

stork

vitals

Smart Home Baby Monitoring System



For Sale in the U.S.A.

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

Wireless Radio:

Masimo Stork Hub:

- FCC ID: 2AC7Z-ESP32WROVERE

- IC: 21098-ESPWROVERE

Masimo Stork Sensor:

- FCC ID: VKF-STORK

- IC: 7362A-STORK



Manufacturer:


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Irvine, CA 92618, USA

www.masimostork.com

Patents: www.masimo.com/patents.htm

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About This Manual

This Manual provides an overview of the Masimo Stork and how to set up and use the system. You must read and understand the warnings and precautions to help ensure safe and effective use of the Stork System. See *Safety Information* on page 7. 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 user.

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

A *caution* is given when special care is to be exercised by the user to avoid injury to the user, 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 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 Stork System.
- Connecting your Stork Hub to Bluetooth and Wi-Fi.
- Stork Sensor pairing.
- Placing sensor in the Stork Boot and boot placement.

Glossary

Hemoglobin: The protein in red blood cells that moves oxygen from the lungs throughout the body and carbon dioxide from the tissues back to the lungs.

Oxygen Saturation: The percentage of hemoglobin in blood that is bound to oxygen.

Parameter: A parameter is an element of a system that is critical in evaluating the system's condition.

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

Pulse Rate: The number of times a heart beats in a minute.

Skin Temperature: Temperature that reflects the surface temperature at the foot and not the body temperature.

Product Description and Intended Use

Product Description

Masimo Stork™ is a smart home baby monitoring system designed for parents to monitor baby at home. Masimo Stork consists of a sensor, boot, and hub that used with a cloud and smart device app.

The Stork smart home baby monitoring system consists of the following:

- **Stork App:** A smart phone application that provides the display of the monitoring data (e.g., SpO₂, Pulse Rate, Temperature).
- **Stork Hub:** Communicates data and notifies wirelessly from the medical technologies to the Masimo Cloud. It also provides audible and visible alarms.
- **Stork Sensor:** A wireless sensor that slots into the bottom of the Stork Boot. The sensor uses Masimo SET® technology to provide pulse oximetry monitoring data, including oxygen saturation, pulse rate. The sensor also provides a temperature measurement. It is also capable of determining the baby's position and notifying you in the app if baby is face up or face down.
- **Stork Boot:** Designed for comfort using soft, medical-grade silicone, the boot has a slot just under baby's foot to allow you to insert the Stork Sensor and hold it in place. The boot comes in three sizes. Small and medium sizes are included. A large size is sold separately.
- **Masimo Cloud:** A server accessed over the internet that securely gathers and stores monitoring data from the Stork Sensor and the Stork Hub.

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

Intended Use

The Masimo Stork™ is a wearable device intended for the monitoring of multiple physiological parameters.

Indications for Use

The Masimo Stork™ is indicated for the spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and Pulse Rate (PR) during no-motion, motion, and low perfusion conditions of infants and neonates who are 0 to 18 months of age and between 6 to 30 lbs. The Masimo Stork™ is also indicated for continuous skin temperature measurements of infants and neonates who are 0 to 18 months and between 6 to 30 lbs. Masimo Stork™ is indicated for use in home environments.

The Masimo Stork™ can be used to supplement a caregiver's decision to seek additional guidance for the care of an infant or neonate. It is not intended to provide notifications for every episode of the unexpected occurrences of elevated or depressed PR or a low SpO₂; rather, the Masimo Stork™ is intended to provide a notification only when sufficient data are available for analysis.

The Masimo Stork™ is not intended to replace the monitoring, diagnosis, or treatment provided by a physician or healthcare provider. The Masimo Stork™ is not intended for use with infants and neonates previously diagnosed with cardiovascular or respiratory disease or conditions.

Safety Information

Before using Stork, read the following safety information carefully. Always consult a physician if you have concerns. Call emergency services if you believe your baby is having a medical emergency. Do not rely on Stork for a clinical assessment. A clinical assessment of your baby should be done by a physician.

Safety Use Information

⚠ WARNING: For safe use, do not use any component of the Stork System if it appears damaged.

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

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

⚠ WARNING: Remove the Stork Sensor before bathing to prevent damage.

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

⚠ WARNING: Secure the Stork Hub where it will not fall on anyone.

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

⚠ WARNING: Avoid strapping the boot too tightly around the foot to avoid skin injury.

⚠ WARNING: To avoid skin injury, consider alternating feet after more than 8 hrs of continuous use.

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

⚠ CAUTION: Remove Stork Boot and Sensor before placing baby in water and dry baby's foot completely before placing sensor and boot back on.

⚠ CAUTION: Remove Stork boot and sensor when baby is standing or walking to minimize impact to baby's balance. Boot may remain on when baby is standing in the crib.

⚠ CAUTION: With the exception of the Stork silicone boot and straps, do not store or leave any part of the Stork baby monitoring system near a body of water such as a baby bathtub, running sink, or shower, in order to reduce risk of water damage.

⚠ CAUTION: Only use the AC power supply and cable included with your Stork Sensor to prevent damage to the device.

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

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

Note: Consult with the baby's healthcare provider if they have concerns regarding sleep interruptions related to the device.

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

Performance Warnings

General

⚠ WARNING: Do not use the device on preterm babies as they may have foot sizes that will not fit the smallest Stork Boot.

