

iSpO₂[®]

Operator's Manual



Not Intended For Medical Use

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Introducing iSpO2®

Not Intended for Medical Use

The Masimo Difference

For more than 20 years, Masimo has been focused on a singular mission – to take non-invasive monitoring to new sites and applications. Visit www.Masimo.com to learn why clinicians worldwide know and trust Masimo.

From the leaders in hospital pulse oximetry comes the world's first pulse oximeter for Apple® iPhone®, iPad®, and iPod touch® that measures during movement and low blood flow to the finger. The iSpO2 is for noninvasive monitoring, tracking and trending of blood oxygenation (SpO2), pulse rate, and perfusion index for sports and aviation use.

For information, updates and manuals in available languages for iSpO2 visit www.ispo2.com.

Product Description

The iSpO2 system includes the following:

- **Sensor (with cable)**
There are two iSpO2 sizes:
 - Small if you have slender fingers and/or weigh under 110 lbs. (50 kg).
 - Large if you weigh more than 66 lbs. (more than 30 kg).
- **App**
Masimo iSpO2 app downloaded from the App StoreSM.

About this Manual

This manual explains how to set up and use the iSpO2. Important safety information relating to general use of the iSpO2 module appears in this manual. 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 (for example, injury, serious adverse effect, death) to the user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the user to avoid injury to the user, 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.

Safety Information, Warnings, and Cautions

The manual including all precautionary information, and specifications should be read before use.

Always use the iSpO2 precisely in accordance with the directions in this manual, including finger selection and finger alignment in the sensor. See *Best Practices For Accurate Readings* on page 13. Failure to follow all of the directions in this manual could lead to inaccurate measurements.

WARNING: To avoid the risk of electrical shock, when using the iSpO2 do not plug anything else into any port of the Apple product, including a headphone jack or docking port.

WARNING: To avoid the risk of electrical shock, do not use the iSpO2 when the Apple product is plugged into an AC power outlet.

WARNING: Carefully route cabling to reduce the possibility of your entanglement or strangulation.

WARNING: Do not adjust, repair, open, disassemble, or modify this unit. Injury or equipment damage could occur. Return unit for servicing.

WARNING: Inaccurate SpO2 readings may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin
- Severe anemia
- Low arterial perfusion
- motion artifact

CAUTION: Do not use a sensor or cable with exposed optical or electrical components.

CAUTION: Do not use damaged sensors or cables.

CAUTION: Do not autoclave or submerge the equipment in any cleaning solution. This will seriously damage the unit.

CAUTION: High-intensity extreme lights (including pulsating strobe lights and direct sunlight) directed on the sensor, may not allow the iSpO2 to obtain readings.

CAUTION: Do not attempt to reprocess, recondition or recycle any Masimo sensors or cables as these processes may damage the electrical components, potentially leading to user harm.

CAUTION: Failure to apply the sensor properly may lead to incorrect measurements.

Intended Use

The iSpO2 by Masimo is for use by sports and aviation users who are interested in knowing their blood oxygenation level (SpO2), pulse rate (PR) and perfusion index (PI). The results will display on an Apple iPhone, iPod touch, or iPad. The iSpO2 is not intended for medical use. The iSpO2 can be used in a wide range of settings, including extreme sports, and for passengers and pilots.

Compatibility



For 30 pin Direct Connect:

Check the App Store for the latest iOS compatibility.

Made for:

- iPhone 4S iPhone 4 iPhone 3GS
- iPad (3rd generation)
- iPod touch (4th generation)

For Lightning™ Direct Connect:

Check the App Store for the latest iOS compatibility.

- iPhone 5
- iPad (4th generation) iPad Mini
- iPod touch (5th generation)

Accessing the iSpO2 App

To access the iSpO2 App

1. Before using the iSpO2 for the first time, download the iSpO2 app from the App Store.
2. Install the app on the Apple product. See **Compatibility** on page 5.
If the app does not recognize iSpO2 module as an accessory, remove and reconnect the module. See **Contacting Tech Support** on page 16.
3. When prompted to connect the app with the iSpO2 module, select **Allow**.



Using iSpO2

Before you begin, see **Safety Information, Warnings, and Cautions** on page 3.

