Opioid Halo™

OPIOID OVERDOSE PREVENTION AND ALERT SYSTEM*

USER MANUAL

MASIMO®

*Opioid Halo continuously monitors certain physiological parameters that are indicative of opioid-induced respiratory depression — a sign of opioid overdose. Read and understand this User's Manual.

There may be information provided in this manual that is not relevant for your system. Do not operate the Opioid Halo System without completely reading and understanding these instructions. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

Wireless Radio:
Contains: FCC ID: 2AC7Z-ESP32SOLO1; FCC ID: VKF-CONNHUB Contains IC: 21098-ESP32SOLO1; IC: 7362A-CONNHUB

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Patents: www.masimo.com/patents.htm

Contents

About This Manual

This Manual provides an overview of the Opioid Halo System and how to set up and use the Opioid Halo System. You must read and understand the warnings and precautions to help ensure safe and effective use of the Opioid Halo System. Please make sure to read the entire manual and notes.

A *warning* is given when there is reasonable evidence of an association of a serious hazard with use of this device that may result in a serious injury, adverse effect, or death to the patient or user.

⚠ **WARNING**: This is an example of a warning statement.

A *caution* is given when special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.

⚠ **CAUTION**: This is an example of a caution statement.

A *note* is given when additional information applies.

Note: This is an example of a note.

Getting Started Guides

Use the quick reference guide included for basic setup and starting your first monitoring session.

In-App Videos

Watch the videos in your app to find out more about:

- Setting up your Opioid Halo System.
- Masimo Sensor placement.
- Connecting your Opioid Halo System to WiFi.

Glossary

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

Naloxone: A medication approved by the Food and Drug Administration (FDA) designed to rapidly reverse opioid overdose and OIRD.

Obstructive Sleep Apnea (OSA): Obstructive sleep apnea occurs when the muscles that support the soft tissues in your throat, such as your tongue and soft palate, temporarily relax. When these muscles relax, your airway is narrowed or closed, and breathing is momentarily cut off.

Opioid Induced Respiratory Depression (OIRD): A side effect of opioids that causes breathing to be slowed or stopped.

Oxygenated Blood: Arterial blood where oxygen is bound to hemoglobin.

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

Physiological: The functions of biological systems and organs.

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

Preventing Opioid Overdoses (SAMHSA)

⚠ **WARNING:** It is strongly recommended supervision be provided with naloxone. Please make sure that anyone providing supervision is aware of signs of opioid overdose and understands how to help.

Opioid overdoses are deadly.

To help prevent opioid overdoses it is important to avoid using opioids without supervision. The Opioid Halo System is designed as a tool to help increase awareness and recognition to prevent opioid overdoses.

The most important part of this solution is that people are aware of signs of opioid overdose and understand how to help. Let someone know about this product and share how they can recognize and help if there is an opioid overdose.

SAMHSA[1] recommends 5 steps to help prevent opioid overdoses.

STEP 1 – Evaluate for Signs of Opioid Overdose

- Are they unconscious or unable to wake up?
- Are they having difficulty breathing?
- Are their fingernails or lips turning blue?

If you think they are having overdose, try to wake them up:

- Call their name.
- Rub your knuckles on the bone in the middle of their chest.

STEP 2 – Call 911 for Help

- If they are not responding or cannot stay responsive, call 911 to get help. Opioid overdose is an emergency.

STEP 3 – Administer Naloxone

- If you still suspect they are overdosing, administer naloxone.
- Administer a 2nd dose of naloxone if not responding 2 to 3 minutes after the first dose.

STEP 4 – Support the Person's Breathing

- Keep their airway clear.

STEP 5 – Monitor the Person's Response

- Naloxone can cause opioid withdrawal symptoms to return or only last of short duration. Watch them to make sure they do not start to overdose again.

[1] SAMHSA Opioid Overdose Prevention Toolkit

Product Description

The Opioid Halo™ System is a monitoring solution designed to continuously monitor to help recognize opioid induced respiratory depression (OIRD) while taking opioids. It uses Opioid Halo, a software, to review your blood oxygen data to recognize when there may be trouble getting enough oxygen while on opioids.

The Opioid Halo System includes the following pieces:

- **Home Medical Hub** – Device that communicates monitoring data wireless from the medical technologies to provide visual/audible alerts.
- **Masimo Sensor** - Wireless wearable sensor that provides the monitoring data.
- **Masimo Halo™ App** - Software application installed on a smart phone that provides the graphical user interface to display live monitoring data and alarm condition status.
- **Opioid Halo** - Software that runs continuously to provide real-time detection of the severe Opioid-Induced Respiratory Depression (OIRD) risk based upon changes or patterns in your oxygenation biomarker data (SpO_2, PR, Pi).
- **Notification Escalation Policy** - Policy that is used to add levels of awareness through the notification of Emergency contact or contracted Emergency Responders.
- **Masimo SafetyNet Alert Cloud** - A server accessed over the internet that gathers and stores measured data communicated wirelessly from a Home Medical Hub.

Who the Device is intended for (Indications for Use)

The Opioid Halo™ System is intended to monitor and alarm when a patient may be experiencing an opioid induced impairment of oxygenation.

The Opioid Halo™ System is indicated for the non-invasive continuous monitoring of individuals 15 years and older for the identification of when they may be experiencing a substance induced impairment of oxygenation (e.g., opioid induced respiratory depression caused by oral or injectable opioids) in hospital and home environments.

Who the Device Should not be used on (Contraindications)

The Opioid Halo System is not indicated for users on supplemental oxygen greater than 2.0 L/min.

Safety Information

Before using the Opioid Halo System, read the following Safety Information carefully.

⚠ **WARNING:** It is strongly recommended supervision be provided with naloxone. Please make sure that anyone providing supervision is aware of signs of opioid overdose and understands how to help.

⚠ **WARNING:** Do not wait for an alarm. If you suspect someone is having an opioid overdose, call 911 and administer naloxone, if needed!

⚠ **WARNING:** Do not take more than the prescribed amount of opioids. Taking more than prescribed can result in an overdose that can stop breathing and lead to death.

For Healthcare Providers

⚠ **WARNING:** Do not prescribe opioids above the standard of care based upon the use of the Opioid Halo. There is no assurance that patients will use this device.

⚠ **WARNING:** Do not make opioid prescription decisions solely on the availability of the Opioid Halo! It is important that you make sure your patient has someone who can respond to any alarms, including the administration of naloxone.

Safe Use Information

⚠ **WARNING:** Do not use in areas where flammable gases such as anesthetics, oxygen, oxygen-enriched environments, or nitrous oxide are present to prevent risk of fire.

⚠ **WARNING:** Do not wait for an alarm. If you suspect someone is having an opioid overdose, call 911 and administer naloxone, if needed!

⚠ **CAUTION:** The complete Opioid Halo System should be used. The system consists of the Home Medical Hub, the Masimo Halo App Installed on a smart phone, Masimo Sensor, and Masimo Chip. To learn more, see ***Home Medical Hub Setup*** on page 22.

⚠ **CAUTION:** Route cables to avoid possible strangulation or entanglement.

⚠ **CAUTION:** Place the Home Medical Hub where it will not fall on anyone, and the alarm sounds will not be muffled.

⚠ **CAUTION:** Check the Opioid Halo indicator is green, Pulse Rate waveform is active, and Pulse Rate is displayed on the Live Data screen to ensure monitoring has started. See ***Step 3: Live Data*** on page 31.

⚠ **CAUTION:** For safe use, avoid the following:

- Do not place the Home Medical Hub on a wet surface.

- Do not soak any part of the system in liquid.
- Do not try to sterilize.
- Only use Masimo recommended solutions for cleaning your system. See ***Cleaning*** on page 63.
- Do not clean while device is in use.

⚠ **CAUTION:** Keep small parts away from small children. Small items can be a choking hazard.

⚠ **CAUTION:** Place the Home Medical Hub where you can easily disconnect it from AC power in case the power needs to be disconnected.

⚠ **CAUTION:** Only use the AC power supply included with your Home Medical Hub to prevent damage to the device.

⚠ **CAUTION:** Do not monitor more than one person at a time with the Opioid Halo System.

⚠ **CAUTION:** Use and store the Opioid Halo System as directed in the Specifications section in this manual.

⚠ **CAUTION:** Only use Masimo-approved parts to make sure the device works correctly.

⚠ **CAUTION:** For your safety, do not try to repair a device that is damaged.

Masimo Sensor

⚠ **CAUTION:** The light on the sensor should be aligned so it shines directly with the sensor detector through your finger. If misaligned, the performance of the sensor maybe impacted. Good sensor placement should be confirmed by checking the following:

- Halo Indicator is green.
- Pulse Rate is displayed.
- Pulse Rate Waveform shows a clear pattern.

Refer to ***Troubleshooting*** on page 39 if readings do not display.

⚠ **CAUTION:** Select a finger free from injury, without nail polish to put on the sensor. Nail polish or finger injury can affect how the light passes through the finger.

⚠ **CAUTION:** Avoid wrapping the sensor too tightly around your finger to avoid injury or restricting blood flow to the finger.

⚠ **CAUTION:** To avoid skin injury, consider moving the sensor to another finger after it has been used for more than 8 hrs. The non-dominant ring or middle finger is preferred.

⚠ **CAUTION:** Avoid light interference from bright light sources and direct sunlight when using the Masimo Sensor. The interference can affect the sensor performance.

Performance Warnings

⚠ **WARNING:** It is strongly recommended supervision be provided with naloxone. Please make sure that anyone providing supervision is aware of signs of opioid overdose and understands how to help.

⚠ **WARNING:** Opioid Halo alarms may be less specific to OIRD when other medical conditions are present (e.g., Obstructive Sleep Apnea). However, due to the emergency condition that opioid overdoses can cause, the US CDC and SAMHSA recommend assuming any suspected opioid overdose be treated as an actual opioid overdose.

⚠ **WARNING:** Obstructive sleep apnea (OSA) can increase the risk of false OIRD alarms by causing oxygenation instability trends that can be mistaken as OIRD, which can disrupt sleep. If you have or think you have OSA, seek advice from your Healthcare provider.