⚠ WARNING: Do not use the device as an apnea monitor or as a monitor to prevent sudden infant death syndrome (SIDS). Oxygen level changes may be delayed from when breathing actually stops.

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

⚠ WARNING: Properly apply the Stork Sensor according to the instructions in this manual. Applying the Sensor incorrectly could result in incorrect or no readings.

⚠ WARNING: Displayed parameter(s) may not be accurate when a low SIQ or low confidence message is provided. You should consider reapplying the sensor. Check the sizing of the Stork Boot and Straps being used.

⚠ WARNING: The Stork is not intended to detect every instance of elevated or depressed Pulse Rate, or low Oxygen Saturation (SpO₂). The notifications are intended to identify instances of the pulse rate and SpO₂ moving outside preset thresholds and when sufficient signal quality is present.

⚠ CAUTION: The sensor and boot should not be worn with a sock as the sensor needs to come in contact with baby's skin to work accurately.

⚠ CAUTION: Check the volume and settings of the alarms so that you can hear them without interrupting the sleep of your baby.

⚠ CAUTION: Check that the Stork notifications 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: Avoid using Stork Sensor under bright light sources and direct sunlight to maintain the performance of the device.

⚠ CAUTION: Keep the Stork Hub plugged in while in use. Loss of power may limit the notifications available.

⚠ CAUTION: Do not connect the Stork Hub to an electrical outlet controlled by a wall switch or dimmer. Someone may accidentally turn the power off to your Stork Hub.

⚠ CAUTION: Apply the Stork on feet free of skin conditions (e.g., open wounds, blistering, skin eczema). Skin conditions may affect the ability to comfortably wear the boot.

SpO₂ and PR Features

⚠ WARNING: Things that interfere with the accuracy of the SpO₂ measurements. Some things can be controlled, while others need awareness.

Controllable things:

- Proper placement of the sensor and boot on the foot.
- Keeping foot dry and free of foreign objects.
- Not blocking the sensor.
- Avoiding direct exposure to bright lights, including direct sunlight.
- Warming the foot to improve circulation.
- Avoid use on same leg with blood pressure cuff inflated.
- Keep away from other electrical equipment that may cause readings to be affected (e.g., microwaves, strong radio transmitters).

Other things that require awareness:

- Skin pigment or color.
- Skin or foot thickness.
- Health conditions affecting how oxygen is carried in your blood (e.g., sickle cell, severe anemia).
- Poor blood circulation.
- Elevated levels of Bilirubin.
- The presence of blood components not able to carry oxygen (e.g., elevated carbon monoxide levels in your blood, recent tobacco use).
- Keeping movement at a minimum.

Temperature Features

⚠ WARNING: Displayed temperature reflects the surface temperature at the foot and not the body temperature. Temperature measurements should be performed rectally or in the axilla by standard thermometer or over the temporal artery by infrared thermometer.

⚠ CAUTION: The temperature readings may not be accurate if there is:

- Obstructed access to the skin surface (e.g., clothing, perspiration, excess oil or lotions).
- An obstructed temperature sensor.

Wireless

⚠ WARNING: When using with a smart phone, keep both devices within the recommended range of each other. See *Specifications* on page 42 for details. Moving outside of this range may cause a loss in connection.

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

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

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

⚠ WARNING: Move the devices away from sources that may interfere with Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI). This may result in loss of Quality of Service. 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 other baby monitors.

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

⚠ CAUTION: To maintain Bluetooth connectivity with the Stork Sensor, ensure that the Stork Hub is within the specified distance and in line-of-sight of the Stork Sensor. See *Specifications* on page 42.

⚠ CAUTION: Failure to charge Stork Sensor promptly after a Low Battery notification may result in the Sensor shutting down.

Cybersecurity

⚠ WARNING: If you suspect your password or smart phone is compromised, reset your password to prevent unauthorized access to your data.

⚠ CAUTION: To ensure security and prevent tampering of your smart phone, while using Stork:

- Smart phones should be located with the responsible users.
- Smart phones should not be left unattended.

- Security features on smart phones should be activated. Unauthorized changes should not be made to the Stork system.

Cleaning and Service

⚠ WARNING: Do not attempt to remanufacture, recondition, or recycle the Stork Sensor or Stork Hub to prevent harm or damage to the system.

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

⚠ CAUTION: Do not clean the Stork Sensor or 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. See *Cleaning* on page 54.

⚠ CAUTION: Do not submerge Stork Sensor or Stork Hub in liquid or attempt to sterilize by any method to prevent damage to the device.

Radio and Disposal Compliance

⚠ 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) are only for indoor use in accordance with international telecommunication requirements.

⚠ 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 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 of the device and/or its accessories.

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

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

Note: 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. Stork generates, uses, and can radiate radio frequency energy and may cause interference with radio communications. To determine if 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 Stork.
- Plug the receiver and Stork into outlets on different circuits.
- Consult the dealer or a radio/TV technician for help.

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: This equipment has been tested and found to comply with the Class B limits for medical devices according to IEC 60601-1-2: 2020. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

Note: To satisfy RF exposure requirements, the Stork Hub 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: 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 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

When using any medical device, there are risks and benefits. The following information is provided to help you understand the risks and benefits of using Stork.

