

Masimo Stork™



There may be information provided in this manual that is not relevant for your system. Do not operate Masimo Stork 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 TBD

Contains IC: 21098-ESP32SOLO1; IC: 7362A-CONNHUB TBD



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About This Manual

Getting Started Guides

Use the quick reference guide included for the following:

- 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 Masimo Stork System.
- Masimo Sensor placement.
- Connecting your Masimo Stork System to WiFi.

Product Description and Intended Use

Product Description

Masimo Stork - a system that provides spot-checking and continuous monitoring of physiological data by wireless communication to medical technologies. The system includes the following pieces:

Masimo Stork App - software application installed on a smart phone that provides the graphical user interface to display your data and alarm condition status.

Masimo Sensor - wireless, wearable sensor that provides the physiological data.

Masimo Chip - attaches to the wireless Masimo Sensor and connects wirelessly to the Masimo Stork Hub.

Masimo Stork Hub - device that communicates monitoring data wirelessly from the medical technologies to the Masimo Cloud.

Masimo Cloud - a server accessed over the internet that gathers and stores measured data communicated wirelessly from the Masimo Stork Hub.

Who the Device is intended to be used on (Indications for Use)

Intended Use

ALL TBD

The Masimo Stork is intended for the spot-checking or continuous monitoring of functional oxygen saturation (SpO₂) and Pulse Rate (PR). The subject device provides the management of notifications and the ability to display and transfer aggregated data communicated from compatible medical technologies.

Indications for Use

ALL TBD

The Masimo Stork is indicated for the spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and Pulse Rate (PR) in adult, pediatric, infants, and neonates during motion, no-motion and low perfusion conditions in hospital and home environments.

Safety Information

Before using the Masimo Stork, read the following safety information carefully.

Safety Warnings

ALL TBD

WARNING: For safe use, do not use if it appears damaged.

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

WARNING: Place the Masimo Stork Hub where it will not fall on anyone.

WARNING: Make sure the oxygen level is displayed to ensure that monitoring has started.

WARNING: For safe use avoid the following:

- Do not place the Masimo Stork 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 56.
- Do not clean while the device is in use.

WARNING: Keep small parts away from small children. Small items can be a choking hazard.

WARNING: Carefully position any cables to avoid possible strangulation or entanglement.

WARNING: Do not place the Masimo Stork Hub in areas where there are a lot of flammable gases such as anesthetics, oxygen, or nitrous oxide present to prevent risk of fire.

WARNING: During defibrillation, avoid contact with any devices applied to the person to prevent electric shock.

CAUTION: Place the Masimo Stork Hub where you can easily disconnect it from AC power in case of an emergency.

CAUTION: Only use the AC power supply included with your Masimo Stork Hub to prevent damage to the device.

Note: Do not monitor more than one person at a time with Masimo Stork.

Masimo Sensor

ALL TBD

WARNING: Avoid wrapping the sensor too tightly around your finger to avoid injury.

WARNING: To avoid skin injury, consider moving the sensor to another finger after it has used more than 8 hrs.

Performance Warnings

ALL TBD

WARNING: Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your physician.

WARNING: Do not use Masimo Stork as an apnea monitor. Masimo Stork is not designed to detect apnea.

WARNING: Only use Masimo-approved parts with Masimo Stork to make sure the device works correctly.

WARNING: Check your device is working before use for longer periods by checking to see your starting oxygen level.

WARNING: Avoid placing liquids on or near the Masimo Stork Hub. Liquids spilled on Masimo Stork may affect how it works.

WARNING: Do not place anything on top of the Masimo Stork Hub to avoid damaging or blocking the wireless signal or muffling the audible alarms.

WARNING: The following factors can cause false oxygen measurements:

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

WARNING: To ensure proper notification function, check the following occasionally:

- Notification features is turned on your Smart device (i.e., sounds, vibrations, etc.).
- Smart device battery is fully charged or plugged in.
- Oxygen values are displayed on the App live view.

CAUTION: Do not place your smart phone where someone can change the App settings without you knowing.

CAUTION: Check that the Masimo Stork 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 Masimo Stork Hub plugged in while in use. Loss of power may limit the notifications available.

CAUTION: Only use the AC power supply that came with the Masimo Stork 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 Masimo Stork, locate the devices away from sources that may interfere with the Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service of the Bluetooth connection (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 smart phone, while using the Masimo SafetyNet Alert:

- Smart device should be located with responsible users.
- Smart device should not be left unattended.
- Security features on smart device should be activated.
- Unauthorized changes should not be made to the Masimo Stork system.

CAUTION: Check your setup by viewing the display on the App and the Masimo Stork Hub. The App and Masimo Stork Hub will provide an indication if there is a problem with the internet connection.

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

CAUTION: Avoid placing Masimo Stork near other wireless devices to prevent loss of performance.

Masimo Sensor

ALL TBD

WARNING: Properly apply the Masimo sensor according to sensor's Directions for Use. Applying the sensor incorrectly could result in incorrect or no readings.

CAUTION: Avoid using Masimo Sensor under bright light sources and direct sunlight to maintain the performance of the device.

CAUTION: To maintain Bluetooth connectivity with the Masimo Sensor, ensure that the Masimo Stork Hub is within the specified distance and in line-of-sight of the Masimo Sensor. See **Specifications** on page 43.

Cleaning and Service Warnings

ALL TBD

WARNING: Do not attempt to remanufacture, recondition or recycle the Masimo sensor, Masimo chip or Masimo Stork Hub to prevent harm or damage to the system.

WARNING: Always turn off and unplug the Masimo Stork Hub before cleaning to prevent harm or damage to the device.

CAUTION: Do not clean Masimo sensor, Masimo chip or Masimo Stork 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.

CAUTION: Do not submerge Masimo sensor, Masimo chip or Masimo Stork Hub in liquid or attempt to sterilize by any method to prevent damage to the device.

Compliance Warnings

ALL TBD

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

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

WARNING: Only use Masimo authorized devices with Masimo Stork. Using unauthorized devices with Masimo Stork may result in damage to the device and/or patient injury.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Masimo Stork, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION: Disposal of product: Comply with local laws when disposing the device and/or its accessories.

CAUTION: Do not place the Masimo Stork near electrical equipment that may affect the device, preventing it from working properly.

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be near Masimo Stork.

CAUTION: Keep the Masimo Stork away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.

Note: Masimo Stork 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. Masimo Stork generates, uses, and can radiate radio frequency energy and may cause interference with radio communications. To determine if Masimo Stork 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 Masimo Stork.

- Plug the receiver and Masimo Stork 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. 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 and Industry Canada's license-exempt RSS standards. 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: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Note: Users are advised that high-power radars are allocated as primary users (i.e., priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Note: When using Masimo Stork 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

Your Body and Oxygen

When we breathe, oxygen moves in our blood around our body. When we are healthy or not fatigued, our lungs are able to bring the oxygen needed by our brain, organs, and tissue. As the state of our body is always changing, it is common to see continual fluctuations in your blood oxygen over time.