1. Insert the iSpO2 connector into the dock connector port of the Apple product.
To avoid electrical shock, do not use the iSpO2 when the Apple product is plugged into an AC power outlet.
To avoid electrical shock when using the iSpO2, do not plug anything else into any port of the Apple product, including a headphone jack or docking port.
2. Select a finger for monitoring. See **Best Practices For Accurate Readings** on page 13.
3. Place your finger in the iSpO2.



The measurements will display on the Apple product as a waveform measurement and numeric display.



About iSpO2 Screens

Main Screen

SpO2 (Oxygenation)

Displays functional blood oxygenation (oxygen in the blood) of arterial hemoglobin

PR (Pulse Rate)

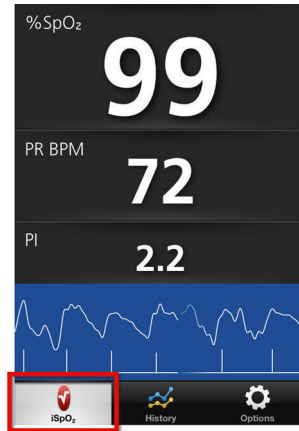
Displays PR as beats per minute (BPM)

PI (Perfusion Index)

Displays arterial pulse signal strength (Perfusion Index)

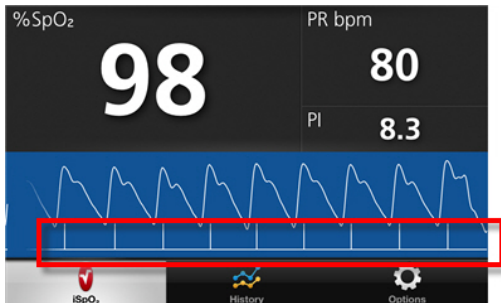
Waveform

Displays arterial pulsations as a waveform.



Signal I.Q.® Indicators

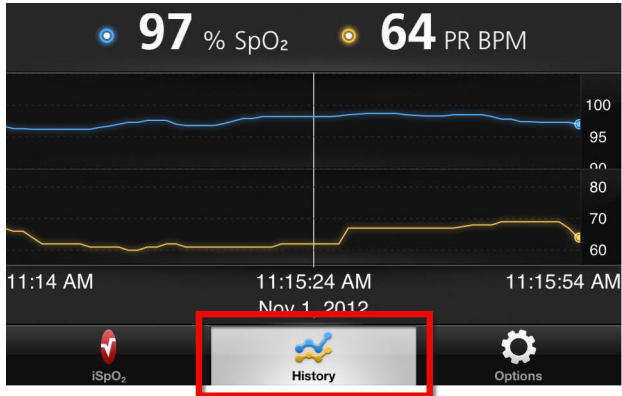
The Signal I.Q. (SIQ) provides an indicator of the assessment of the confidence in the displayed SpO₂ value. The height of the vertical line of the SpO₂ SIQ provides an assessment of the confidence in the measurement displayed. A high vertical line indicates higher confidence in the measurement. A small vertical line indicates lower confidence in the displayed measurement.



SIQ Indicators with high vertical lines

History Screen

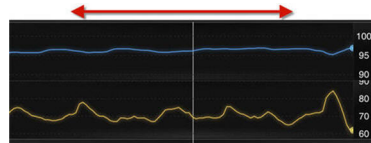
The *History* screen allows you to access customizable Trend views.



About the Trend Feature

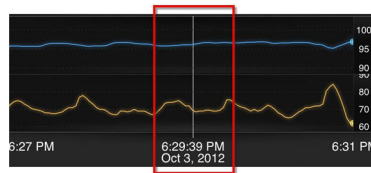
Expand and contract trend views

You can expand or contract the trend data display by using a pinch gesture with two fingers.



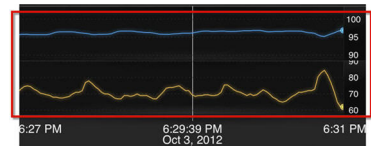
Trend time views

Three separate times are shown at the bottom of the screen. Visible from the left, they are: the beginning time of the trend, the midpoint (stationary white line highlighted shown), and the time of the last data point within the trend. You can view trend data and increase or decrease the amount of trending time by swiping the display to the left or to the right.



Track and email trend data

The Trend feature shows several readings. You can track the data, email it and then display it in any .csv file spreadsheet program. See **Options Screen** on page 12.



Options Screen

Sound

To turn on or turn off, slide the **Sound** button.