⚠ **CAUTION:** Do not use the Opioid Halo System as an apnea monitor. The Opioid Halo System is not designed to detect apnea.

⚠ **CAUTION:** The Opioid Halo System is not a replacement for individuals that require post-surgical monitoring directed by a physician.

⚠ **CAUTION:** The following factors can affect the effectiveness of Opioid Halo:

- Sensor is applied incorrectly.
- Restricted blood flow to the sensor site.
- Sensor site has nail polish, acrylic nails, glitter, etc.
- A sensor site with moisture, birthmarks, skin discoloration, or foreign objects that block the sensor.
- Placed near other devices that may interfere with its operation.
- Excessive movement of the sensor is present.
- Possible medical conditions (e.g., Obstructive Sleep Apnea).

⚠ **CAUTION:** To ensure proper notification function, check the following occasionally:

- Notification features is turned on your smart phone(i.e., sounds, vibrations, etc.)
- Smart phone battery is fully charged or plugged in.
- Halo indicator is active and green.
- Check your smart phone connection occasionally.

⚠ **CAUTION:** Do not place the Opioid Halo System where someone can change the App settings without you knowing.

⚠ **CAUTION:** Check that the Opioid Halo System alarm can be heard from other rooms in your home, especially when noisy appliances such as vacuum cleaners, dishwashers, clothes dryers, televisions, or radios are operating.

⚠ **CAUTION:** Keep the Home Medical Hub plugged in while in use. Loss of power may limit the notifications available in case of an event.

⚠ **CAUTION**: Only use the AC power supply that came with the Home Medical Hub to prevent damage to the device.

⚠ **CAUTION:** Do not connect to an electrical outlet controlled by a wall switch or dimmer.

⚠ **CAUTION:** When using the Opioid Halo System, locate the devices away from sources that may interfere with the wireless communication. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service of the wireless connection or loss of performance (see Specifications for details). Devices that may cause RFI include but are not limited to the following: cell phones, laptops and tablets, pagers, Bluetooth devices, devices with remote controls, electrocautery equipment, diathermy equipment, and baby monitors.

⚠ **CAUTION:** To ensure security and prevent tampering of your mobile device, follow the directions below:

- Smart phone should be located with responsible users.
- Smart phone should not be left unattended.
- Security features on smart phone should be activated.

⚠ **CAUTION:** Check your system setup by viewing the display on smartphone for the Masimo Halo App. The Masimo Halo App will provide an indication if there is a problem with the internet connection.

For Supervisors or Caregivers

⚠ **WARNING:** Do not wait for an alarm. If you suspect someone is having an opioid overdose, call 911 and administer naloxone, if needed!

⚠ **WARNING:** If you suspect an opioid overdose, the CDC and SAMHSA recommend treating it as an actual opioid overdose.

⚠ **WARNING:** Obstructive sleep apnea (OSA) can increase the risk of false OIRD alarms. The Opioid Halo utilizes the instability trends in oxygenation biomarker data caused by opioid induced respiratory depression (OIRD). OSA can also cause oxygenation instability trends that can be mistaken as OIRD. However, if you suspect an opioid overdose, the CDC and SAMHSA recommend treating it as an actual opioid overdose.

⚠ **WARNING:** When used for monitoring someone on supplemental oxygen, periodically check on their breathing. High flow rates (>2.0 L/min) of supplemental oxygen can indicate high oxygen level readings even if they are having trouble breathing. The Opioid Halo System is not indicated for O_2 flow rates >2.0 L/min.

⚠ **CAUTION:** Relocate the Home Medical Hub if necessary. However, keep the Home Medical Hub in the line of site of the sensor to ensure the most reliable Bluetooth connection.

Cleaning and Service

- Do not attempt to remanufacture, recondition, or recycle the Masimo sensor, Masimo chip or Home Medical Hub. to prevent harm or damage to the system.
- Always turn off and unplug the Home Medical Hub before cleaning to prevent harm or damage to the device.
- Do not clean Masimo sensor, Masimo chip or Home Medical Hub with undiluted bleach, petroleum-based products, acetone, or other harsh solvents. Clean only with the solutions specified in this manual to prevent damage to the device.
- Do not submerge Masimo sensor, Masimo chip or Home Medical Hub in liquid or attempt to sterilize by any method to prevent damage to the device.

Radio Compliance

⚠ **WARNING:** Changes or modifications not approved by Masimo can void the user's authority to operate the equipment.

- Only use Masimo authorized devices with the Opioid Halo System. Using unauthorized devices with the Opioid Halo System may result in damage to the device and/or patient injury.
- 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.
- Disposal of product: Comply with local laws when disposing of the device and/or its accessories.
- Do not place the Opioid Halo System components near electrical equipment that may affect the device, preventing it from working properly.

Note: The Opioid Halo System complies with the limits for a Class B digital device, per Part 15 of the FCC Rules. These limits were designed to provide reasonable protection against harmful interference in a residential installation. The Opioid Halo System generates, uses, and can radiate radio frequency energy and may cause interference with radio communications. To determine if the Opioid Halo System interferes with radio or television reception, turn it off and see if the interference stops. To correct the interference, try the following:

- Adjust or move the receiver's antenna.
- Move the receiver farther away from the Opioid Halo System.
- Plug the receiver and the Opioid Halo System into outlets on different circuits.
- Consult the dealer or a radio/TV technician for help.

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the IEC 60601-1-2: 2014, 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 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: To satisfy RF exposure requirements, this device and its antenna must operate with a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Note: When using the Opioid Halo System consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

Risks and Benefits

Opioid Induced Respiratory Depression (OIRD)

One of the side effects of opioids is the risk of OIRD. OIRD affects your body's ability to work normally including breathing.

When OIRD occurs and you stop breathing, your blood oxygen level can drop or desaturate or become very unstable. Without enough oxygen in your blood, your brain, organs, and tissues can be damaged and may fail.

The Opioid Halo System provides Opioid Halo that works to monitor your blood oxygenation biomarker data (e.g., SpO_2, Pulse Rate) to detect severe risk for OIRD. The Opioid Halo analyzes the stability of your oxygenation to detect a risk of an opioid overdose. Because other medical conditions can also cause instability in your oxygenation (e.g., obstructive sleep apnea), you may also get an alarm for an oxygenation issue that is not opioid related. Regardless, if there is an alarm and you suspect or know someone has taken opioids it is better to act as if they maybe having an opioid overdose.

According to US CDC[1], the recognition of opioid overdoses can be difficult. If unsure it is best to treat the situation like an overdose - it could save a life. Call 911 or seek medical care for the individual. Do not leave the person alone. Signs of overdose may include:

- Small, constricted "pinpoint pupils"
- Falling asleep or loss of consciousness
- Slow, shallow breathing
- Choking or gurgling sounds
- Limp body
- Pale, blue, or cold skin

[1] https://www.cdc.gov/opioids/overdoseprevention/index.html

Risks of Opioid Halo

- Supplemental oxygen greater than 2.0 L/min will add oxygen to the blood. This may delay the detection of OIRD.
- Opioids can stop breathing immediately. In these cases, the Opioid Halo may not alarm soon fast enough. Make sure that anyone providing supervision is aware of signs of opioid overdose and understands how to help.
- Because there are skin-contacting components, there is a risk of skin irritation, pressure injury, and general discomfort while a sensor or cuff is applied to a user. Periodically check the areas where the user's skin contacts with the sensor or blood pressure cuff to prevent potential issues.

Benefits of Opioid Halo

- The Opioid Halo System is equipped with audible and visual physiological alarms that can alert potential opioid overdose.
- The Opioid Halo System can add your emergency contacts to provide increased awareness to an opioid overdose.
- The Opioid Halo System can trigger a wellness call if your oxygenation is showing signs of an opioid overdose.

Description

Opioid Halo System

These items make up the Opioid Halo System:

Item	Description
1	Home Medical Hub
2	Masimo Halo App (smart phone not included)
3	Masimo Sensor
4	Masimo Chip

Features

Features of the Opioid Halo System.

Home Medical Hub Overview

The Home Medical Hub is a device that transfers measured data from the wireless Masimo Sensor to the Masimo SafetyNet Alert Cloud. It transfers data from the wireless Masimo Sensor to the Masimo SafetyNet Alert Cloud and provides audible and visible alarms.

1. Pairing Symbol

Location on the Home Medical Hub for pairing the Masimo Chip.

2. Home Medical Hub Button

Used for pairing and silencing alarms.

3. Bluetooth Status LED

Shows the Home Medical Hub Bluetooth status. See ***Home Medical Hub Lights*** on page 49.

4. Home Medical Hub Status LED

Shows the Home Medical Hub power and monitoring status. See ***Home Medical Hub Lights*** on page 49.

5. Wi-Fi Status LED

Shows the Home Medical Hub Wi-Fi status. See ***Home Medical Hub Lights*** on page 49.

6. USB Power Connector

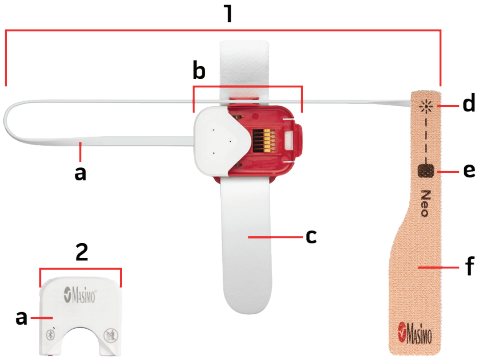
Power is provided to the Home Medical Hub from the AC adapter and a USB cable.

7. Masimo Chip Storage Tray

Location on the Home Medical Hub for storage of the chip when not in use.

Masimo Sensor and Chip Overview

The Masimo Sensor and Masimo Chip are for use with the Opioid Halo system.