However, when we are sick, fatigued, or having trouble breathing, the body can require more oxygen than can be delivered. When this occurs, your blood oxygen level can drop. These changes cannot be seen, but if our oxygen gets too low, you may feel the effects such as being lightheaded, dizzy, or having difficulty breathing. If your oxygen level stays too low for too long, the lack of oxygen to your brain, organs, and tissue or hypoxia can have serious long-term effects to your health including death.

The Masimo Stork allows you to see your oxygen level so that you can understand how your body and oxygen are connected.

If you have a medical condition that effects your breathing (e.g., asthma, COPD), your normal blood oxygen level may be lower. For these conditions, it is important that you seek the advice of your physician.

For other conditions where your blood oxygen becomes low, it is good to remember that our blood oxygen is connected to our breathing and always changing.

If you have any concerns that your oxygen level is constantly decreasing, staying low, or you are not feeling well, it is very important to not self-diagnose and seek the advice of your physician.

When using any medical device, there are risks and benefits.

Risks of Masimo Stork

- As with all medical electrical devices, there is always a risk of electrical, mechanical, and fire hazards. However, these risks have been mitigated through the design and testing of Masimo Stork.
- As with all devices with small parts, there is always a risk of a child's swallowing a component or choking. Keep small parts away from small children to prevent swallowing or choking.
- Items applied directly to the skin may cause skin irritation, pressure injury, or general discomfort. Periodically check the area where the Masimo sensor is applied to prevent potential irritations.
- As with all types of alarms, there is always a risk of missing or not hearing an alarm. To minimize this risk, ensure Masimo Stork is placed where it can be heard and the speaker is not blocked by other objects.

- As with all types of alarms, there is always a risk of false alarms. To minimize false alarms, ensure you follow all device and Masimo sensor directions, and follow troubleshooting instructions. Never assume an alarm is false; promptly address every alarm.

Benefits of Masimo Stork

- Masimo Stork has the ability to monitor wirelessly without being tethered to a monitor. This allows users the freedom of movement during activities, including sleep, not conveniently possible with a cabled connection.
- Masimo Stork is equipped with audible and visual physiological alarms that can alert you to changes in the user's condition while monitoring within a home environment.
- Masimo Stork uses the same proven pulse oximetry used in hospitals shown to have fewer false alarms¹ compared to other brand technology.
- Masimo Stork allows for the storage and review of your blood oxygen level as you go about your normal activities, including exercise or sleep.

¹ *Barker S.J. Anesth Analg. 2002 Oct;95(4):967-72.*

Description

Masimo Stork System

The Masimo Stork system consists of the following:



IMAGE TBD

Item	Description
1	Masimo Stork Hub
2	Smart phone with Masimo Stork App Installed*
3	Masimo Sensor
4	Masimo Stork Boot

* Smart phone not included.

Features

The following describes the Masimo Stork system parts.

Masimo Stork Hub Overview

The Masimo Stork Hub is a device that transfers measured data from the wireless Masimo Sensor to the Masimo Cloud and provides audible and visible alarms.



NEED NEW IMAGE

NEED TO KNOW WHAT INDICATORS THE HUB WILL HAVE

1. Pairing Symbol

Location on the Masimo Stork Hub for pairing the Masimo Chip.

2. Masimo Stork Hub Button

Used for pairing and silencing alarms.

3. Bluetooth Status LED

Shows the Masimo Stork Hub Bluetooth status. See *Masimo Stork Hub Lights* on page 14.

4. Masimo Stork Hub Status LED

Shows the Masimo Stork Hub power and monitoring status. See *Masimo Stork Hub Lights* on page 14.

5. Wi-Fi Status LED

Shows the Masimo Stork Hub Wi-Fi status. See *Masimo Stork Hub Lights* on page 14.

6. USB Power Connector

Power is provided to the Masimo Stork Hub from the AC adapter and a USB cable.

7. Masimo Chip Storage Tray

Location on the Masimo Stork Hub for storage of the chip when not in use.

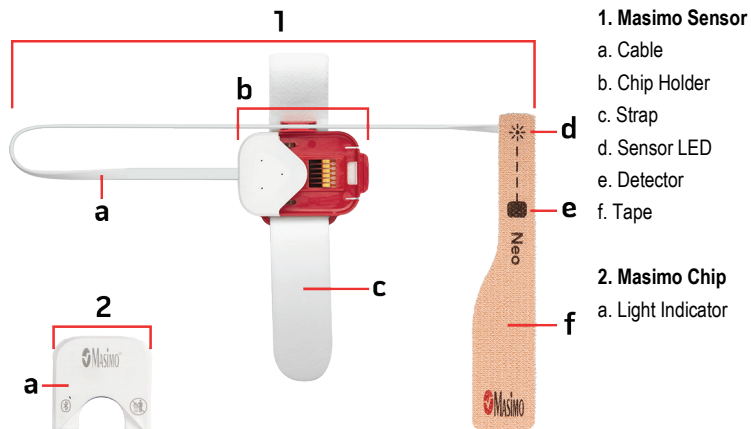
Masimo Stork Hub Lights

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

Indicator/LED Color	What does it mean?
Masimo Stork Hub Status LED	
Solid White	Hub is on and needs to be set up.
Solid Green	Hub is paired with the sensor, connected to the Wi-Fi and communicating with the Masimo Cloud.
Flashing Orange	Active Level 1 Alert. See Alarms and Alerts_O_App.
Solid Orange	Level 1 Alert is acknowledged.
Flashing Red	Active Level 2 or 3 Alert. See Alarms and Alerts_O_App.
Solid Red	Level 2 or 3 Alert is acknowledged.
Flashing Orange	Sensor battery ports are blocked.
Flashing Red	A Hub fault has been detected.
Bluetooth Status LED	
Solid White	Hub is on and needs to be set up.
Off	Hub is paired with the sensor.
Flashing White	Hub is pairing with the sensor.
Solid Orange	Sensor is disconnected from the Hub.
Wi-Fi Status LED	
Solid White	Hub is on and needs to be set up.
Off	Hub is connected to the Wi-Fi network.
Flashing White	Hub is searching for or connecting to the Wi-Fi network.
Solid Orange	Hub is connected to the Wi-Fi and the Sensor is no longer connected.

Masimo Sensor Overview

The Masimo Sensor is for use with the Masimo Stork system.



ALL TBD NEED SENSOR AND SPECS

Sensor Lights

The light indicator on the Masimo Sensor shows the status of the sensor connection and battery.