E-Mail CSV

Measurement trend history can be compiled into a .csv file and emailed. To email trend history, touch **E-Mail CSV**, and enter desired email address. The e-mail can be saved as a draft, deleted, or sent. All stored trend history will be sent in one e-mail.

Auto-Remove Old Data

The iSpO2 can store up to 12 (twelve) hours of oxygen saturation (SpO2) and pulse rate (PR) data. Select the amount of measurement history to store in the device (between 1 and 12 hours). Any data beyond this range will overwrite previously recorded measurements. For instance, if you record one hour of measurement data and then go beyond the one hour, the new data beyond the 1 hour mark will overwrite a portion of the previously recorded data. A 12 hour setting is recommended unless the device memory is full. Clear existing measurement history at any time by pressing "Clear All History".

Clear History

Stored measurement history and trend data can be deleted. To delete all stored data, touch **Clear All History**.

Module Info

The information here may be helpful for troubleshooting.

About

A general definition of Pulse Oximetry and a description of theiSpO2 measurements.

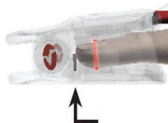
Support

Website links, and contact information for support and customer service.

Tutorial

A graphic explanation on how to use theiSpO2.

Best Practices For Accurate Readings



- Ensure that your finger and the sensor are aligned (i.e. the iSpO2 is parallel to the finger). Ensure that the iSpO2 cable is not twisted, as that can cause incorrect alignment.
- Ensure that your finger is inserted correctly and completely into the iSpO2. The tip of your finger should be touching the soft rubber stop inside the sensor.
- Select your testing finger, in the following priority:
 1. Non-dominant ring finger (*non-dominant* is the hand used less often).
 2. Non-dominant middle finger
 3. Dominant ring finger (*dominant* is the hand used more often).
 4. Dominant middle finger
- Do not use on an anatomically incorrect finger (e.g. damaged, clubbed, deviated, etc.).
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- Do not use on a finger with occlusive jewelry, such as a ring.
- Your finger should be cleaned of debris and dry prior to sensor placement.
- Do not expose the iSpO2 to moisture, humid environments or liquids.

- If possible, ensure that the iSpO2 is placed in a location with low ambient light. Excessive ambient light may cause readings to be incorrect.
- Check for possible EMI radiation interference such as computer displays and/or LCD/plasma TVs.
- Failure to apply the sensor properly may lead to incorrect measurements.
- The iSpO2 has no alarms and is not designed for continuous monitoring. It should be removed and repositioned after each session.

Screen Messages

Message	Potential Resolution
<i>Ensure cable is connected</i>	Make sure the iSpO2 is securely connected.
<i>Sensor not working</i>	See Contacting Tech Support on page 16.
<i>Place sensor on properly</i>	See .Best Practices For Accurate Readings on page 13.
<i>Searching for pulse (for > 30 seconds)</i>	See Best Practices For Accurate Readings on page 13.
<i>Interference detected, see manual</i>	See Best Practices For Accurate Readings on page 13.
<i>Low perfusion, see manual</i>	See Best Practices For Accurate Readings on page 13.
<i>Too much surrounding light</i>	Move to a location with normal or low light.

Message	Potential Resolution
<i>Low signal quality, see manual</i>	See Best Practices For Accurate Readings on page 13.
<i>Connecting - Please wait</i>	See Best Practices For Accurate Readings on page 13.

Contacting Tech Support

If there is an issue and assistance is needed, call 1-877-964-8378 or e-mail TechSupport-US@Masimo.com with the following information:

- Name
- Phone number and e-mail address
- Problem description
- iSpO2 serial number (found on the back of the iSpO2 cable)
- Software revision (See **Options Screen** on page 12)
- Best time to call back

Technical Information

Cleaning

See **Safety Information, Warnings, and Cautions** on page 3.

Avoid getting dirt, dust, blood, body fluids, water or any other liquid on the sensor, cable, connector or iOS product.

Disinfecting the iSpO2

1. Remove the sensor from your finger and disconnect the iSpO2 module from the iOS product.
2. Clean the sensor, cable and connector by wiping with a 70% isopropyl alcohol pad.
3. Allow the iSpO2 module to dry thoroughly prior to placement on your finger.

or

1. If low-level disinfection is required, use a 1:10 bleach/water solution.
2. Saturate a cloth or gauze pad with the cleaning solution and wipe all surfaces of the sensor, cable and connector.
3. Saturate another cloth or gauze pad with sterile or distilled water and wipe all surfaces of the sensor, cable and connector.
4. Dry with a clean cloth or dry gauze pad.