1. Masimo Sensor

a. Cable

b. Chip Holder

c. Strap

d. Sensor LED

e. Detector

f. Tape

2. Masimo Chip

a. Light Indicator

Basic Setup and Use

Getting Started

The Opioid Halo system can be ready to use in the following steps:

1. Setup the Smart Phone - Prepare the smart phone for use with the Masimo Halo App.
   - Download the Masimo Halo App on your smart phone and complete the registration and login process.
   - Select the option that applies to the user for the Masimo Halo App. The option determines when alerts and notifications are triggered.
2. Setup the Opioid Halo System – Use the Masimo Halo App and complete the following:
   - Connect the Home Medical Hub using local Wi-Fi with the Masimo SafetyNet Alert Cloud.
   - Pair the Masimo Sensor with the Home Medical Hub.
   - Select emergency contacts.
   - Enable emergency dispatch services.
3. View Live Data – The Masimo Halo App and phone are ready for monitoring.

Step 1: Smart Phone Setup

Prepare the Smart Phone for Use

A compatible smart phone is required to install and operate the Masimo Halo App.

To use your smart phone with the Masimo Halo App check the following:

- **Compatibility**

  Note: For a list of smart phones and operating systems that work with the Masimo Halo App, check www.masimo.com/support before upgrading the smart phone or its operating system.
- **Smart Phone Battery is charged**
- **Bluetooth is ON**
- **Wi-Fi is ON and the smart phone in connected to the internet**
- **Time is set to the Current Local Time**

Download and install the Masimo Halo App on the smart phone:

Download and install the Masimo Halo App. Follow the on-screen instructions to install. For more on how to install an app, see the smart phone's manual.

Note: If the Masimo Halo App requests for the smart phone to share its location, select ***OK*** or ***Allow***. The smart phone location is required for Bluetooth connection.

1. After installation, open the Masimo Halo App and login to the user account
   - If you do not have an existing account, select **Sign Up**. Follow the on-screen instructions to create a new account and login.
2. The app walks you through the steps to set up Opioid Halo starting with the Home Medical Hub.

   Note: Make sure your smartphone Bluetooth connection is turned on to connect to Masimo Sensor. Refer to the smart phone's instructions to change its settings.

Step 2: Opioid Halo System Setup

After the Masimo Halo App is installed and setup, follow the app instructions to set up your Opioid Halo System:

- Pair the App to the Home Medical Hub.
- Connect the Home Medical Hub to the Wi-Fi.
- Setup the Masimo Sensor and pair to the Home Medical Hub.
- Add your Emergency Contacts.
- Enable emergency dispatch services.

Home Medical Hub Setup

Follow the instructions below to set up the Opioid Halo system. The Home Medical Hub is set up in two (2) steps.

Step 1: Pair the Masimo Halo App to the Home Medical Hub using Bluetooth.

Step 2: Connect the Home Medical Hub to the wireless network (Wi-Fi).

⚠ **WARNING:** Place the Home Medical Hub in a safe location so as not to fall on anyone and where the alarm sounds can be heard.

1. Following the on-screen instructions, connect the Home Medical Hub to a power outlet using the AC power cord and adapter and select **Continue**.

   Note: The Home Medical Hub Status LED is white when powered on.

2. Hold your smart phone near the Home Medical Hub during setup. When complete, the App screen will display: *Success*.

   Note: If the Bluetooth connection fails, hold the smart phone closer to the Home Medical Hub and try to reconnect. If the Home Medical Hub cannot connect, see ***Troubleshooting*** on page 39.

3. Next, connect to your Wi-Fi by selecting **Set Up Wi-Fi** and follow the app instructions.
4. Select the wireless *Network* and enter the *Password*. Select **Continue**.

   Note: To view available Wi-Fi networks within range of the Home Medical Hub, click the *Network* field and select from the displayed list

5. Once the Wi-Fi connection is established, the *Home Medical Hub Wi-Fi Setup Successful* screen will appear. If the Home Medical Hub cannot connect, follow the on-screen instructions to verify the network and try again or view ***Troubleshooting*** on page 39.
6. Next, you will need to attach the Masimo Sensor and connect it with the Home Medical Hub. See ***Masimo Sensor Setup*** on page 24 for additional instructions.

Masimo Sensor Setup

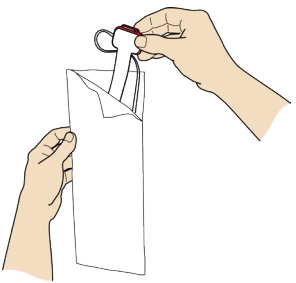
After the Home Medical Hub is set up, follow the on-screen instructions to:

- Set up the Masimo Sensor.
- Attach the sensor to your hand.
- Pair the sensor to the Home Medical Hub.
- Insert the Masimo Chip into the sensor.

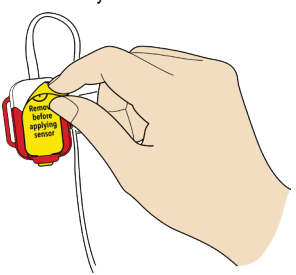
Attaching the Wireless Masimo Sensor

Follow the instructions to attach the Masimo Sensor to your hand. An in-app video is provided showing proper sensor application.

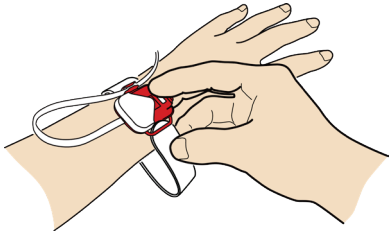
1. Gather all components required for monitoring. See ***Masimo Sensor and Chip Overview*** on page 19.
2. Remove the sensor from the pouch.



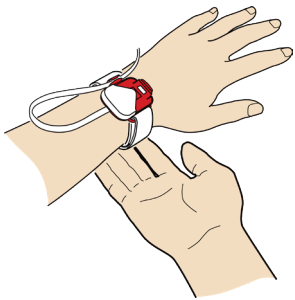
3. Peel off the yellow label to activate the battery.



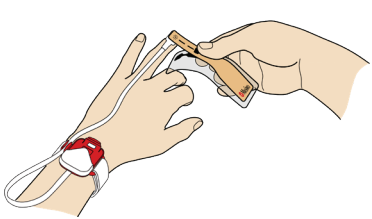
4. Place the sensor on the wrist as shown and carefully thread the tip of the strap through the open red c loop.

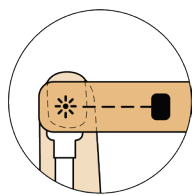


5. Wrap the loose attachment strap around the wrist and press to secure.

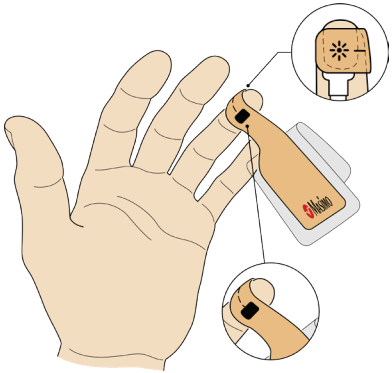


6. Remove part of the plastic film and place the star ✳ on top of the fingernail of your finger. The non-dominant ring or middle finger is preferred.

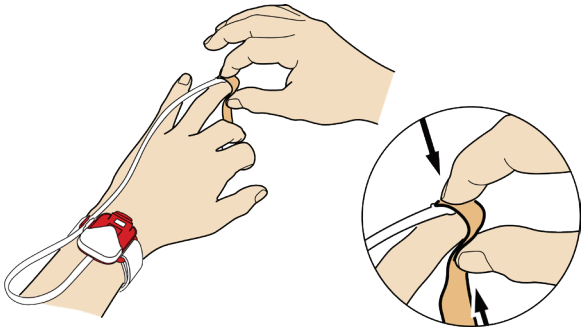




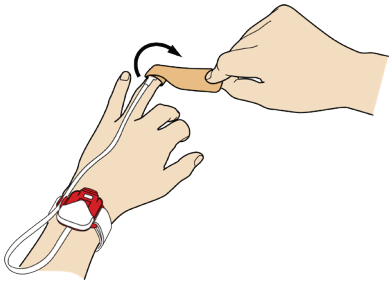
7. Wrap the tape around your finger so the square marking ■ on the sensor tape is centered on the finger pad directly across from the star ✳ marking on the fingernail. **Ensure alignment between the square marking ■ and star ✳ is correct**; reposition as necessary.



8. Squeeze top and bottom of finger to secure tape.

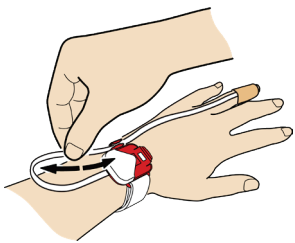


9. Remove plastic film and continue to wrap remaining tape around your finger.



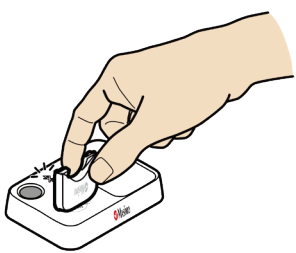
⚠ **CAUTION:** Avoid wrapping the sensor too tightly around your finger to avoid injury or restrict blood flow to the finger.

10. Adjust the sensor cable to a comfortable length.

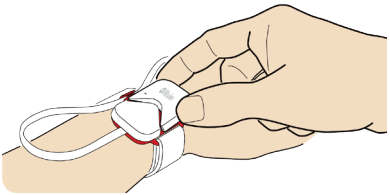


Pairing the Masimo Sensor

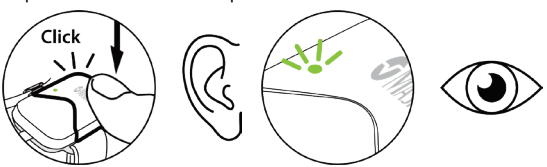
1. To pair the Masimo Sensor to the Home Medical Hub, hold the chip near the Home Medical Hub pairing symbol until an audible beep is heard and the Home Medical Hub Bluetooth LED flashes. See ***Home Medical Hub Overview*** on page 18.



2. Insert the Masimo Chip into open compartment on the sensor.



3. Press down on the Masimo Chip to secure. Listen for a click and look for a green light on the chip to confirm successful chip connection to sensor.