Risks of 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 Stork.
- As with all devices with small parts, there is always a risk of a child 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 Stork 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 the Stork Hub 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 Stork Sensor directions, and follow troubleshooting instructions. Never assume an alarm is false; promptly address every alarm.

Benefits of Stork

- 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.
- 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.
- Stork uses the same proven pulse oximetry used in hospitals shown to have fewer false alarms¹ compared to other brand technology.
- Stork allows for the storage and review of your blood oxygen level as you go about your normal activities, including sleep.

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

Meet the Stork System

Stork System

The Stork System consists of the following:



1 Stork Hub

2 Smart phone with Stork app Installed*

3 Stork Sensor

4 Stork Boot (small and medium included)

5 Straps

* Smart phone not included.

Also included in the Stork System but not pictured:

- Stork Quick Start Guide
- Stork Sensor 5W AC power adapter
- Stork Hub 5W AC power adapter
- Stork Sensor charge cable and cable clip
- Stork Hub power cable

Components of Stork

Stork Hub Overview

The Stork Hub supports the communication between the Stork System parts, captures audio, provides alerts and alert acknowledgement, provides room ambient temperature and humidity, and supports 2-way audio communication.



1 Power Connector	Located on the back of the hub. Power is provided by the AC adapter and the power cable.
2 Status Light Ring	Shows alerts, hub operation and connection status. See <i>Stork Hub Notifications</i> on page 34 and <i>Hub Status Light</i> on page 46.
3 Temperature and Humidity Sensors	Measures ambient temperature and humidity of the room.
4 Microphone	For listening to the baby.
5 Hub Button	Used to silence alarms.
6 Speaker	Used for communication.

Note: A factory reset button is located on the bottom of the hub.

Stork Sensor Overview

The Stork Sensor is for use with the Stork System.



A Rear of Sensor (Side that contacts bottom of baby's foot)

1 Detector	Detects the light from the sensor LED that is placed on the bottom of the foot.
2 Sensor LED	Provides the light that is measured by the detector.
3 Temperature Sensor	Monitors the temperature of the foot.

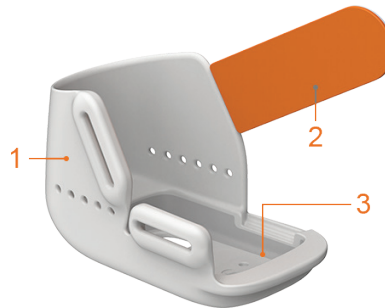
B Front of Sensor (Side toward the boot)

4 Sensor Status Light	Displays the sensor status. See <i>Sensor Status Light</i> on page 42.
5 Charging Contacts	Charge the sensor battery using the charging cable and AC power adapter. See <i>Charging the Stork Sensor</i> on page 24.

Stork Boot Overview

The Stork Boot secures and aligns the Stork Sensor to the foot.

⚠ WARNING: Do not use the boot if it appears to be damaged. Damage to the boot may result in poor performance and/or injury.



-
- | | |
|------------------------------|--|
| 1 Stork Boot | Secures the Stork Sensor to the baby's foot. |
| 2 Strap | Attaches to the boot. |
| 3 Stork Sensor Pocket | The sensor is placed into this pocket. |
-

Stork Grows with Your Baby

Age	Developmental Milestones	Stork Monitoring
0-6 months	Baby is: <ul style="list-style-type: none"> • Sleeping for more than 50% of the day • Crying when hungry, tired, uncomfortable, or needs attention • Rolling over on their own • Pushing up with arms when on tummy • Holding head up while on tummy 	<ul style="list-style-type: none"> • Track baby's vital signs. • Check that baby is not sleeping face down.
6-12 months	Baby is: <ul style="list-style-type: none"> • Consistently rolling over on their own • Crawling • Pulling up to stand • Sitting up on own and without support 	<ul style="list-style-type: none"> • Assess if it is time to move up to a larger Stork Boot size and use the longer Straps. • The Baby Position Alert (Face Down Notification) can be turned "off" to avoid unnecessary notifications once you no longer have concerns about your baby's sleeping position. • Limit tracking of baby's vital signs data to while baby is sleeping. If baby is crawling, standing, or walking, remove the boot when awake or active.
12-18 months	Baby is: <ul style="list-style-type: none"> • Walking 	<ul style="list-style-type: none"> • Time to move up to a larger Stork Boot size and to use longer straps. • Limit tracking of baby's vital signs data to while baby is sleeping. baby is crawling, standing, or walking, remove the boot when awake or active.

Note: Consult with the baby's healthcare provider if they have concerns regarding sleep interruptions related to the device.

Why is my Stork Vitals Alarming

Stork provides vital signs alarms to help monitor your baby.

Note: Alarms are provided to let you know to check on your baby. They are not provided as a diagnosis of medical conditions. Clinicians rely on years of clinical experience and education to make medical treatment decisions.

In general, if there is an alarm, check if your baby is responsive by gently rubbing their body or stimulating their feet.

Call 911 if you suspect that there is something wrong with your baby.

The information below is provided to give you some ways to check on your baby. It is not provided for diagnosing or treatment of your baby.