Indicator/LED Color	What does it mean?
Bluetooth Status	
Flashing Blue	Sensor is paired with the Hub.
Flashing Green	Sensor is not paired with the Hub.
Battery Status	
Flashing Orange	Sensor battery is low.
Flashing Red	Sensor battery is very low.
LED TBD	Charging TBD
LED TBD	Fully Charged TBD

ALL TBD NEED SENSOR AND SPECS FOR INDICATORS

Basic Setup and Use

Getting Started

The Masimo Stork system can be ready to use in the following steps:

1. Setup the Smart Phone - Prepare the smart phone for use with the Masimo Stork App.
 - Download the Masimo Stork App on your smart phone and complete the registration and login process.
2. Setup the Masimo Stork System – Use the Masimo Stork App and complete the following:
 - Create a profile for the baby (or babies) to be monitored.
 - Connect the Masimo Stork Hub to the App using local Wi-Fi.
 - Connect the Masimo Sensor with the Masimo Stork Hub.
 - Attach the Masimo Stork Boot to the baby.
3. View Live Data – After the Boot with Sensor is attached to the baby, open the Masimo Stork App to start monitoring and view live data on the *Vitals Dashboard*.

Step 1: Smart Phone Setup



Prepare the Smart Phone for Use:

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

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

- **Compatibility**
Note: For a list of smart phones and operating systems that work with the Masimo Stork App, check TBD WWW.??? 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 is connected to the internet**
- **Time is set to the Current Local Time**

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

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



NEED NEW
TBD

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

Create a User Account:

After installation, open the Masimo Stork App and select **Create Account**. Follow the on-screen instructions to create a new user account.

- If you have an existing user account, simply log in using the account credentials.

Step 2: Masimo Stork System Setup



After the Masimo Stork App is installed and user account created, follow the on-screen instructions to set up your Masimo Stork System:

- Set up a *Baby Profile* for the baby (or babies) to be monitored.
- Connect the Masimo Stork App to the Masimo Stork Hub and local Wi-Fi network.
- Charge the Masimo Sensor and connect the Sensor to the Masimo Stork Hub.
- Attach the Sensor to the Masimo Stork Boot and attach the Boot to the baby for monitoring.

Create a Baby Profile

After creating an account, login to the Masimo Stork App and follow the on-screen instructions to and set up a *Baby Profile*.

1. Enter the requested information about the baby when prompted and select **Continue**, or select **Skip** to not enter that information.

Note: Multiple profiles can be created to monitor different babies.

2. When the *Baby Profile* is complete, select **Set Up HUB** to continue.

Masimo Stork Hub Setup

Follow the instructions below to set up the Masimo Stork Hub.

Note: Make sure your smartphone Wi-Fi and Bluetooth connections are turned on. Refer to the smart phone's instructions to change its settings.

WARNING: Place the Masimo Stork 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 Masimo Stork Hub to a power outlet using the AC power cord and adapter and select **Continue**.

Note: The Masimo Stork Hub Status LED is white when powered on.



NEED NEW TBD

2. Scan the QR code located on the Hub as instructed on the App.
Note: If the Hub is not found when scanning the QR code, enter the Hub serial code (located on the back of the Hub) manually into the App and select **Continue**. If the Masimo Stork Hub still cannot connect, see **Troubleshooting** on page 33.
3. Next, select the wireless *Network* and enter the *Password*. Select **Continue**.
 - To view available Wi-Fi networks within range of the Masimo Stork Hub, click the *Tap to select network* field and select from the displayed list.**Note:** When prompted on the smart phone, allow Masimo Stork to access the phone's Wi-Fi settings.
4. Once the Wi-Fi connection is established, the *Masimo Stork Hub Wi-Fi Setup Successful* TBD screen will appear. If the Masimo Stork Hub cannot connect, follow the on-screen instructions to verify the network and try again or view **Troubleshooting** on page 33.
5. Next, you will connect the Masimo Sensor to the Masimo Stork Hub. See **Masimo Sensor Setup** on page 19 for additional instructions.

Masimo Sensor Setup

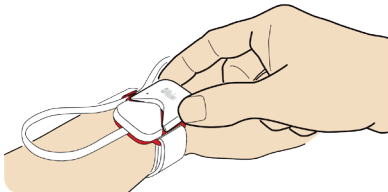
Follow the on-screen instructions to:

- Charge the Sensor.

- Pair the Sensor to the Masimo Stork Hub
- Attach the Sensor to the Masimo Stork Boot.
- Attach the Boot with Sensor to the Baby's foot.

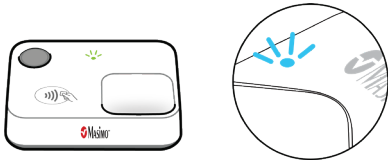
Charging the Masimo Sensor

1. To charge the Masimo Sensor, remove it from the Masimo Stork Boot.
2. Connect the Masimo Stork Sensor to a power outlet using the AC power cord and adapter and connect the charging cable to the Sensor charging port.



NEED NEW

3. Confirm successful charging of the sensor by observing the light indicators.
 - Light Indicator - turns blue TBD



NEED NEW FOR SENSOR

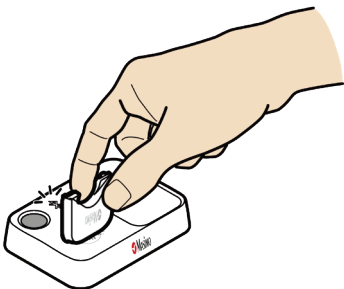
- If the sensor does not charge, see **Troubleshooting** on page 33.

Pairing the Masimo Sensor

ALL TBD NEED TO KNOW ON BOARDING PROCESS - SEE APP SCREENS

1. To pair the Masimo Sensor to the Masimo Stork Hub, follow the on-screen instructions to scan the QR code on the sensor. Confirmation TBD.

Note: If the Sensor is not found when scanning the QR code, enter the Sensor serial code (located on the Sensor) manually into the App and select **Continue**. If the Sensor still cannot connect, see **Troubleshooting** on page 33.



NEED NEW TBD

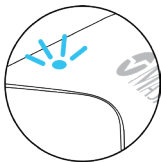
2. Confirm successful pairing once the chip is inserted into the sensor by observing the light indicators.

Masimo Stork Hub:

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

Masimo Sensor:

- Light Indicator - turns blue TBD



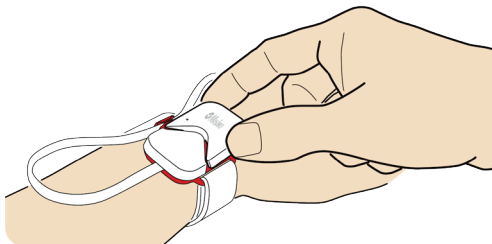
NEED NEW TBD

- If the sensor and Masimo Stork Hub cannot pair, see **Troubleshooting** on page 33.
3. After connecting the Sensor, the *Your System is Connected* screen displays indicating the <prod_name_short> App setup is completed. Select **Continue**.