CAUTION: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor may occur.

Disinfecting the Mobile Device

Instructions on how to disinfect the iPhone, iPod touch or iPad device

CAUTION: Never immerse the device in water or any other liquid solution. Be careful when disinfecting the mobile device. Avoid getting liquid into the port, or into the dock connector.

Use a pre-saturated germicidal disposable wipe. These types of wipes are approved by the Environmental Protection Agency (EPA) to kill bacteria and viruses. More information can be found online at <http://www.epa.gov>. under "Registered Antimicrobial Products Effective Against Human HIV-1 and Hepatitis B virus".

1. Pre-clean the outside of the device with a disinfecting wipe.
2. With a new disinfecting wipe, disinfect the iPhone, iPad or iPod touch following the instructions below. Additionally, follow the instructions on the disinfecting wipe packaging for safe handling of the wipes.
3. Wipe each side of the iPhone, iPad or iPod touch with moderate pressure three (3) times using the following method:
 1. Wipe up and down three (3) times.
 2. Wipe right and left three (3) times.Avoid getting the disinfectant inside the dock connector or port.
4. After wiping, allow the device to air dry. If the cleaned area of the device becomes dry before the recommended drying time (2 minutes), re-wipe.



Refer to the disinfectant wipe's packaging for hand-cleaning and wipe disposal instructions.

Specifications

Measurement	Display Ranges
SpO2 (Blood Oxygenation)	0% to 100%
PR (Pulse Rate)	25 bpm to 240 bpm
PI (Perfusion Index)	0.02% to 20%

Accuracy

Blood oxygenation accuracy in the 70 - 100% range

Under no motion conditions¹, is $\pm 2\%$

Under motion conditions,² is $\pm 3\%$

Under low perfusion conditions,³ is $\pm 2\%$

Pulse rate accuracy⁴ in the range of 25-240 range

Under no motion conditions, is ± 3 bpm

Under motion conditions, is ± 5 bpm

The emitted wavelengths range from 600 to 1000 nm and the peak optical power is less than 15 mW.






For more information and updates about iSpO2, visit www.ispo2.com.





Citations

1. *The Masimo SET® Technology used in the iSpO2 module has been validated for no motion accuracy in human blood studies on healthy adult volunteers 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 iSpO2 module has been validated for motion accuracy in human blood studies on healthy adult volunteers 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 iSpO2 module 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 iSpO2 module 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
	See Instructions for Use
	Follow Instructions for Use
	Manufacturer
	Date of Manufacture
	Do not use if package is damaged or opened

Symbol	Definition
	Not for Continuous Monitoring (No Alarm for SpO2)
IPX1	Protection against liquid drops falling vertically
	Conforms to UL STD 60601-1 and certified to CAN/CSA STD C22.2 No. 601.1
	Mark of Conformity to European Medical Device Directive 93/42/EEC
	WEEE Compliant

Contacting Masimo

Masimo Corporation
40 Parker
Irvine, California 92618
Tel:+1 949 297 7000
Fax:+1 949 297 7001

Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: each new Product and the Software media as delivered are free from defects in workmanship or materials.

To request a replacement under warranty, Purchaser must contact Masimo for a returned goods authorization. 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 shall be the responsibility of Purchaser.

Masimo's sole obligation under this warranty is to replace any product that it deems to be covered under warranty with a replacement iSpO2 Pulse Oximeter.

Exclusions

The warranty does not extend to, and Masimo is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the Product or Software without Masimo's written authorization; b) supplies, instruments or electrical work external to the Product or not manufactured by Masimo; c) disassembly or reassembly of the Product by anyone other than an authorized Masimo agent; d) use of the Product with Sensors or other accessories other than those manufactured and distributed by Masimo; e) use of the Product and Software in ways or in environments for which they are not labeled; and f) neglect, misuse, improper operation, accident, fire, water, vandalism, weather, war, or any act of God. This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product. This warranty does not extend to any Product that has been reprocessed, reconditioned or recycled.

This warranty also does not apply to any Products provided to Purchaser for testing or demonstration purposes, any temporary Products Modules or any Products for which Seller does not otherwise receive a usage or purchase fee; all such Products are provided AS-IS without warranty.

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Patents: www.Masimo.com/patents.htm

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Lightning is a trademark of Apple Inc.

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