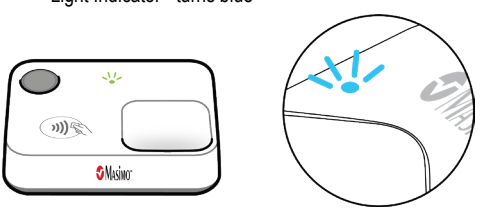
4. Confirm successful pairing once the chip is inserted into the sensor by observing the light indicators.

Home Medical Hub:

- Bluetooth Status LED - turns off
- Status LED - turns green

Masimo Chip:

- Light Indicator - turns blue



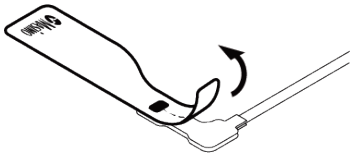
- If the sensor and Home Medical Hub cannot pair, see ***Troubleshooting*** on page 39.

Reapplying the Sensor

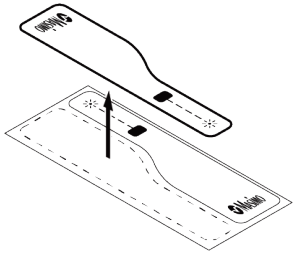
The Masimo Sensor may be reapplied to the same user if the emitter and detector windows are clear, and the adhesive still sticks to the skin. Use the replacement tape when the adhesive no longer sticks.

Applying Replacement Tape

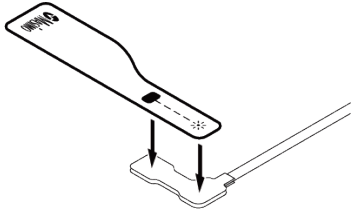
1. Remove the existing tape and discard.



2. Remove the replacement tape from the backing.

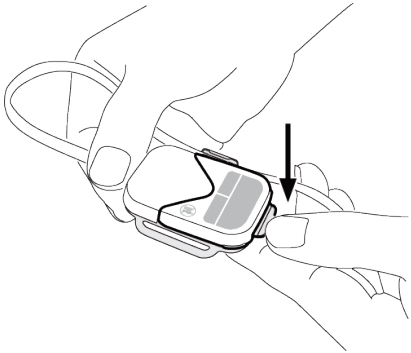


3. Place the replacement tape over the Masimo Sensor. Align the emitter component with the sensor cable.



Disconnecting the Masimo Chip

1. Push down on the tab to release the Masimo Chip from the Masimo sensor.



2. After cleaning, store the chip in the chip holder on top of the Home Medical Hub.

Add Emergency Contacts

Follow the on-screen prompts to select your Emergency Contacts from your smart phone. This allows the Masimo Halo App to contact them in case of an emergency. An emergency contact is someone who will be alerted if you experience an Alert event.

1. Choose *Add From Contacts* or *Add Manually* to get started.
2. If prompted to *Allow Opioid Halo to access your contacts*, select **Allow**.

   Note: If you **Deny** access, Opioid Halo cannot add contacts for use in case of an emergency.
3. Select your emergency contacts from your contact list or add manually by entering the contact's name and mobile phone number.

   ⚠ **CAUTION:** Do not use contacts with a landline phone number since they will not be able to receive text notifications in case of an emergency.
4. Select the types of alerts for the emergency contacts to receive and add the emergency contact.

Once contacts are added to receive alerts, the *Request Sent* screen appears. Select **Finish** to complete.

- The emergency contact should receive a text message with instructions on how to accept or deny the request. They must accept the request to be an emergency contact.
- A message is also sent to you when the emergency contact has accepted.

Enable Emergency Dispatch Services

Follow the on-screen prompts to allow Emergency Dispatch Services to be notified if a low oxygen event occurs.

1. When prompted, select *I Agree*.

   Note: If you Opt Out, you agree to take full responsibility for contacting EMS if the need arises.

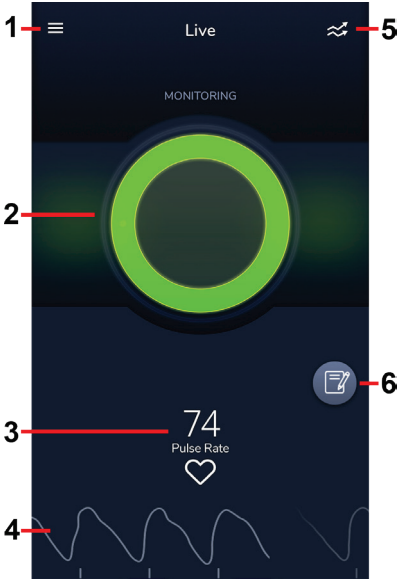
2. Enter your address (the address where you are physically present for EMS to go to) and phone number.

   Note: EMS will be sent to this address in the case of an emergency.

When finished, the *Live Data* screen appears. See ***Step 3: Live Data*** on page 31.

Step 3: Live Data

After setting up the Opioid Halo system, the app displays data from the Masimo Sensor. The *Live* screen is also the App Main Screen, with access to other Masimo Halo App functions.



1. App Menu

Displays the *App Menu* screen.

2. Opioid Halo Indicator

Indicates the monitored and alert status. Green indicates the monitoring is started. Indicator will be Gray if there is an issue preventing monitoring (e.g., bad sensor placement).

3. Pulse Rate

Displays numerical pulse rate.

4. Pulse Rate Waveform Display

Displays the waveform of the heart rate and indicator of the signal quality. Check the sensor placement by checking the waveform has a clear pattern and pulse rate value is displayed.

5. Trend

Tap to display trend view.

6. Timeline Notes

Tap to view and add Timeline notes.

* If a sensor is not paired to the Home Medical Hub, the reading displays as dashes.

Verify Sensor is Properly Applied

It is important to make sure your sensor is properly applied. The light from the sensor LED should be aligned so that it shines through the finger to the detector. Make sure the detector is flush against the padded side (non-nail side of the fingertip). The following items can help identify good sensor placement:

- Halo Indicator is Green
- Pulse Rate is displayed
- Heart Rate Waveform is showing a clear pattern

Alarms and Notifications

The Opioid Halo System provides visual and audible alarms when it detects a risk of severe OIRD. The Opioid Halo continuously monitors your blood oxygen data patterns. Three different alarm levels (Level 1, Level 2, and Level 3) help to identify the risk of severe OIRD. When correctly configured, Opioid Halo will audibly and visually alarm at the Home Medical Hub and your phone (Level 1). Will additionally notify your emergency contacts (Level 2). Will additionally trigger an automated wellness call (Level 3) to you by an emergency response dispatch service. If you indicate you need assistance or do not respond, the emergency response dispatch service will request the dispatch of Emergency Medical Services (EMS). EMS will be sent to the location based off of the address input by the user in the app during setup.

Alarm Levels and Messages

To help ensure your safety, a notification escalation policy can be activated to establish (3) levels of notifications. The level of notification is based on your oxygen level and length of time at a low oxygen level.

Notification Level	Alarm Trigger	Visual Alarm	Audible Alarm	Emergency Contact	Emergency Dispatch
Level 1	Early signs of unstable oxygen levels or low oxygen levels.	Yes	Yes	No	No
Level 2	Medically meaningful or very unusual signs of unstable oxygen levels or sustained low levels of oxygen.	Yes	Yes	Yes	No
Level 3	Extremely unusual signs of unstable oxygen levels or a long period of low levels of oxygen or an extreme drop in your oxygen level.	Yes	Yes	Yes	Yes

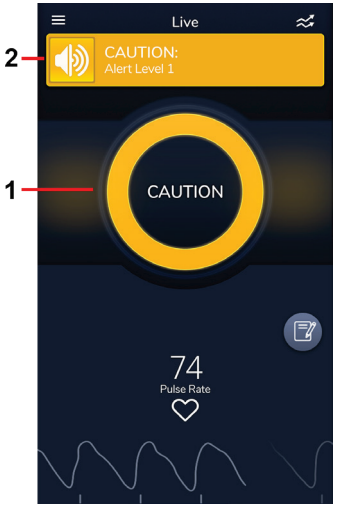
Level 1

Notification Level	Alarm Trigger	Visual Alarm	Audible Alarm	Emergency Contact	Emergency Dispatch
Level 1	Early signs of unstable oxygen levels or low oxygen levels.	Caution (Yellow)	Yes	Not Contacted	Not Contacted

When Level 1 is triggered, an alarm sounds on the Home Medical Hub and the App. A notification banner will be at the top of the App screen that displays ***CAUTION: Alert Level 1***

Reason for the Alarm

Caution of OIRD risk due to early signs of unstable oxygenation being detected or low levels of oxygen.



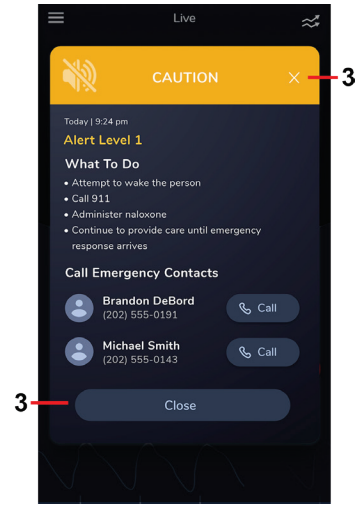
Touch the **CAUTION** Opioid Halo Indicator **(1)** or the **CAUTION** banner **(2)** to view how to respond (alarm will be silenced for 2 minutes or until a higher level alarm is triggered).

What to Do in case of an Opioid Overdose:

- Attempt to wake the person.
- Call 911
- Administer naloxone
- If the person overdosing does not respond in 2 to 3 minutes, administer a second dose of naloxone.
- Continue to provide care until emergency response arrives.

> ⚠ **WARNING:** Do not wait for an alarm. If you suspect someone is having an opioid overdose, call 911 and administer naloxone, if needed!

To exit the screen, tap the "X" **(3)** or select the **Close** button **(3)**.