Attaching the Sensor to the Masimo Stork Boot

ALL TBD - DO NOT HAVE INSTRUCTIONS

Follow the instructions to attach the Masimo Sensor to the Masimo Stork Boot.



NEED NEW TBD

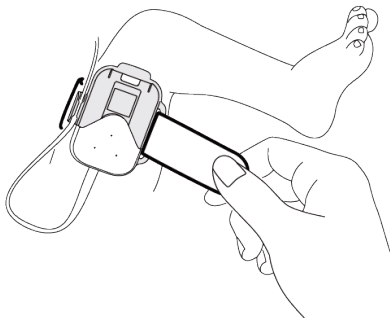
1. Step 2 TBD
2. Step 3 TBD

Attaching the Masimo Stork Boot to the Baby

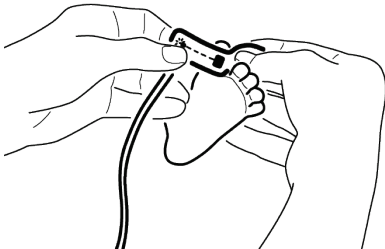
Follow the instructions to attach the Masimo Sensor and Masimo Stork Boot to the foot.


ALL TBD - DO NOT HAVE INSTRUCTIONS

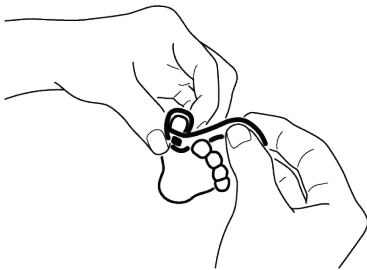
1. Place the sensor on the leg or wrist (not shown) and carefully thread the tip of the strap through the open red c loop.
2. Wrap the loose attachment strap around the leg or wrist (not shown) and press to secure.



3. Route the sensor cable so that it runs along the top of the foot. Peel off the plastic backing and place the square detector mark on the fleshy pad of the great toe. The toe next to the great toe, or the thumb can be used (not shown).



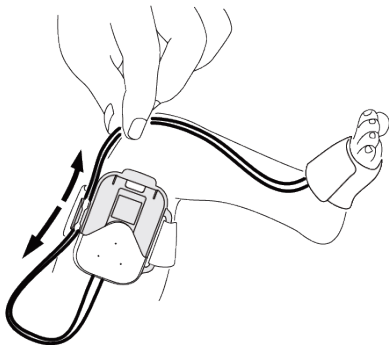
4. Wrap the adhesive tape around the toe so the emitter star  is positioned on the nail bed of the great toe.



5. Remove plastic film and continue to wrap remaining tape around the toe with the square marking directly across from the star.



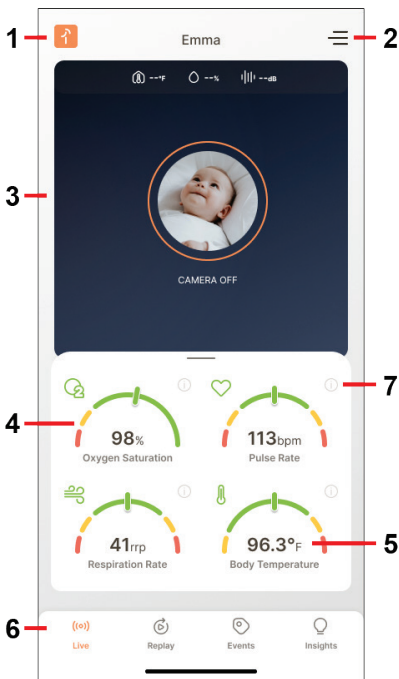
6. Adjust the sensor cable to a comfortable length. Go to **Pairing the Masimo Sensor** on page 20 for additional instructions.



Step 3: View Live Data



After setting up the Masimo Stork App, connecting the Hub and Sensor and attaching the Boot to the baby, select **Open Stork** from the App screen. The *Vitals Dashboard* screen displays data from the Masimo Sensor. The *Live* screen is also the Masimo Stork App Home Screen, with access to other App functions.



1. System Status

Displays connected devices. Access to turn connected devices On or Off.

2. Side Menu

Displays the *App Menu* and provides links to App functions and features.

3. Camera Display

Displays the camera image, ambient temperature, humidity and sound level where the camera is located.

4. Vitals Gauge *

Displays the data in a gauge style.

5. Vitals Display *

Displays the data in numerical format. See **Health Settings** on page 31.

6. Bottom Navigation

Provides links to data specific functions and features. See **Bottom Navigation** on page 31.

7. Data Information

Displays detailed information about the data measurement.

* If a sensor is not paired to the Masimo Stork Hub, a dash displays for the number, and the pointer does not show on the gauge.

Alarms and Notifications

ALL TBD - I HAVE NOTHING ABOUT ALARMS

Masimo Stork provides visual and audible alarms when your oxygen level becomes low. Masimo Stork will also contact your emergency contacts and notify if your oxygen level drops too low and you are unaware or unable to respond.

Alarm Levels and Messages

To help ensure your safety, a notification escalation policy is provided to establish three (3) levels of notifications. The level of notification is based on your risk level taking into account your oxygen level and length of time at a low oxygen level.

Alert Events

Some Alert Events are pre-configured. Alert Event can be customized by you or on the advice of your physician. See Oxygen Level for Alert Event defaults and available settings.

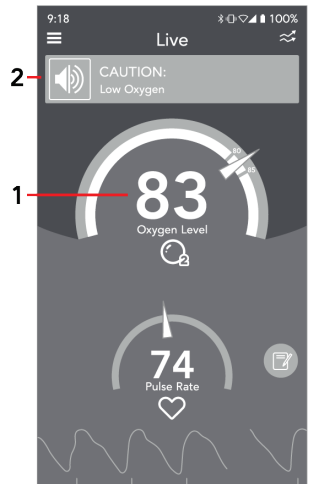
Level 1

Visual Alarm	Audible Alarm	Emergency Contact
CAUTION (Yellow)	Yes	Not Contacted

When Level 1 is triggered, an alarm sounds on your Masimo Stork Hub and the App.

The App displays a yellow CAUTION banner at the top of screen.

Touch the Oxygen Level (1) or the yellow banner (2) to learn what the Level 1 notification means.



LEVEL 1 CAUTION Alert Event Information

Information about the low oxygen level event is shown along with steps on how to help your oxygen level recovery.

You have the option to:

1. Call a designated emergency contact (1) to assist you.
2. Silence the alarm

On the App: Tap the alarm icon on the top left corner of the pop-up (2)

Masimo Stork Hub: Press the button once.