Alarm Displayed	Why is it Alarming?	Ways to Check on Your Baby
<i>Low SpO₂</i> <i>(Oxygen saturation)</i>	Has your baby stopped breathing?	<p>Check on your baby:</p> <ul style="list-style-type: none"> • Look for signs of breathing. <p>Call 911, if the baby is not breathing or you think they need help.</p>
	Does your baby have slow breathing?	<p>Check on your baby:</p> <ul style="list-style-type: none"> • Look for signs of slow breathing (e.g., baby appears blue or pale). • Gently rub the baby’s stomach, back, sides, arms, or legs with the palm of your hand or soft towel. • Tickle the soles of the baby’s foot with your fingers. <p>Call 911, if you think your baby needs help.</p>
	Is something blocking your baby’s breathing?	<p>Check on your baby:</p> <ul style="list-style-type: none"> • Check for a stuffy nose. • Check for mucous or vomit in the throat. • Check for blanket or soft bumpers of the crib covering the baby’s mouth and nose. <p>If you can, clear their nose and mouth.</p> <p>Call 911, if you think your baby needs help.</p>

Alarm Displayed	Why is it Alarming?	Ways to Check on Your Baby
<i>Low Pulse Rate</i>	Is your baby sleeping deeply?	<p>Check on your baby:</p> <ul style="list-style-type: none"> • Check baby's breathing. • Check for a stuffy nose or blocked throat. • Check baby's temperature. • Check when baby had their last bowel movement. • Gently rub the baby's stomach, back, sides, arms, or legs with the palm of your hand or soft towel. <p>Call 911, if you think your baby needs help.</p>
<i>High Pulse Rate</i>	Is your baby crying or irritable?	<p>Check on your baby:</p> <ul style="list-style-type: none"> • Attempt to comfort your baby. • Check baby's temperature. • Check your baby is not too hot. Remove extra blankets and clothing. <p>Call 911, if you think your baby needs help.</p>

Basic Setup and Use of Stork

Getting Started

You can get the Stork system up and running by following these steps and the in-app instructions and tutorials:

1. Set up your smart phone with the Stork app.
 - Download the app on your smart phone and follow the app instructions to create an account and a baby profile.
2. Set up the Stork System through the app and complete the following:
 - Connect the Stork Hub to the app using local Wi-Fi.
 - Charge the Stork Sensor.
 - Pair sensor using the Stork app.
 - Insert the sensor into the Stork Boot.
 - Secure the boot to the foot.
3. Confirm the correct setup
 - After the Boot is attached to the foot, open the app.
 - Confirm live data on the *Live Dashboard*.

Step 1: Smart Phone Setup



Prepare the Smart Phone for Use:

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

To use your smart phone with the Stork app, check the following:

- **Compatibility**
Note: For a list of smart phones and operating systems that work with the Stork app, check www.masimostork.com 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 Stork app on your smart phone:

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



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

Create a User Account

After installation, open the app and follow the app instructions to create a new user account. If you have an existing user account, log in using the account credentials.

Note: If you need to make changes to the account, see *Side Menu* on page 35.

Create a Baby Profile

Follow the app instructions to and set up a *Baby Profile*. Enter the requested information about the baby when prompted.

Note: If you need to make changes to the baby profile or create a baby profile, see *Side Menu* on page 35.

Add Stork Devices

After creating an account and baby profile, select Add Device to continue. On the next screen, select a device that came with Stork to connect with the Stork system. If additional devices need to be connected to Stork, see *Device Management* on page 36.

Step 2: Setting up the Stork System



After the Stork app is installed and a user account and baby profile are created, follow the app instructions to set up your Stork System. See *Device Management* on page 36 to connect Stork devices.

- Place the Stork Hub in a safe place, connect the hub to the app and local Wi-Fi network.
- Charge the Stork Sensor and use the app to pair the sensor.
- Attach the sensor to the Stork Boot, and then attach the boot to the baby's foot for monitoring.

After these items are set up, monitoring of the baby's health data begins.

Stork Hub Setup

See *Device Management* on page 36 to connect the Stork Hub and follow the app instructions to:

- Place the hub in a safe location and connect to power.
- Pair the hub to the Stork app using Bluetooth.
- Connect the hub to your wireless network (Wi-Fi).

Choosing a Location and Connecting the Stork Hub

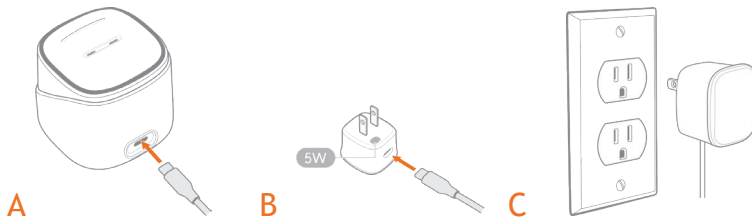
The hub is set up in two steps.

Step 1: Pair the Stork app to the Stork Hub using Bluetooth.

Step 2: Connect the Stork Hub to your wireless network (Wi-Fi).

1. Place the hub in a safe location so as not to fall on anyone and where communication is not muffled so that notifications can be heard. The hub is designed to be set on a flat surface (for example: a dresser or a nightstand).
2. Plug the power cable into the hub (A), the power cable into the 5W AC power adapter (B) and plug the power adapter into a wall socket (C).

Note: The hub Indicator is white when powered on. See *Hub Status Light* on page 46.



- Follow the app instructions to pair the hub. Hold your smart phone near the hub during setup. When pairing is complete, the *Bluetooth Pairing is Successful* screen appears.