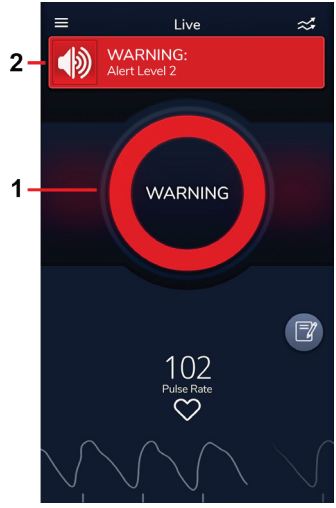
Level 2

Notification Level	Trigger	Visual Alarm	Audible Alarm	Emergency Contact	Emergency Dispatch
Level 2	Medically meaningful or very unusual signs of unstable oxygen levels or sustained low levels of oxygen.	Warning (Red)	Yes	Message sent to Emergency Contact	Not Contacted

When Level 2 is triggered, an alarm will sound on the Home Medical Hub and the App. A notification banner will be provided on the top of screen that displays ***WARNING: Alert Level 2***

Reason for the Alarm

Warning of OIRD risk due to very unstable oxygenation being detected or sustained low levels of oxygen.



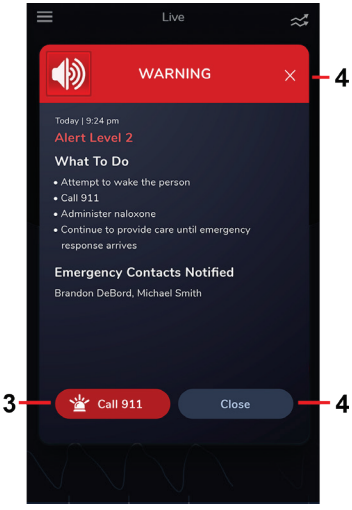
Touch the **WARNING** Opioid Halo Indicator **(1)** or the **WARNING** banner **(2)** to view how to respond (alarm will be silenced for 2 minutes or until a higher level alarm is triggered).

What to Do in case of an Opioid Overdose:

- Attempt to wake the person.
- Call 911 **(3)**
- Administer naloxone
- If the person overdosing does not respond in 2 to 3 minutes, administer a second dose of naloxone.
- Continue to provide care until emergency response arrives.

> ⚠ **WARNING:** Do not wait for an alarm. If you suspect someone is having an opioid overdose, call 911 and administer naloxone, if needed!

To exit the screen, select "X" **(4)** or select the **Close** button **(4)**.



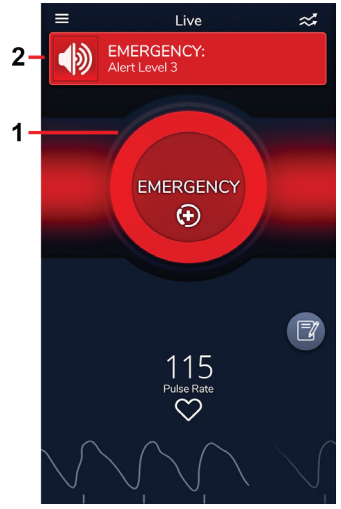
Level 3

Notification Level	Trigger	Visual Alarm	Audible Alarm	Emergency Contact	Emergency Dispatch
Level 3	Extremely unusual signs of unstable oxygen levels or a long period of low levels of oxygen or an extreme drop in your oxygen level.	Emergency (Red)	Yes	Message sent to Emergency Contact	Emergency Medical Dispatch Contacted

When Level 3 is triggered, an alarm will sound on the Home Medical Hub and the App. A notification banner will be provided on the top of screen that displays ***EMERGENCY: Alert Level 3***

Reason for the Alarm

Emergency of OIRD risk due to extremely unstable oxygenation being detected or a long period of low levels of oxygen or an extreme drop in your oxygen level.



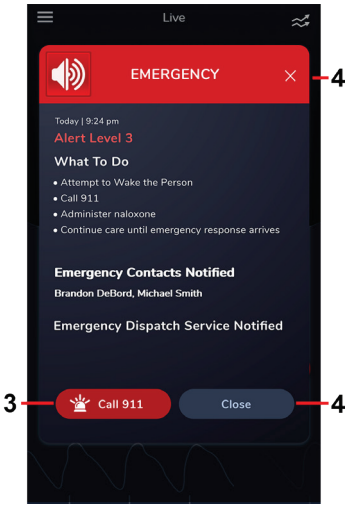
Touch the **EMERGENCY** Opioid Halo Indicator **(1)** or the **EMERGENCY** banner **(2)** to view how to respond (alarm will be silenced for 2 minutes).

What to Do in case of an Opioid Overdose:

- Attempt to wake the person.
- Call 911 **(3)**
- Administer first dose of naloxone.
- If the person overdosing does not respond in 2 to 3 minutes, administer a second dose of naloxone.
- Continue to provide care until emergency response arrives.

> ⚠ **WARNING:** Do not wait for an alarm. If you suspect someone is having an opioid overdose, call 911 and administer naloxone, if needed!

To exit the screen, select "X" **(4)** or select the **Close** button **(4)**.



Silence Alarms

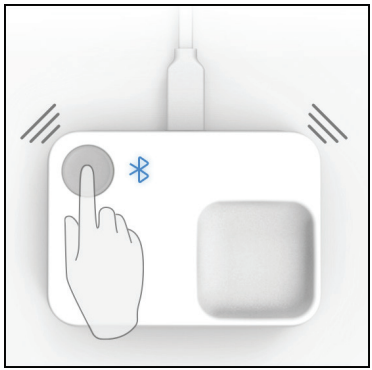
An audio alarm can only be silenced for 2 minutes. After the 2 minutes, the alarm sounds again. You can continue to temporarily silence the alarm for 2 minutes at a time if the low oxygen level condition continues. If your oxygen level returns to a non-alarm level, the alarm will stop.

Silence Alarms from the App

Then touch the Speaker icon shown on the banner to silence the App alarm.

Silence Alarms from the Home Medical Hub

Press and release the Home Medical Hub button to silence the Home Medical Hub alarm.



Opioid Halo Messages

The following section is intended to provide guidance for solving some of the most common issues users may face with the Opioid Halo System.

Displayed Messages	Potential Causes	Next Steps
"Difficulty in obtaining a reading" *"There is an issue getting a reading"*	Difficulty in obtaining a reading.	There is an issue with getting your reading. Please ensure that: 1. The sensor is on a finger without jewelry, such as a ring. 2. You move away from ambient lighting and computer displays or TVs. 3. You are not wearing artificial nails or excessive nail polish on the monitored finger. If you still experience issues, please contact Masimo Technical Support. See ***Contacting Masimo*** on page 64.
	Sensor is not working.	There seems to be an issue with your sensor. Contact Masimo Technical Support. See ***Contacting Masimo*** on page 64.
"Replace Radius PPG sensor"	Sensor is not working.	There seems to be an issue with your sensor. Contact Masimo Technical Support. See ***Contacting Masimo*** on page 64.
"Your Emergency Contact list is empty. Touch the plus icon to start adding Emergency Contacts"	The App would like you to add emergency contacts.	Follow instruction on the App or the Emergency Contacts section of this manual to complete setup.
Add Home Medical Hub Device	Home Medical Hub is not connected to the app.	Follow instructions on the App or the Home Medical Hub section of this manual to complete setup.
"Home Medical Hub not found"	Home Medical Hub is not set up correctly.	Follow instructions on the App or the Home Medical Hub section of this manual to setup.

Displayed Messages	Potential Causes	Next Steps
"Home Medical Hub Disconnected"	Home Medical Hub has disconnected from the App.	Attempt to connect the Home Medical Hub again. Follow instructions on the App or the Home Medical Hub section of this manual to reconnect.
"Home Medical Hub Disconnected from Server"	Home Medical Hub has disconnected from the Masimo SafetyNet Alert Cloud.	Check Wi-Fi connection of Home Medical Hub. Follow instructions on the App or the Home Medical Hub section of this manual to reconnect.
"Home Medical Hub Error"	Internal error.	There seems to be an issue with your Home Medical Hub. Contact Masimo Technical Support. See ***Contacting Masimo*** on page 64.
"Unable to connect to Wi-Fi"	When connecting to Wi-Fi Fails due to timeout or invalid password.	Retry connecting or enter the correct password.
"The username entered already exists, please try another"	Username already exists with another user.	Please choose another username.
"This Home Medical Hub has already been registered to an account"	Home Medical Hub has been registered by another user.	Contact Masimo Service. See ***Contacting Masimo*** on page 64.
"The Entered Code is Invalid"	• Emergency contact confirmation code is entered incorrectly. • Password reset code was entered incorrectly.	Enter the correct code.
"Battery low Warning"	Sensor battery is low.	Replace sensor.
"Wireless Sensor Disconnected"	Sensor is not monitoring.	Ensure proper sensor placement steps are completed and you are obtaining readings.
"Wireless Sensor Disconnected during an alert"	Sensor becomes disconnected from Home medical Hub during an alarm event.	Reconnect the sensor to the Home Medical Hub. Follow instructions on the setup section of this manual to complete setup. If you still experience issues, please contact Masimo Technical Support. See ***Contacting Masimo*** on page 64.

Displayed Messages	Potential Causes	Next Steps
"Obstructed Battery Port"	Sensor is not monitoring.	Please keep the sensor battery clear of any direct contact.
"Place Sensor on Properly"	Sensor is not monitoring.	Reapply the sensor. You can also visit the options menu to view the sensor placement videos
"EMS Disabled"	• The Home Medical Hub has disconnected from the sensor. • The App has disconnected from the Masimo SafetyNet Alert Cloud.	• Please restore the connection between the sensor and the Home Medical Hub. • Please check your Wi-Fi Network to ensure the App can connect to the Masimo SafetyNet Alert Cloud. If you still experience issues, please contact Masimo Technical Support. See ***Contacting Masimo*** on page 64.
"EMS Location may be Inaccurate"	The App cannot determine if you are currently at the registered EMS address.	If you are not at the registered address, EMS might not be able to reach you. This message appears when the sensor is disconnected from the Home Medical Hub, or your location cannot be determined. Please check your Wi-Fi Network to ensure the App can connect to the Masimo SafetyNet Alert Cloud. If you still experience issues, please contact Masimo Technical Support. See ***Contacting Masimo*** on page 64.