See Silence Alarms for additional information. To exit the screen, tap the "X" (3) or select the **Close** button.



Levels 2 and 3

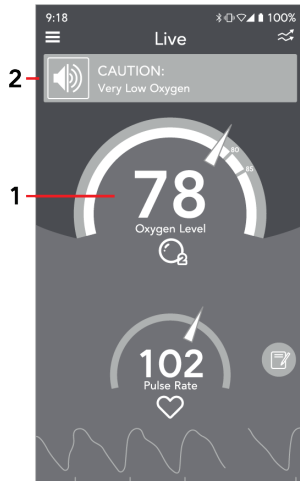
Notification Level	Visual Alarm	Audible Alarm	Emergency Contact
Level 2	WARNING (Red)	Yes	Message sent to Emergency Contact
Level 3	EMERGENCY (Flashing Red)		

When Level 2 or 3 alarms are triggered, an alarm will sound on your Masimo Stork Hub and the App.

The App will display your Oxygen Level in the red zone and a red banner at the top of screen.

- Level 2 Alarm: WARNING message.
- Level 3 Alarm: EMERGENCY message.

Touch the Oxygen Level (1) or red banner (2) to learn what the Level 2 or 3 alarm means.



LEVEL 2 WARNING/LEVEL 3 EMERGENCY Alert Event Information

Information about the low oxygen level event is given along with steps on how to help your oxygen level recovery.

Designated emergency contacts are notified to assist you.

You have the option to:

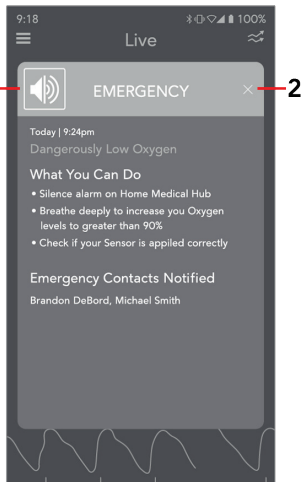
1. Silence the alarm

Silence the Alarm

On the App: Tap the alarm icon on the top left corner of the pop-up (1)

Masimo Stork Hub: Press the button once.

See Silence Alarms for additional information. To exit the screen, select the "X" (2) or select the **Close** button.



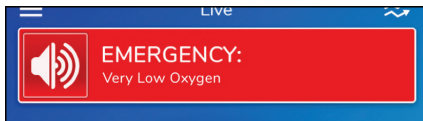
Silence Alarms

ALL TBD NEED TO KNOW HOW TO SILENCE ALARMS

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

Silencing Alarms From the App

Touch the Speaker icon  shown on the banner to silence the App alarm.



NEED NEW SCREEN SHOT

Silencing Alarms From the Masimo Stork Hub

Press and release the Masimo Stork Hub button to silence the Masimo Stork Hub alarm.



NEED NEW IMAGE

Advanced Use

Health Settings

The *Health Settings* menu is located within the *App Menu*. See **Step 3: View Live Data** on page 24. Options available include:

- Body Temp - Information about the Body Temp and available settings.
- Room Temp - Displays information about the Room Temp and available settings.
- Humidity - Displays information about the room Humidity and available settings.

Bottom Navigation

Use the Bottom Navigation to view data in the following ways:

Live - View live data

Replay - View previous data TBD

Events - TBD

Insights - TBD

Troubleshooting

Masimo Stork Messages

ALL TBD

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

Displayed Messages	Potential Causes	Next Steps
<i>"Difficulty in obtaining a reading"</i>	Interference while monitoring.	Please ensure that: <ol style="list-style-type: none">1. The sensor is not on a finger with jewelry, such as a ring.2. You move away from ambient lighting and computer displays/TVs.3. You are not wearing artificial nails or excessive nail polish on the monitored finger. If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.
<i>"Replace your sensor"</i>	Sensor is not working.	Replace sensor.
<i>"Wireless sensor disconnected during an alert"</i>	Sensor became disconnected during audible alerts for including: <ul style="list-style-type: none">• Physiology alert or technical alert• Low SpO₂• Sensor off• Obstructed battery• Low battery• Depleted battery	<ul style="list-style-type: none">• Press the alarm silence button on the Masimo Stork Hub. Follow the instructions and attempt to pair the sensor again. See Pairing the Masimo Sensor on page 20.• If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.
<i>"Allow Masimo Stork to access your contacts"</i>	Access to contacts on smart phone has not been granted.	Allow smart phone permissions to share contacts with the Masimo Stork App.
<i>"Your Emergency Contact list is empty. Touch the plus icon to start adding Emergency Contacts"</i>	When emergency contact list does not include a contact.	Follow instructions on the app to add emergency contacts.
<i>"Cannot modify a device that is in an active monitoring state. Please end your monitoring session and try again."</i>	When trying to change a setting that may disrupt alarms/notifications while in a monitoring state.	End the monitoring session before attempting to modify the device.

Displayed Messages	Potential Causes	Next Steps
"Confirm you Email"	When an unverified email address was used to log into the app.	Confirm the email as requested.
"A confirmation email was sent to emailaddress@example.com. Follow the instructions for confirming your email address then return to the App."	When a new email address is submitted during setup.	Follow the instructions on the confirmation email.
"An Emergency Contact is a designated friend, family member or caregiver that will be alerted in the event you need immediate assistance regarding your Oxygen levels. SafetyNet gives you the option to Add an Emergency Contact now or later."	When adding an emergency contact to describe an emergency contact.	<ul style="list-style-type: none"> • For information only, no action is required. • For more information on emergency contacts go to mymasimo.co.uk/safetynet-alert.
"Add Manually" "Create a new emergency contact. Please fill out the following information below"	When adding an emergency contact manually.	For information only, no action is required.
"Request Sent" "A request has been sent to your Emergency Contact. Follow up with your Emergency Contact to make sure they accept."	Displayed after successfully sending an emergency contact invitation	For information only, no action is required.
"Email Sent!" "Please check your email to confirm"	Resend button was pressed to request a new email verification link.	For information only, no action is required.
"Device in use" "Cannot modify a device that is actively monitoring. Please end your monitoring session and try again."	When an attempt was made to modify or delete the Masimo Stork Hub during active monitoring.	End the monitoring session before attempting to modify the device.