Note: If multiple devices are found, follow the app instructions to select the correct hub from a list.

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

- Connect to your Wi-Fi by selecting **Setup Wi-Fi** and follow the app instructions.

Note: If requested to *Share Wi-Fi Settings*, select **Allow**.

- Select the wireless *Network* and enter the *Password*. Select **Continue**.

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

- Once the Wi-Fi connection is made, the *Success!* screen appears.

Note: If the hub cannot connect, follow the app instructions to verify the network and try again or view **Troubleshooting** on page 39.

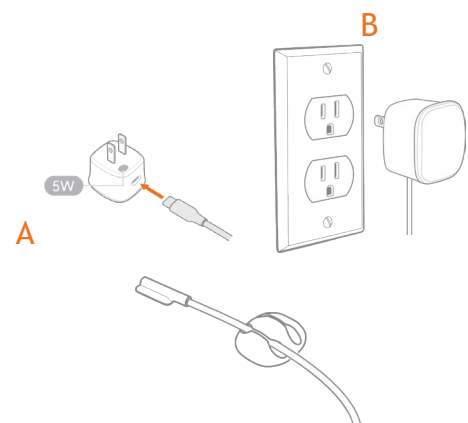
Stork Sensor Setup

See *Device Management* on page 36 to connect the Stork Sensor and follow the app instructions to:

- Charge the sensor.
- Pair the sensor using the Stork app.

Charging the Stork Sensor

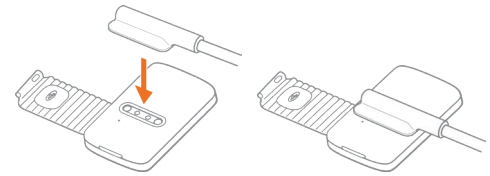
- To charge the Stork Sensor, plug the charge cable into the 5W AC power adapter (A) and plug the power adapter into a wall socket (B).



- Use the peel-and-stick cable clip to secure the charge cable to a flat surface like a dresser or nightstand.

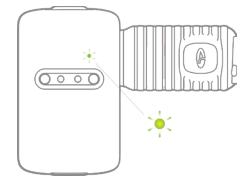
3. Connect the magnetic charge cable to the sensor charging port.

Note: If the sensor is in the boot, remove it from the Stork Boot to charge.



4. Confirm successful charging of the sensor by checking the light indicator.

- The sensor light indicator flashes white when charging and turns solid White when fully charged.
- If the sensor does not charge, see ***Troubleshooting*** on page 39.



To disconnect the magnetic charge cable from the sensor charging port when charging is complete, simply pull the cable away from the sensor.

Pairing the Stork Sensor

Follow the app instructions to pair the Stork Sensor. Connect the sensor to the charge cable and hold your smart phone near the sensor during setup. When pairing is complete, the *Bluetooth Pairing is Successful* screen appears.

Note: If multiple devices are found, follow the app instructions to select the correct sensor from a list.

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

Stork Boot Setup

Follow the app instructions to:

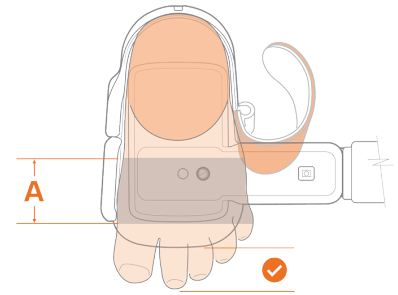
- Select the proper Stork Boot and strap size.
- Attach the Stork Sensor to the boot.
- Place the boot on the foot.

Note: The Stork Boot should not be used while the baby is standing or walking.

Boot Size Selection

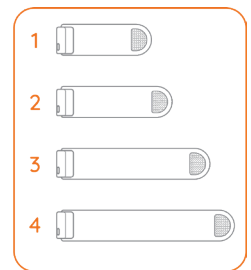
When sizing, your baby's heel should be all the way back against the boot. It is acceptable if the baby's toes overhang a little, as shown.

If the toes hang over farther than the picture, or the sensor does not fit within the desired zone (A), use a larger boot.



Strap Sizes

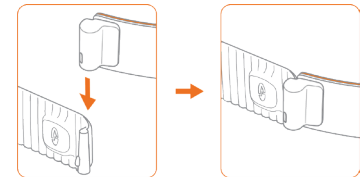
Straps come in 4 sizes. The small and medium boots come attached with strap sizes 3 and 4. Size 1 and 2 come in separate packaging.



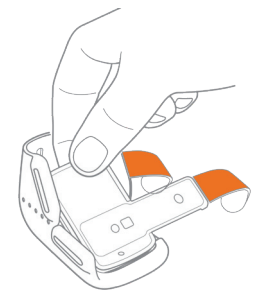
Attaching the Stork Sensor to the Boot

1. Slide the longer strap on to the top of the boot (will be near baby's ankle) and slide the shorter strap onto the sensor.

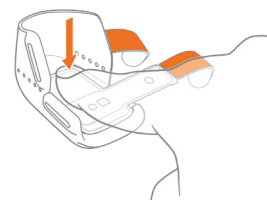
To remove the strap, simply slide back off.