Troubleshooting Opioid Halo

The following section lists possible symptoms, the potential cause, and next steps.

Symptom	Potential Causes	Next Steps
Masimo Halo App does not turn on	• Low battery on smart phone. • Masimo Halo App needs to be updated. • Incompatible smart phone.	• Recharge your smart phone. Refer to the Smart phones Operator's Manual or Directions for Use. • Check for Masimo Halo App updates. • Check compatibility for your Smart phone. See ***Specifications*** on page 47. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Masimo Halo App turns off	• Low battery on smart phone. • Masimo Halo App needs to be updated. • Incompatible smart phone.	• Recharge your smart phone. Refer to the smart phones Operator's Manual or Directions for Use. • Check compatibility for your smart phone. See ***Specifications*** on page 47. • Check for Masimo Halo App updates. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Masimo Halo App does not communicate with Home Medical Hub	• The Home Medical Hub is not powered on. • smart phone is out of proximity to the Home Medical Hub. • Bluetooth on the smart phone is not turned on and/or not correctly configured. • Smart phone does not support Bluetooth Low Energy (BLE).	• Ensure the Home Medical Hub is plugged in. • Ensure your smart phone is near the Home Medical Hub. • Ensure Bluetooth on the smart phone is turned on. • Check smart phone compatibility. See ***Specifications*** on page 47. • Update the smart phone software. Refer to the smart phones Operator's Manual or Directions for Use. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.

Symptom	Potential Causes	Next Steps
Home Medical Hub does not connect to Wi-Fi or Cloud	• The Home Medical Hub is not plugged in. • Incorrect Wi-Fi network selected. • Incorrect Wi-Fi password in entered. • Wi-Fi network is not correctly configured. • Masimo SafetyNet Alert Cloud may be down.	• Ensure the Home Medical Hub is plugged in. • Ensure smart phone is connected to correct Wi-Fi network. • Ensure correct Wi-Fi network is selected. • Ensure correct Wi-Fi password is entered. • Check that the wireless features are correctly configured. Refer to the smart phones Operator's Manual or Directions for Use. • Check network settings and availability. You may need to call the network provider for further assistance. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Opioid Halo sensor does not pair with Home Medical Hub	• The Home Medical Hub is not plugged in. • Masimo chip is not plugged into sensor. • Sensor is not in close proximity with Home Medical Hub during pairing. • Incorrect user logged in. • The Home Medical Hub has been registered with another account. • Depleted sensor battery.	• Ensure the Home Medical Hub is plugged in. • Ensure the chip is firmly plugged into sensor. See ***Attaching the Wireless Sensor*** on page 24. • Ensure <sensor is in close proximity with the Home Medical Hub during pairing. • Ensure correct user is logged in. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Home Medical Hub turns off (not lit up)	• The Home Medical Hub is not plugged in. • Internal components may not be working properly.	• Ensure the Home Medical Hub is plugged in. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Home Medical Hub speaker does not work (no sound or muffled sound)	• Speaker may be blocked by environment (ex. blankets or other appliances). • Internal components may not be working properly.	• Turn the Home Medical Hub on and off by unplugging the unit. • Check that the device speaker is not muffled. • Check that the Home Medical Hub is on a flat surface with minimal objects surrounding it. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.

Symptom	Potential Causes	Next Steps
Cloud unavailable	• Wi-Fi is not turned on and/or not correctly configured. • Wireless service is weak or unavailable in the current location.	• Ensure the smart phone is within range of the wireless network for connection to the system. • Check that the wireless feature for smart phone is on and correctly configured. Refer to the smart phones Operator's Manual or Directions For Use. • Check Wi-Fi network settings and availability. • Check wireless availability for location. • Update the smart phone software. Refer to the smart phones Operator's Manual or Directions for Use. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Incorrect user data is displayed	• Incorrect user currently logged into Opioid Halo.	• Ensure the correct user is logged into the Masimo Halo App. • Restart App and login to the system. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
NO user data is displayed	• Incorrect user logged in. • Wi-Fi is not correctly configured. • smart phone settings are incorrect.	• Ensure the correct user is logged into the Masimo Halo App. • Restart App and login to the system. • Check that the wireless feature is correctly configured. Refer to the smart phones Operator's Manual or Directions for Use. • Check network settings and availability. May have to call the network provider for further assistance. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Delayed data updates	• Wi-Fi is not correctly configured.	• Check that the wireless feature is correctly configured. Refer to the smart phones Operator's Manual or Directions for Use. • Check network settings and availability. You may need to call the network provider for further assistance. • Restart App and login to the system. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.

Symptom	Potential Causes	Next Steps
User alarms do not appear during events	• Incorrect user currently logged into the App. • Wi-Fi network not available. • System settings have changed.	• Ensure Opioid Halo is connected to Wi-Fi. • Ensure the correct user is logged into Masimo Halo App. • Restart And login to the system. • Ensure alert notification settings are turned on. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Masimo Halo App does not detect that the sensor is connected	• Sensor not properly placed on user. • Sensor not properly paired to the Home Medical Hub. • Damaged sensor. • Internal failure.	• Reapply the sensor. • Pair the chip with the Home Medical Hub. • Replace sensor. • Turn the Home Medical Hub off and on by unplugging the device then plug it in to start up • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.

Troubleshooting Measurements

The following section lists possible measurement symptoms, potential causes, and next steps. For more information, see ***Safety Information*** on page 9.

Symptom	Potential Causes	Next Steps
Difficulty obtaining a reading.	• Incorrect placement of sensor on user. • Misalignment of sensor components. • Low perfusion (blood flow). • Excessive user motion. • Excessive ambient or strobing light. • Low battery/Home Medical Hub not plugged into AC power supply.	• Check the placement and alignment of the sensor on the hand. Re-apply sensor or move to a different location. • Allow time for the parameter measurement to stabilize. • Check if blood flow to the sensor location is restricted. Warm the hand where the sensor is placed. • Minimize or eliminate motion at the monitoring location. • Shield the sensor from excessive or strobing light. • Replace sensor. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Measurement values displayed as dashes.	• Measurement may still be in progress. • Incorrect placement of sensor on user. • No Connection to Masimo SafetyNet Alert Cloud. • Sensor is damaged, not functioning or has a dead battery.	• Allow time for the parameter measurement to stabilize. • Check the placement of the sensor on the hand. Re-apply sensor or move to a different location. • Check if blood flow to the sensor location is restricted. • Replace sensor. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.
Unexpected or unlikely measurement values	• Incorrect placement of sensor on user. • Low signal quality.	• Check the placement of the sensor on the hand. Re-apply sensor or move to a different location. • Move the sensor to a location on the user's body with stronger blood flow. Warm the hand where the sensor is placed. • Contact Masimo Customer Support. See ***Contacting Masimo*** on page 64.

Appendix

Specifications

Masimo Halo App

Measurement Range

Measurement	Display Range	Unit of Measure
Oxygen Level	0 to 100	%
Pulse Rate	25 to 240	bpm
Perfusion Index	0.02 to 20	%

Smart Phone Compatibility

For full list of compatible devices go to www.masimo.com/support

Masimo Sensor

Sensor Lights

When inserted in the sensor, the light indicator on the Masimo Chip shows the status of the sensor.

Light Indicator Color	What does it mean?
Flashing Blue	Sensor is paired with the Home Medical Hub.
Flashing Purple	Sensor battery ports are blocked.
Flashing Green	Sensor is not paired with the Home Medical Hub.
Flashing Orange	Sensor battery is low.
Flashing Red	Sensor battery is very low.

Accuracy (ARMS*)

Oxygen Level (SpO_2)		
Range	70% to 100%	
No Motion [1]	Adults, Pediatrics	2%
Motion [2]	Adults, Pediatrics	3%

Low perfusion [3]	Adults, Pediatrics	2%
Pulse Rate (PR)		
Range	25 bpm to 240 bpm	
No motion	Adults, Pediatrics	3 bpm
Motion	Adults, Pediatrics	5 bpm
Low Perfusion [4]	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.

Electrical

Battery - Masimo Sensor	
Run Time	96 hours in typical continuous usage

Environmental

Masimo Sensor Environmental Conditions	
Operating Temperature	32°F to 104°F (0°C to 40°C)
Storage Temperature	32°F to 122°F (0°C to 50°C)
Operating Humidity	5% to 95%, non-condensing
Storage Humidity	5% to 95%, non-condensing

Masimo Chip

Physical Characteristics

Masimo Chip	
Dimensions	L=1.2" x W=1.3" x H=0.3" (3.05 cm x 3.3 cm x 0.76 cm)
Weight	0.18 oz. (5g) TBD
Expected Service Life	3 Years

Environmental

Masimo Chip Environmental Conditions	
Operating Temperature	32°F to 104°F (0°C to 40°C)
Storage Temperature	-40°F to 158°F (-40°C to 70°C)
Operating Humidity	5% to 95%, non-condensing
Storage Humidity	5% to 95%, non-condensing
Atmospheric Pressure	540 to 1060 mBar @ ambient temperature and humidity

Home Medical Hub

Home Medical Hub Lights

The LED lights on the Home Medical Hub show the status of Bluetooth pairing and Wi-Fi connections.

Indicator/LED Color	What does it mean?
Home Medical Hub Status LED	
Solid White	Home Medical Hub is on and needs to be set up.
Solid Green	Home Medical Hub is paired with the sensor, connected to the Wi-Fi and communicating with the Masimo SafetyNet Alert Cloud.
Flashing Orange	Active Level 1 Alert. See ***Alarms and Notifications*** on page 33.
Solid Orange	Level 1 Alert is acknowledged.
Flashing Red/Orange	Active Level 2 or 3 Alert. See ***Alarms and Notifications*** on page 33.
Solid Red	Level 2 or 3 Alert is acknowledged.
Flashing Orange	Sensor battery ports are blocked.
Flashing Red	A Home Medical Hub fault has been detected.
Bluetooth Status LED	
Solid White	Home Medical Hub is on and needs to be set up.
Off	Home Medical Hub is paired with the sensor.
Flashing White	Home Medical Hub is pairing with the sensor.
Solid Orange	Sensor is disconnected from the Home Medical Hub.
Wi-Fi Status LED	
Solid White	Home Medical Hub is on and needs to be set up.