Displayed Messages	Potential Causes	Next Steps
"Remove this emergency contact?" "Remove selected emergency contacts?"	Displayed when removing one or more emergency contacts.	Select Remove to confirm or Cancel to cancel the operation.
"Remove this device?"	Displayed when attempting to remove Masimo Stork Hub	Select Remove to confirm or Cancel to cancel the operation.
"Save Changes?" "Your unsaved changes will be lost. Save changes before closing?"	Displayed when attempting to update profile information.	Select Yes to confirm or No to not save changes.
"Your Masimo Stork Hub is paired"	The Masimo Stork Hub has paired successfully.	For information only, no action is required.
"No Masimo Stork Hub added"	Masimo Stork Hub is not connected to the app.	Follow instruction on the app or this manual to complete set up. See Masimo Stork Hub Setup on page 19.
"Masimo Stork Hub not found"	Timeout has occurred during setup when searching for Masimo Stork Hub.	Follow the troubleshooting section of this manual to resolve the issue.
"Masimo Stork Hub Disconnected from Server"	Masimo Stork Hub is disconnected from the cloud server.	Follow the troubleshooting section of this manual to resolve the issue.
"Masimo Stork Hub Error"	Masimo Stork Hub internal hardware fault.	The Masimo Stork Hub requires replacement, please contact Masimo Customer Support. See Customer Support on page 57.
"Unable to connect to Wi-Fi"	Wi-Fi connection failure due to timeout or invalid password.	Enter the correct password.
"No Internet Connection"	<ul style="list-style-type: none"> The smart phone is not connected to a Wi-Fi network. The smart phone is not connected to a cellular network. 	Ensure the smart phone is connected to a Wi-Fi or cellular network.
"Enable phone Bluetooth"	Smart phone Bluetooth is turned off.	Turn on the smart phone Bluetooth.
"The username entered already exists, please try another"	User name already exist with another user.	Please choose another user name.
"Battery low Warning"	Sensor battery is low.	Replace sensor.
"Depleted Battery"	Sensor battery is depleted.	Replace sensor.

Displayed Messages	Potential Causes	Next Steps
"Wireless Sensor Disconnected"	Sensor is not monitoring.	Ensure sensor placement steps are completed and you are obtaining readings.
"Your oxygen level measurement has a low value of 76%"	Level 1 alarm is triggered.	Follow instruction on the app to resolve the condition.
"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.	Place the sensor on properly. You may go to the options menu to view the sensor placement videos. See Masimo Sensor Setup on page 19.
"Allow Masimo Stork to access this device's location"	Location services permissions have not yet been granted when attempting to search for a Bluetooth device.	Allow the smart phone permission to share its location with the Masimo Stork App.
"Please Enable App Notifications"	Notifications are not enabled on the smart phone for the Masimo Stork App.	Enable notifications on the smart phone for the Masimo Stork App.
"Low Disc Space Warning!"	Low diskspace during active monitoring and writing session trend.	Clear diskspace on the smart phone. A minimum of 100MB free disc space is required on the smart phone for the Masimo Stork App to operate properly.
"You cannot access this item at the moment."	Error when connecting to the server.	<ul style="list-style-type: none"> • Try again. • If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.
"There was an error processing your request."	Error when connecting to the server.	<ul style="list-style-type: none"> • Try again. • If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.
"This request is not understood."	Error when connecting to the server.	<ul style="list-style-type: none"> • Try again. • If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.
"Username or password invalid, please try again."	Error when connecting to the server. Displayed when invalid credentials are used during the sign in process	<ul style="list-style-type: none"> • Reenter the Username and Password. • If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.
"The username entered already exists, please try another."	Error when connecting to the server. Displayed during registration when the username/email is already in use by	Try a new Username and Password.

Displayed Messages	Potential Causes	Next Steps
	another user.	
<i>"This account has already been verified."</i>	When attempting to resend an email Verification link to an already verified account.	Continue with Masimo Stork App setup, as email has already been verified.
<i>"There is no account registered under this username."</i>	Error when connecting to the server. Displayed when a user attempts to sign in with a username that does not exist.	Reenter the Username and Password. If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.
<i>"User has already registered a different device"</i>	Error adding a new device. When adding a device fails due to different existing device	Follow steps to remove current device in order to add new device.
<i>"This Masimo Stork Hub has already been registered to an account."</i>	Error adding a device. When attempting to register a device that has already been registered to another user	Remove the device from the original account. If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.
<i>"Device deleted successfully"</i>	When attempting to remove a device that no longer exists for this user on the cloud.	For information only, no action is required.
<i>"Invitation already sent to this Emergency Contact."</i>	When attempting to add an emergency contact that has a pending/active invitation with the current user.	For information only, no action is required.
<i>"Emergency Contact deleted successfully"</i>	When attempting to remove an emergency contact that no longer exists for this user on the cloud.	For information only, no action is required.
<i>"Maximum number of emergency contacts reached."</i>	When attempting to add an emergency contact when the limit has reached. Limit = 10	For information only, no action is required.
<i>"Something unexpected happened. Please try again later."</i>	System error.	<ul style="list-style-type: none"> • Try again. • If you still experience issues, please contact Masimo Customer Support. See Customer Support on page 57.

Troubleshooting Masimo Stork

ALL TBD

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

Symptom	Potential Causes	Next Steps
<i>Masimo Stork App does not turn on</i>	<ul style="list-style-type: none">• Depleted smart phone battery.• Masimo Stork App needs to be updated.• Incompatible smart phone.	<ul style="list-style-type: none">• Connect smart phone to battery charger and charge battery. Refer to the smart phone's Operator's Manual or Directions For Use.• Check for Masimo Stork App updates.• Check smart phone compatibility. See Specifications on page 43.• Contact Masimo Customer Support. See Customer Support on page 57.
<i>Masimo Stork App turns off</i>	<ul style="list-style-type: none">• Depleted smart phone battery.• Masimo Stork App needs to be updated.• Incompatible smart phone.	<ul style="list-style-type: none">• Connect smart phone to battery charger and charge battery. Refer to the smart phone's Operator's Manual or Directions For Use.• Check smart phone compatibility. See Specifications on page 43.• Check for Masimo Stork App updates.• Contact Masimo Customer Support. See Customer Support on page 57.
<i>Masimo Stork App does not communicate with Masimo Stork Hub</i>	<ul style="list-style-type: none">• Masimo Stork Hub is not powered on.• Smart phone is not in close proximity to Masimo Stork Hub.• Bluetooth on the smart phone is not turned on and/or not correctly configured.• Smart phone does not support Bluetooth Low Energy (BLE).	<ul style="list-style-type: none">• Check that Masimo Stork Hub is plugged into the AC power supply.• Ensure the smart phone is in close proximity with Masimo Stork Hub.• Ensure Bluetooth on the smart phone is turned on.• Check smart phone compatibility. See Specifications on page 43.• Update the smart phone software. Refer to the smart phone's Operator's Manual or Directions For Use.• Contact Masimo Customer Support. See Customer Support on page 57.