2. Insert the sensor into the boot at an angle, toe end first, with the Masimo logo facing down.

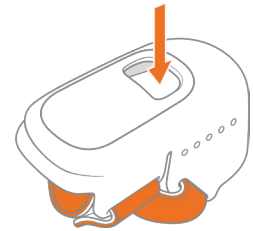


3. Press down to secure the sensor. The sensor should sit flush in the boot.



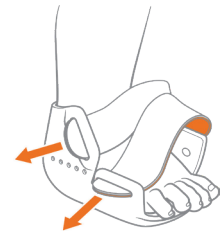
Removing the Sensor from the Boot

To remove the sensor, push through the opening in the bottom of the boot.

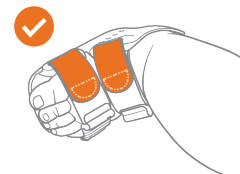


Attaching the Boot to the Foot

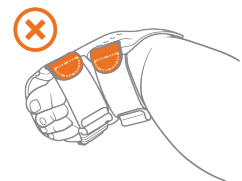
1. Place the boot to either foot. Check for proper alignment. The boot should be snug, but not tight.
2. Wrap the cloth straps for the boot and the sensor around the foot and feed the straps through the openings in the boot.



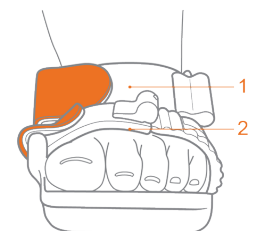
3. Fold the straps over to secure to the boot to the foot. Check the strap length. Change the straps as needed to fit your baby.



When sizing the straps for proper fit, for example, a small newborn will most likely require the Size 2 strap at the ankle and the Size 1 strap at the sensor.



4. The strap at the ankle strap (1) should be snug but not tight. The sensor strap (2) should sit flush against the top of the foot, with no gap.




⚠ CAUTION: Using excessive force when removing the boot may damage it.

Best Practices to Avoid Skin Irritation on Baby's Foot

Skin redness and irritation is common for babies, however there are preventive steps that can be taken.

- Check that the sensor, boot and foot are dry and free from excessive moisture.
- Alternate feet
- Use the correct boot size and straps.
- Do not over tighten the boot.
- Ensure hook and loop fastener is not touching baby's skin.
- Spot clean as necessary and clean both boot and straps daily or before each use or when they appear soiled or dirty. See cleaning instructions for more details.

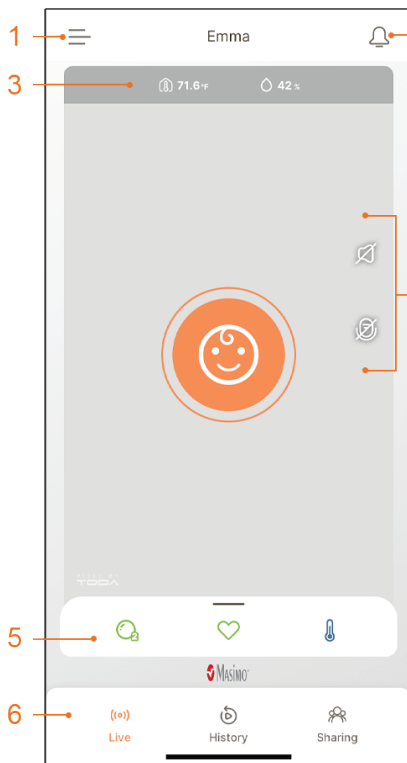
 **CAUTION:** Do not apply the boot on feet that have redness or irritation. Skin conditions may affect the ability to comfortably wear the boot.

Step 3: View Live Data



After setting everything up, open the Stork app to view the *Live Dashboard*. The *Live Dashboard* is also the Stork app home screen, with access to other app functions.

Disclaimer: The app screens shown in this document might differ from the actual ones displayed in the app due to periodical app updates.



1 **Side Menu** - Displays the *Side Menu* with links to app functions and features. See *Side Menu* on page 35.

2 **Notifications** - Provides device, account, and environmental and physiological notifications. Notifications are available when an Orange dot appears on the icon.

4 Alarms are active when the icon turn Red. Touch the icon to open the *Notifications* screen. See *App Notifications* on page 32.

3 **Room Conditions** - Displays the in-room temperature and humidity.

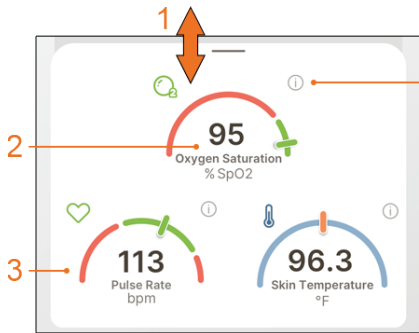
4 **Live Controls** - Touch the screen and the *Live Controls* appear. See *Live Controls* on page 35.

5 **Health Data Dashboard** - Swipe up to view health data readings. See *Health Data Dashboard* on page 29.

6 **Bottom Menu** - Shortcuts to additional app functions and features. See *Bottom Menu* on page 37.

Health Data Dashboard

The *Health Data Dashboard* displays data from the Stork Sensor. Swipe up to open and swipe down to close.



- 1 **Show/Hide Health Data Dashboard** - Swipe up on the screen to show and swipe down to hide.
- 2 **Reading Display*** - Displays the name of the reading and the reading value from the sensor.
- 3 **Reading Gauge*** - Displays the reading from the sensor in a gauge style.
- 4 **Information about the Reading/Reading Confidence Indicator** - Touch the icon to see a description about the reading. This icon also informs about confidence in the reading. See *Confidence in Displayed Readings* on page 30.