Indicator/LED Color	What does it mean?
Off	Home Medical Hub is connected to the Wi-Fi network.
Flashing White	Home Medical Hub is searching for or connecting to the Wi-Fi network.
Solid Orange	Home Medical Hub is connected to the Wi-Fi and the Sensor is no longer connected.

Electrical

AC Power Requirements	
AC Power Input (External Power Supply)	100 to 240 VAC, 50 to 60 Hz, 1.2 A
DC Power Input (Home Medical Hub)	5 VDC, 750 mA

Physical Characteristics

Home Medical Hub	
Dimensions	L=3.5" x W=2.5" x H=0.8" (8.89 cm x 6.35 cm x 2.03 cm)
Weight	1.97 oz. (56g)
Expected Service Life	3 Years

Environmental

Environmental Conditions - Home Medical Hub	
Operating Temperature	41°F to 104°F (5°C to 40°C)
Storage Temperature	-13°F to 158°F (-25°C to 70°C)
Operating Humidity	10% to 95%, non-condensing
Storage Humidity	10% to 95%, non-condensing

Alarms

Alarm Priority	Alarm Status Color	Audio Alarm Description
Medium	Flashing yellow	500 Hz tone, 3-pulse burst, effective pulse duration: 0.18s, repeat time: 3.6s
High	Flashing red	800 Hz tone, 10-pulse burst, effective pulse duration: 0.18s, burst interval: 6s

Alarm Characteristic	Description
Alarm Volume	High Priority: 75 dB (min) Medium Priority: 66 dB (min)

Alarm Condition	Alarm Priority	Details
Level 1	Medium	Based upon Opioid Halo
Level 2	High	Based upon Opioid Halo
Level 3	High	Based upon Opioid Halo
Sensor Off	High	Will alarm after monitoring has started. No alarm before monitoring has started.
Low Battery	Medium	When sensor enters a low battery condition
Depleted Battery	High	After low battery condition is persisted
Sensor Defective	High	Hardware malfunction
Sensor Disconnected	High	After entering a monitoring a state and the sensor is disconnected from the Home Medical Hub and Masimo Halo App
Server Disconnected	High	After entering a monitoring a state and the Home Medical Hub disconnected from Masimo SafetyNet Alert Cloud
Monitoring with Alarm Interrupted	High	Wireless sensor disconnected from Home Medical Hub and Masimo Halo App during an alarm condition
Home Medical Hub Speaker Fault	High	Home Medical Hub speaker hardware malfunction

Compliance

EMC Compliance
IEC 60601-1-2:2014, Class B

Safety Standards Compliance
IEC 60601-1
IEC 60601-1-8
IEC 60601-1-11

Equipment Classification per IEC 60601-1	
Type of Protection	Class II (AC Power)
Degree of Protection against Electrical Shock	Type BF-Applied Part
Protection against harm from Water and Particulate Matter	
Home Medical Hub	IP22 (Protection from solid foreign objects ≥12.5 mm diameter and against ingress from vertically falling water drops when enclose tilted up to 15°)
Masimo Chip	IP47 (Protection from solid foreign objects <1 mm diameter and against immersion between 15 centimeters and 1 meter in depth)
Mode of Operation	Continuous

Wireless Specifications

Communication (Bluetooth)	
Type	Bluetooth
Frequency	2402-2480 MHz
Max Peak Output Power	Bluetooth 8.26 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	GFSK
Modulation Signals	Analog and Digital
Available Data Rates	Bluetooth 1 Mbps

Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 b/g/n
Frequency	802.11b/g/n(HT20): 2412-2462 MHz 802.11n(HT40): 2422-2452 MHz
Max Peak Output Power	WLAN 27.12 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	802.11b: DSSS 802.11g/n(HT20/HT40): OFDM
Modulation Signals	Analog and Digital

Communication (Wi-Fi)	
Available Data Rates	802.11b - 1, 2, 5.5, 11 Mbps. 802.11g - 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11n- MCS0 – MCS7

Security and Authentication	
Encryption	64/128-bit WEP, Dynamic WEP, WPA-TKIP, WPA2-AES
Authentication	Open System, Shared Key, Pre-Shared Key (PSK), 802.1X: LEAP, PEAP, TTLS, TLS, EAP-FAST

Radio Compliance	
USA	Contains FCC ID: 2AC7Z-ESP32SOLO1 FCC ID: VKF-CONNHUB
Canada	Contains IC: 21098-ESP32SOLO1 IC: 7362A-CONNHUB
Europe	EU Radio Equipment Directive (RED 2014/53/EU) EN 300 330 V2.1.1:2017 EN 301 489-3 V2.1.1:2019 1999/519/EC EN 62311:2020
Radio Compliance	
USA	FCC ID: 2AC7Z-ESP32SOLO1 and VKF-CONNHUB Model: Masimo SafetyNet

Clinical Study Data

Oxygen Level (SpO2) Performance Specifications

The tables below provide A_{RMS} (Accuracy Root Mean Square) values measured using the Radius PPG sensors under no motion, with Masimo Technology in a clinical study.

Measurement A_{RMS} Values for Radius PPG Sensors	
SpO_2 Accuracy Range (%)	**ARMS (%)**
90-100	1.73
80-90	1.80
70-80	1.73
70-100	1.75

Clinical testing found the equivalent SpO_2 performance between light and dark subjects. Dark subjects identified by a Massey-Martin scale score of 4 or higher.

Group	No. Subjects	Bias	MAB	Prec.	ARMS	LOA	Npairs
Light	13	0.05	1.48	1.79	1.79	[-3.46 3.56]	449
Dark	9	0.03	1.34	1.74	1.75	[-3.39 3.45]	313

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

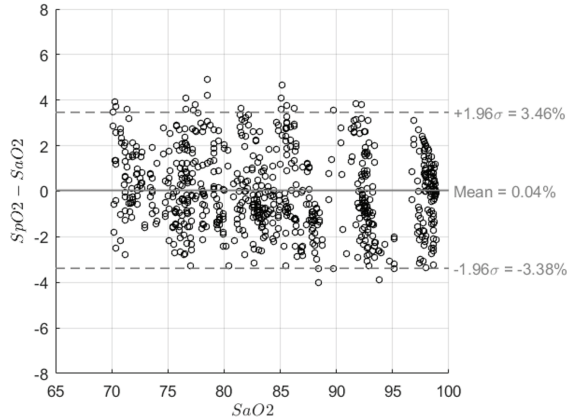


Figure 1: Residual plot with repeated measures adjusted LOA for overall flattened dataset

Opioid Halo Performance Testing

The Opioid Halo Performance was tested for 2 things: 1. How well severe OIRD was detected or "sensitivity". 2. How well it doesn't falsely detect severe OIRD or "specificity". The sensitivity and specificity can be a number between 0-100%. The higher the percentage the better the performance. However, it can be difficult to understand what a good percentage is without a comparison. Therefore, it was compared to a benchmark of a pulse oximeter alarm of 90% SpO_2 for greater 30s. The benchmark helps to see the improvement provided by Opioid Halo.

Because there are different types of opioids used in different places, the testing was done on 4 different type of opioid users: 1. Naïve users or those just prescribed opioids, 2. Chronic users or those who are regularly prescribed opioids, 3. Hospital users or those who are being administered opioids in a hospital setting, 4. Illicit users or those who are using opioids without a prescription. There was a total of 641

opioid use cases that were used to look at the Opioid Halo performance. Those cases breakdown to 135 Home Prescribed Naïve, Chronic), 242 Hospital, and 264 Illicit.

The Naïve, Chronic, and Hospital Opioid data came from pulse oximeter recordings using a Masimo SET pulse oximeter. The data from the illicit opioid users used the Opioid Halo system to collect data from illicit opioid users.

Performance data of the Opioid Halo supporting the improved detection of Oxygen Induced Respiratory Depression (OIRD) as compared to the Benchmark.

The table below shows the specificity improvement from the benchmark. Higher the specificity the more likely the alarm is due to a potential opioid overdose.

Subject Type	Data Segments		Benchmark		Halo – Level 1		Halo – Level 2		Halo – Level 3	
	Used	OIRD	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Overall	40,322	130	99.2%	80.6%	100.0%	93.9%	100.0%	97.5%	79.2%	99.5%
Naive	3,640	2	100.0%	87.4%	100.0%	97.8%	100.0%	99.3%	100.0%	100.0%
Chronic	4,478	13	100.0%	80.2%	100.0%	95.7%	100.0%	98.4%	100.0%	99.6%
Hospital	31,940	98	99.0%	79.9%	100.0%	93.2%	100.0%	97.2%	75.5%	99.5%
Illicit	264	17	100.0%	83.4%	100.0%	85.8%	100.0%	93.5%	82.4%	99.6%

Performance data of the Opioid Halo supporting the reduction of alarms as compared to the Benchmark Overall Alarms Reductions

As with all types of alarms, there is always a risk of false alarms. The table below shows how the Opioid Halo reduced the number of false alarms.

Subject Type	Subject Used	Benchmark	Halo – Level 1		Halo – Level 2		Halo – Level 3	
		Alarms	Alarms	%Reduction	Alarms	%Reduction	Alarms	%Reduction
Overall	936	33,415	8,366	75.0%	3,663	89.0%	1,097	96.7%
Naïve	58	2,196	217	90.1%	81	96.3%	5	99.8%
Chronic	77	4,991	756	84.9%	347	93.0%	145	97.1%
Hospital	242	25,928	7,212	72.2%	3,119	88.0%	923	96.4%
Illicit	264	141	87	38.3%	55	61.0%	15	89.4%
Sleeping Non-opioid users	295	159	94	40.9%	61	61.6%	9	94.3%

Sensitivity and Specificity Performance by Opioid Type

The table below shows how well the Opioid Halo alarms were able to detect severe OIRD due to different types of opioids in a hospital setting.