Symptom	Potential Causes	Next Steps
<i>Masimo Stork Hub does not connect to Wi-Fi or Masimo Cloud</i>	<ul style="list-style-type: none"> • Masimo Stork Hub is not plugged in. • Incorrect Wi-Fi network selected. • Incorrect Wi-Fi password is entered. • Wi-Fi network is not correctly configured. • Masimo Cloud may be down. 	<ul style="list-style-type: none"> • Ensure Masimo Stork Hub is plugged in. • Ensure smart phone is connected to correct Wi-Fi network. See Masimo Stork Hub Setup on page 19. • Ensure correct Wi-Fi network is selected. See Masimo Stork Hub Setup on page 19. • Ensure correct Wi-Fi password is entered. See Masimo Stork Hub Setup on page 19. • Check that the wireless features are correctly configured. Refer to the smart phone's Operator's Manual or Directions For Use. • Check network settings and availability. You may need to call network provider for further assistance. • Contact Masimo Customer Support. See Customer Support on page 57.
<i>Masimo Sensor does not pair with Masimo Stork Hub</i>	<ul style="list-style-type: none"> • Masimo Stork Hub is not plugged in. • Chip is not inserted into sensor. • Sensor is not in close proximity with Masimo Stork Hub during pairing. • Pairing button is released too soon. • Incorrect user logged into the Masimo Stork App. • Masimo Stork Hub has been registered with another account. • Depleted sensor battery. 	<ul style="list-style-type: none"> • Ensure Masimo Stork Hub is plugged in. • Ensure the chip is firmly inserted into the sensor. See Attaching the Sensor to the Masimo Stork Boot on page 21. • Ensure the sensor is in close proximity with Masimo Stork Hub during pairing. • Ensure to press and hold the pairing button for 5 seconds until an audible tone is heard. See Masimo Stork Hub Setup on page 19. • Ensure correct user is logged into the Masimo Stork App. • Contact Masimo Customer Support. See Customer Support on page 57.
<i>Masimo Stork Hub turns off (not lit up)</i>	<ul style="list-style-type: none"> • Masimo Stork Hub is not plugged in. • Internal components may not be working properly. 	<ul style="list-style-type: none"> • Ensure Masimo Stork Hub is plugged in. • Contact Masimo Customer Support.
<i>Masimo Stork Hub speaker does not work (no sound or muffled sound)</i>	<ul style="list-style-type: none"> • Speaker may be blocked by environment (ex. blankets or other appliances). • Internal components may not be working properly. 	<ul style="list-style-type: none"> • Turn Masimo Stork Hub on and off by unplugging the unit. • Check that the device speaker is not being muffled. • Check that the Masimo Stork Hub is on a flat surface with minimal objects surrounding it. • Contact Masimo Customer Support. See Customer Support on page 57.

Symptom	Potential Causes	Next Steps
<i>Masimo Cloud unavailable</i>	<ul style="list-style-type: none"> • Wi-Fi is not turned on and/or not correctly configured. • Wireless service is weak or unavailable in the current location. 	<ul style="list-style-type: none"> • 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 phone's 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 phone's Operator's Manual or Directions For Use. • Contact Masimo Customer Support. See Customer Support on page 57.
<i>Incorrect user data is displayed</i>	<ul style="list-style-type: none"> • Incorrect user currently logged into the Masimo Stork App. 	<ul style="list-style-type: none"> • Ensure the correct user is logged into the Masimo Stork App. • Log out the incorrect user and log into the correct account. • Restart the Masimo Stork App and login to the system. • Contact Masimo Customer Support. See Customer Support on page 57.
<i>NO user data is displayed</i>	<ul style="list-style-type: none"> • Incorrect user logged into the Masimo Stork App. • Wi-Fi is not correctly configured. • Smart phone settings are incorrect. • Sensor is not connected to the Masimo Stork Hub. • No previous sessions have been recorded. 	<ul style="list-style-type: none"> • Ensure the correct user is logged into the Masimo Stork App. • Restart Masimo Stork App and login to the system. • Check that the wireless feature is correctly configured. Refer to the smart phone's Operator's Manual or Directions For Use. • Check network settings and availability. May have to call network provider for further assistance. • Contact Masimo Customer Support. See Customer Support on page 57.
<i>Delayed data updates</i>	<ul style="list-style-type: none"> • Wi-Fi is not correctly configured. 	<ul style="list-style-type: none"> • Check that the wireless feature is correctly configured. Refer to the smart phone's Operator's Manual or Directions For Use. • Check network settings and availability. You may need to call network provider for further assistance. • Restart Masimo Stork App and login to the system. See • Contact Masimo Customer Support. See Customer Support on page 57.
<i>User alarms do not appear during events</i>	<ul style="list-style-type: none"> • Incorrect user currently logged into Masimo Stork App. • Wi-Fi network not available. • System settings have changed. 	<ul style="list-style-type: none"> • Ensure Masimo Stork is connected to Wi-Fi. See Masimo Stork Hub Setup on page 19. • Ensure the correct user is logged into Masimo Stork App. • Restart Masimo Stork App and login to the system. • Ensure alert notification settings are turned on. • Contact Masimo Customer Support. See Customer Support on page 57.

Symptom	Potential Causes	Next Steps
<i>Masimo Stork App does not detect that the sensor is applied to the hand</i>	<ul style="list-style-type: none"> • Sensor not properly placed on user. • Sensor not properly paired to Masimo Stork Hub. • Damaged sensor. • Internal failure. 	<ul style="list-style-type: none"> • Reapply the sensor. • Pair the sensor with Masimo Stork Hub. See Pairing the Masimo Sensor on page 20. • Replace sensor. • Turn Masimo Stork Hub Off and On by unplugging the device then plug it in to start up • Contact Masimo Customer Support. See Customer Support on page 57. •

Troubleshooting Measurements

ALL TBD

The following section lists possible measurement symptoms, potential causes, and next steps. For more information, see **Safety Information** on page 5.

Symptom	Potential Causes	Next Steps
<i>Difficulty obtaining a reading.</i>	<ul style="list-style-type: none"> • Incorrect placement of sensor on user. • Misalignment of sensor components. • Low perfusion (blood flow). • Excessive user motion. • Excessive ambient or strobing light. • Low battery/SafetyNet Masimo Stork Hub not plugged into AC power supply. 	<ul style="list-style-type: none"> • 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 Customer Support on page 57.
<i>Measurement values displayed as dashes.</i>	<ul style="list-style-type: none"> • Measurement may still be in progress. • Incorrect placement of sensor on user. • No Connection to Masimo Cloud. • Sensor is damaged, not functioning or has a dead battery. 	<ul style="list-style-type: none"> • 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 Customer Support on page 57.

Symptom	Potential Causes	Next Steps
<p><i>Unexpected or unlikely measurement values</i></p>	<ul style="list-style-type: none"> • Incorrect placement of sensor on user. • Low signal quality. 	<ul style="list-style-type: none"> • 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 Customer Support on page 57.