* If a sensor is not connected to Stork, dashes display for the readings and the gauge pointers do not appear.

Confidence in Displayed Readings

The information icon provides an assessment of the confidence in the reading displayed (also known as SIQ). A caution icon appears in its place with low confidence in the reading. Touch the caution icon to display information about the low confidence condition.

 Caution Icon (Low Confidence in the reading displayed)

Verify Sensor is Properly Applied

It is important to make sure your sensor is properly applied. The following items on the *Health Data Dashboard* can help identify good sensor placement:

- Oxygen saturation is displayed
- Pulse Rate is displayed
- Temperature is displayed

Alarms and Notifications

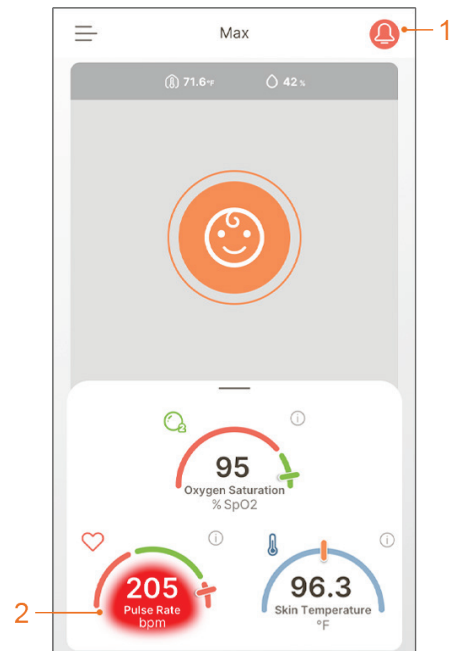
Stork provides visual and audible *High Priority* alarms for the following:

WARNING: These default alarms are set based upon the assumption of a healthy baby without known medical conditions. Review them with your baby’s physician to determine if these are safe limits for your baby. The Stork is not intended to detect every instance of elevated or depressed Pulse Rate, or low Oxygen Saturation (SpO₂).

Parameter Data	Default Alarm Limit	Expected Alarm
SpO ₂ - Low Oxygen Level	<80 %SpO ₂ for longer than 10 seconds	High Priority Alarm - Visual and Audible Alarm
Pulse Rate - Low Pulse Rate	<70 BPM for longer than 30 seconds	High Priority Alarm - Visual and Audible Alarm
Pulse Rate - High Pulse Rate	>200 BPM for longer than 30 seconds	High Priority Alarm - Visual and Audible Alarm

When an alarm condition is triggered, an alarm sounds on your Stork Hub and the Stork app.

- The notification Bell (1) will be solid red.
- The app highlights the parameter alarming in red (2) on the Health Data Dashboard and displays the measurement in the red zone.
- After visually alarming for 10 seconds for SpO₂ or 30 seconds for PR, the audible alarm sounds.
- When the audible alarm sounds, a pop-up notification displays allowing you to select the **Silence Alarm for 2 Minutes** or **Dismiss** button to temporarily silence the alarm for two (2) minutes.
- If the alarm condition is still present after the 2 minutes, the audible alarm will sound again.
- The alarm condition stays active as long as the alarm condition persists.



Silence Alarms

WARNING: It is important to check on any alarm that occurs on the Stork. Alarm conditions that persist longer than 2 minutes should be checked on immediately. See Why is my Stork Vitals Alarming.

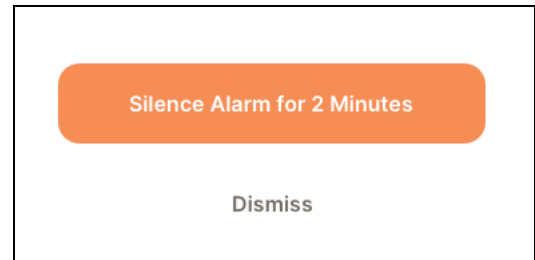
An audio alarm can only be silenced for 2 minutes at a time. After 2 minutes, the alarm will sound again.

Silencing Alarms from the Stork app

When the audible alarm sounds, a pop-up notification displays allowing you to select the Silence Alarm for 2 Minutes or Dismiss button.

OR

Touch the notification bell to open the *Notification Center*. Select the Alarms tab and the active alarm from the list to view the alarm. Select the Silence Alarm for 2 Minutes or Dismiss button.



Silencing Alarms from the Stork Hub

Press and release the top of the hub to silence the hub alarm.



Advanced Use



Notifications

App Notifications

Pop-Up Notifications

Notifications appear on the Stork app screen related to parameter alarms, the Stork Hub and Stork Sensor. In many cases, an alarm or notification also appears on the Stork Hub.

Notifications Center Screen

The *Notification Center* screen is accessed by touching the notifications icon on the app main screen. A dot on the icon  means there are notifications available. A red icon  means alarms are active. Touch the icon to open the *Notification Center* screen and select the Alarms or Notification tab. Touch an alarm or notification to view additional information and acknowledge. Any "next steps" to address the alarm or notification may also be shown (when available).

Alarms

Examples of alarms include:

Parameter Alarms - When a parameter goes above or below the set alarm limits.