Delivery Method	Medication	OIRD Events	Sensitivity			Specificity		
			Halo – Level 1	Halo – Level 2	Halo – Level 3	Halo – Level 1	Halo – Level 2	Halo – Level 3
Oral	Fentanyl Rx	2	100.0%	100.0%	100.0%	85.8%	96.4%	99.4%
	Hydromorphone	26	100.0%	100.0%	80.8%	92.7%	97.3%	99.6%
	Morphine	10	100.0%	100.0%	50.0%	86.9%	92.9%	96.4%
	Oxycodone	55	100.0%	100.0%	80.0%	92.7%	97.0%	99.4%
	Hydrocodone	2	100.0%	100.0%	50.0%	93.8%	98.5%	99.9%
	Tramadol	14	100.0%	100.0%	57.1%	92.8%	96.9%	99.4%
IV	Fentanyl Rx	14	100.0%	100.0%	78.6%	93.5%	97.8%	99.9%
	Hydromorphone	16	100.0%	100.0%	75.0%	94.8%	98.0%	99.7%
	Morphine	9	100.0%	100.0%	66.7%	93.3%	97.1%	99.5%
	Oxycodone	55	100.0%	100.0%	80.0%	92.7%	97.0%	99.4%

PPV and NPV Performance by Opioid Type

The table below shows what percentage of alarms were because of severe OIRD or "PPV" and what percentage of no alarms had no severe OIRD or "NPV" in hospital setting. The higher the number the more likely an alarm is because of a potential opioid overdose.

Note: PPV may be lower in hospital patients because they are sick and have oxygen issues for reasons other than opioid overdose (e.g., COPD, Lung Injury).

Delivery Method	Medication	OIRD Events	PPV			NPV		
			Halo – Level 1	Halo – Level 2	Halo – Level 3	Halo – Level 1	Halo – Level 2	Halo – Level 3
Oral	Fentanyl Rx	2	7.7%	25.0%	66.7%	100.0%	100.0%	100.0%
	Hydromorphone	26	4.3%	10.8%	41.2%	100.0%	100.0%	99.9%
	Morphine	10	8.3%	14.3%	14.3%	100.0%	100.0%	99.4%
	Oxycodone	55	4.1%	9.3%	31.0%	100.0%	100.0%	99.9%
	Hydrocodone	2	4.0%	14.3%	50.0%	100.0%	100.0%	99.9%
	Tramadol	14	5.4%	11.8%	28.6%	100.0%	100.0%	99.8%

Delivery Method	Medication	OIRD Events	PPV			NPV		
			Halo – Level 1	Halo – Level 2	Halo – Level 3	Halo – Level 1	Halo – Level 2	Halo – Level 3
IV	Fentanyl Rx	14	13.2%	30.4%	84.6%	100.0%	100.0%	99.8%
	Hydromorphone	16	3.5%	8.7%	29.3%	100.0%	100.0%	100.0%
	Morphine	9	6.3%	13.4%	40.0%	100.0%	100.0%	99.8%
	Oxycodone	55	4.1%	9.3%	31.0%	100.0%	100.0%	99.9%

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 and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

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	+8 kV contact +15 kV air	+5 kV contact +15 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 lines +/- 1 kV for input/ output lines	+/- 2 kV for power lines +/- 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Surge IEC 61000-4-5	+/-1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/-1 kV line(s) to line(s) +/- 2 kV line(s) to earth	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	100% dip in mains voltage for 0.5 cycle 60% dip in mains voltage for 5 cycle 30% dip in mains voltage for 25 cycle	100% dip in mains voltage for 0.5 cycle 60% dip in mains voltage for 5 cycle 30% dip in mains voltage for 25 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 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	3 Vrms 10 V/m 80 MHz to 2.5 GHz	3V 10 V/m	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 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[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment. **b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Test Specifications for Enclosure Port Immunity to RF Wireless Communication Equipment

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-395	TETRA 400	Pulse modulation **(b)** 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM **(c)** +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation **(b)** 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation **(b)** 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3. 4. 35: UMTS	Pulse modulation **(b)** 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation **(b)** 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation **(b)** 217 Hz	0.2	0.3	9
5500						
5785						

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

(a) For some services, only the uplink frequencies are included.
(b) The carrier shall be modulated use a 50% duty cycle square wave signal.
(c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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*Sqrt (P)	80 MHz to 800 MHz d = 0.35*Sqrt (P)	800 MHz to 2.5GHz d = 0.7*Sqrt (P)
0.01	0.12	0.035	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.7	1.11	2.21
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		Separate collection for electrical and electronic equipment (WEEE)
IP22	Protection from solid foreign objects ≥12.5 mm diameter and against ingress from vertically falling water drops when enclose tilted up to 15°	IP47	Protection from solid foreign objects <1 mm diameter and against immersion between 15 centimeters and 1 meter in depth
	Non-Sterile		Federal Communications Commission (FCC) Licensing
	Authorized representative in the European community		Recyclable
IC Model:	Innovation, Science and Economic Development Canada (ISED)	FCC ID:	Identifies unit has been registered as a radio device
	Warning		Caution
	No		Product contains no PVC (polyvinyl chloride) material
	Manufacturer		Not made with natural rubber latex
	Date of manufacture YYYY-MM-DD	REF	Catalog number (model number)
	Storage temperature range	####	Masimo reference number

Symbol	Description	Symbol	Description
	Keep dry	SN	Serial number
	Storage humidity limitation		Do not use if package is damaged
	Atmospheric pressure limitation		AC current
	Wireless Symbol level		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
	China Restriction of Hazardous Substances	--	--
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

[1] The Masimo SET Technology has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70%-100% SpO_2 against a laboratory co-oximeter.

[2] The Masimo SET Technology has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70%-100% SpO_2 against a laboratory co-oximeter.

[3] The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%.

[4] The Masimo SET Technology has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%.

**Registered trademark of Fluke Biomedical Corporation, Everett, Washington.*

Service and Maintenance

Cleaning

The Home Medical Hub and Masimo Chip are reusable devices. The devices are supplied and used non-sterile.

The Masimo Chip should be cleaned before and after it has been applied to a user and/or in accordance with local and governmental regulations to minimize the risk of cross-contamination.

Smart Phone Cleaning

To properly clean the smart phone, refer to the smart phone's Operator's Manual or Directions For Use.

Home Medical Hub Cleaning

⚠ **CAUTION:** Check the Home Medical Hub for possible cracks or opening before cleaning.

⚠ **CAUTION:** Do not allow liquids to enter the interior of the Home Medical Hub.

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:

- 70% isopropyl alcohol
- 1:10 bleach to water solution (0.5% sodium hypochlorite)
- Super Sani-Cloth® Wipes (55% isopropyl alcohol, 0.5% quaternary ammonium chloride)
- Windex® (1.5% 2-Butoxyethanol, 1.5% ethylene glycol hexyl ether, 5% isopropyl alcohol)
- Formula 409® Antibacterial All-Purpose Cleaner (1.5% Lauramine oxide, 0.4% n-Alkyl dimethyl benzyl ammonium chloride)

Masimo Chip Cleaning

⚠ **WARNING:** Before cleaning, make sure the Masimo chip is not attached to the Masimo Sensor.

To clean the surface of the chip:

1. Wipe all surfaces of the Masimo chip with one of the following:
   a. 70% Isopropyl alcohol
   b. 10% (1:10) chlorine bleach to water solution
   c. Quaternary ammonium chloride solution
2. Inspect for visible debris and repeat the above cleaning step as needed.
3. Ensure parts are dry before use.

⚠ **CAUTIONS:**

- To avoid permanent damage to the chip, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.
- Do not immerse the chip in any liquid solution.
- Do not sterilize by irradiation, steam, autoclave, or ethylene oxide.

Customer Support

For answers to frequently asked questions (FAQ's) and product support, along with troubleshooting for your Opioid Halo product, please go to www.masimo.com/support or email *customercare@masimo.com*.

Return and Warranty

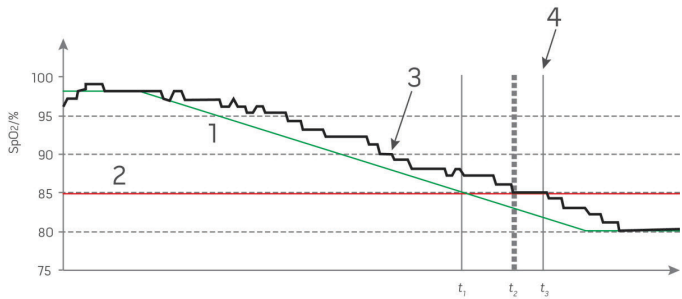
For repair, warranty and returns policy refer to https://www.masimopersonalhealth.com/pages/warranty-returns or contact Masimo Customer Support.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Concepts of Alarm Response Delay

As with any pulse oximeter equipment, the audible and visual alarms are subject to alarm response delay, which is composed of Alarm Condition Delay and Alarm Signal Generation Delay. Alarm Condition Delay is the time from the occurrence of the triggering event to when the alarm system determines the alarm condition exists. The Alarm Signal Generation Delay is the time from the onset of an alarm condition to the generation of its alarm signal. The graphic below is a simplified illustration of the concept of Alarm Response Delay and does not reflect actual lengths of delays.



Ref	Definition	Ref	Definition
1	SaO_2	**4**	Alarm Signal Generation
2	Alarm Limit	**SpO_2**	Saturation
3	Displayed SpO_2	**t**	Time

- The Alarm Condition Delay is graphically represented as $t_2 – t_1$ in the figure above to show the delay due to processing and averaging.
- The Alarm Signal Generation Delay is graphically represented as $t_3 – t_2$ in the figure above to show the delay due to alarm system strategy and communication time.
- The overall alarm system delay time is graphically represented as $t_3 – t_1$.
- For more information about alarm response delay, refer to ISO 80601-2-61.

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ALERTS WHEN HELP MAY BE NEEDED

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