Appendix

Specifications

Masimo Stork App

Measurement Range

Measurement	Display Range	Unit of Measure
Oxygen Level (SpO ₂)	0 to 100	%
Pulse Rate (PR)	0 to 240	bpm
Perfusion Index (Pi)	0 to 20	N/A

Smart Phone Compatibility

Item	Specification*
Operating System	Android 6.0 (Marshmallow) (minimum)
	iOS 12.0 (minimum)

* For complete specifications, refer to www.mymasimo.co.uk/safetynet-alert.

Masimo Sensor

Weight Range and Measurement Site

Population	Weight	Measurement Site
Adult and Pediatric	> 40 kg (> 88.2 lbs)	Finger
Neonate	< 3 kg (< 6.6lbs)	Finger or Foot

Accuracy (ARMS*)

Oxygen Level (SpO ₂)		
Range	70% to 100%	
No Motion [1]	Pediatrics	2%
	Neonates	3%
Motion [2]	Pediatrics, Neonates	3%
Low perfusion [3]	Pediatrics	2%
	Neonates	3%
Pulse Rate (PR)		
Range	25 bpm to 240 bpm	
No motion	Pediatrics, Neonates	3 bpm
Motion	Pediatrics, Neonates	5 bpm
Low Perfusion [4]	Pediatrics, Neonates	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 $\pm A_{RMS}$ of the reference measurements in a controlled study.

Oxygen Level (SpO₂) ARMS Performance Specifications

The tables below provides A_{RMS} (Accuracy Root Mean Square) values measured using the Masimo Sensor (Radius PPG) 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	1.14
80-90	1.29
70-80	1.41
70-100	1.33

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.

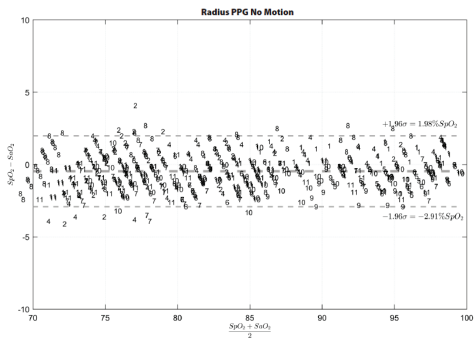


Figure 1: Radius PPG Sensors (ARMS 70-100%)

Electrical

Battery - Masimo Sensor

Run Time	96 hours in typical continuous usage
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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 Stork Hub

Electrical

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

Physical Characteristics

Masimo Stork Hub	
Dimensions	3.45" x 2.48" x 0.78" (8.76 cm x 6.3 cm x 2 cm)
Weight	0.12 lbs. (56g)

Environmental

Environmental Conditions - Masimo Stork 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

Compliance

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

Safety Standards Compliance
IEC 60601-1

Safety Standards Compliance
IEC 62304
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	IP22 (Protection from solid foreign objects ≥ 12.5 mm diameter and against ingress from vertically falling water drops when enclosure tilted up to 15°)
Mode of Operation	Continuous

Wireless Specifications

Communication (Bluetooth)	
Type	Bluetooth
Frequency	2402-2480 MHz
Max Peak Output Power	8.45 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	1 Mbps
Recommended Max. Range	100 ft (~30 meters) line-of-sight

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
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

Guidance and Manufacturer's Declarations - Electromagnetic Compliance

Electromagnetic Emissions

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 (Radiated) CISPR 11	Group 1 Class B	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 (Conducted) CISPR 11	Group 1 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	

Electromagnetic Immunity

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	+/- 8 kV contact +/- 15 air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electromagnetic Immunity			
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.
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.
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	Performed over 0.15-80 MHz
	6 Vrms	6 Vrms	Performed on the following ISM (industrial, scientific and medical) bands of frequency: The bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz
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.

Electromagnetic Immunity			
Voltage dips on power supply input lines IEC 61000-4-11	0% U_T^1 , 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°; 0% U_T 1 cycle, and 70% U_T 25/30 cycles at 0°	0% U_T^1 , 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°; 0% U_T 1 cycle, and 70% U_T 25/30 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Interruptions on power supply input lines IEC 61000-4-11	0% U_T , 250/300 cycle	0% U_T , 250/300 cycle	
Radiated RF IEC 61000-4-3	10 V/m	10 V/m	Performed over 80 MHz to 2.7 GHz
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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.</p>			

¹ U_T : Rated voltage for the equipment.

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)
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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)
	$d = 0.6 \cdot \sqrt{P}$
0.01	0.06
0.1	0.19
1	0.6
10	1.9
100	6

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.













Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment















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
	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 enclosure 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
	Caution		Product contains no PVC (polyvinyl chloride) material
	Manufacturer		Not made with natural rubber latex

Symbol	Description	Symbol	Description
	Date of manufacture YYYY-MM-DD		Catalog number (model number)
	Storage temperature range		Masimo reference number
	Keep dry		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: eFU 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% SpO₂ 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% SpO₂ 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 Masimo Stork Hub is a reusable device. The devices are supplied and used non-sterile.

The Masimo Sensor should be removed from the Masimo Stork Boot and both cleaned separately before and after they have 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.

Masimo Stork Hub Cleaning

ALL TBD

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

CAUTION: Do not allow liquids to enter the interior of the Masimo Stork 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 Sensor Cleaning

ALL TBD

WARNING: Before cleaning, make sure the sensor and chip are not applied to the hand.

To surface clean the chip and wireless receiver:

1. Wipe all surfaces of the chip and wireless receiver 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. Dry cleaned parts before use.

CAUTIONS:

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

Masimo Sensor Cleaning

ALL TBD

WARNING: Before cleaning, make sure the sensor and chip are not applied to the hand.

To surface clean the chip and wireless receiver:

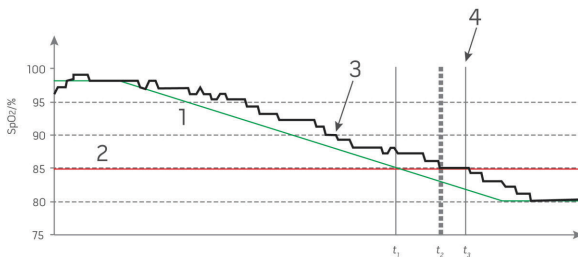
1. Wipe all surfaces of the chip and wireless receiver with one of the following:
 - a. 70% Isopropyl alcohol
 - b. 10% (1:10) chlorine bleach to water solution
 - c. Quaternary ammonium chloride solution
2. Inspect for visible debris and repeat the above cleaning step as needed.
3. Dry cleaned parts before use.**CAUTIONS:**
 - To avoid permanent damage to the chip and wireless receiver, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.
 - Do not immerse the chip and wireless receiver 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 Masimo Stork product, please go to www.mymasimo.co.uk/safetynet-alert or email customercare@masimo.com.

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. While 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.



Reference	Definition	Reference	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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