		Manufacturer
	Catalog number (model number)		Serial number
	Lot Code		MR Unsafe. Not appropriate for use in MR environment (i.e.: inside the MR magnet room)
	Type BF applied part		Non-Sterile
	Not made with natural rubber latex		Caution
	Atmospheric pressure limitation		Storage temperature range
	No parameter alarms		Storage humidity limitation

Symbols	Definition	Symbols	Definition
	Battery		Body weight
	Bluetooth	-	--
	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 MightySat® Medical 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 MightySat® Medical 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%.

[3] The MightySat® Medical 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%.

Cleaning, Disinfecting, and Service

Cleaning and Disinfecting

WARNING: Before cleaning, read **Cleaning and Service Warnings** on page 6.

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

CAUTION: Thoroughly clean and low level disinfect before applying it to on a new person.

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

As good practice, you should clean the device if you see visible debris and disinfect before use each day.

To clean, 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 to dry thoroughly before using again.

To conduct low level surface disinfection of the MightySat, 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 to dry thoroughly before using again.

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

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

If you see a color change to the finger pads, the device may be at the end of its reuse life. Performance may start to become affected. If this occurs, you should stop using the device.

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** on page 15 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® Medical Pulse Oximeter 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 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.

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