Notifications

Examples of notifications include:

Baby Position Alert (Face Down Notification) - A push notification on the app that indicates when the baby is laying face down. This feature can be turned "off" to avoid unnecessary notifications once you no longer have concerns about your baby's sleeping position. See *Device Management* on page 36 for how to manage this notification.

Ambient Temperature Notification - Room temperature levels high or low and when it returns to normal.*

Account Notification - Such as an incomplete baby profile or a shared user action item.

Device Notification - If software updates are available for a device, a device goes off line, or the sensor battery is low.

* Can be enabled through Room Settings for the device. See *Device Management* on page 36.

Acknowledge and Clear Alarms or Notifications

WARNING: It is important to check on any alarm that occurs on the Stork. Alarm conditions that persist longer than 2 minutes should be checked on immediately. See Responding to High Priority Alarms_Stork.

Pop-Up Notifications

Touch the either button at the bottom of the screen to acknowledge an alarm or notification.

Notifications Screen

Alarm Notifications - Acknowledge the alarm through the pop-up notification or through the *Notification Center*.

Individual Notifications - Touch the notification to acknowledge or swipe left on the notification and select the remove icon.

All notifications - Select More in the upper right corner of the screen. Select Mark all as read to acknowledge all notifications or select Delete all to delete all notifications.

Stork Hub Notifications

Alarms and notifications are also communicated through the hub status light and speaker. Medium and high priority notifications are available. See *Hub Status Light* on page 46. When a low or medium priority notification is present, the hub status light flashes Yellow, and in some cases, an audible notification sounds. When a high priority alarm or notification is present, the hub status light flashes Red and an audible notification sounds. The app also shows pop-up notifications and some notifications appear on the *Notification Center* screen.

Examples of low/medium priority notifications:

- The Stork Sensor battery is low (low priority notification) or depleted (medium priority notification).
- The Masimo Cloud server is disconnected from the Stork System.

Examples of high priority notifications:

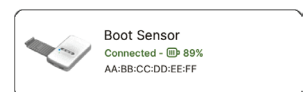
- The Stork Sensor has come off or has been removed from the baby while measuring the baby's health data.
- The Stork Sensor has disconnected from the system while measuring the baby's health data.
- When the SpO₂ or PR parameter readings go above or below the set alarm limits.

How to Silence and Acknowledge Notifications

Press the hub button to acknowledge and silence the notification. See *Stork Hub Overview* on page 16.

Sensor Battery Charge Status

Battery charge status for the Stork Sensor is viewed through the *Side Menu* under *Devices*. See *Device Management* on page 36. Current battery charge status is shown on the sensor device tile next to the sensor connection status.



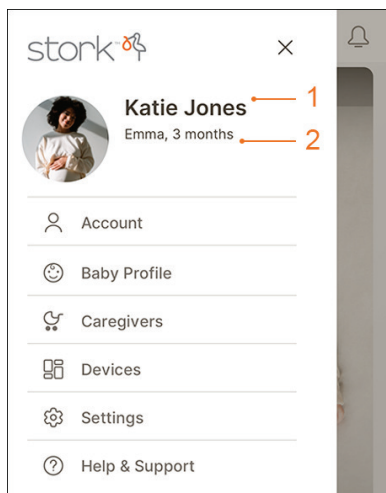
Live Controls



- 1 **Background Audio** - Touch to toggle the sound from Stork between off to "on with app open" or "on with another app displayed or phone locked". Volume controls display on the screen above the *Health Data Dashboard* when on.
- 2 **Hold-to-Talk** - Press and hold to turn the Stork app microphone on (shown as off) for two-way communication.

Side Menu

The *Side Menu* provides access to functions and features of Stork.



Account - View and make changes to the account. Touching the name for the account (1) also opens the account. See *Account Management* on page 35.

Baby Profile - View and make changes to the baby profile. Touching the baby's name (2) also opens the baby profile. See *Baby Profile Management* on page 36.

Caregivers - Invite trusted people to view Stork health data. See *Caregivers* on page 36.

Devices - View device status and info, add new devices or remove current devices. If an orange dot displays on the *Devices* icon, this indicates software updates are available for a device. See *Device Management* on page 36.

Settings - Select the units of measurement or turn off the alarms on the Stork Hub. See *Settings* on page 37.

Help & Support - View information and tutorials about the app along with ways to contact customer service.

Sign Out - Select to sign out of the Stork app.

Account Management

From the *Account* screen, the first and last name can be updated, a picture can be added, the password can be changed, or the account can be deleted.

Baby Profile Management

From the *Baby Profile* screen, the first and last name, biological sex, birthday, weight and length can be updated.

Caregivers

Your baby's live health data as well as history health data can be shared with people you trust. From the *Caregivers* screen, select *Add Caregiver* and enter the email for who you want to be a caregiver.

The caregiver can accept or reject the email invitation. When the invitation is accepted, they will download the Stork app, and create an account to view the shared health data. Once complete, the shared data is viewed using the *Sharing* link in the *Bottom Menu*. See *Bottom Menu* on page 37.

Remove caregiver access - Swipe left on the caregiver and select the remove icon.

Cancel or resend an invitation - Swipe left on the invitation and select to cancel or resend the invitation.

- *Private Mode* can be enabled to stop sharing health data with caregivers at anytime, without revoking a caregivers access. See *Live Controls* on page 35.

Device Management

The *Devices* screen displays all connected Stork devices and their current connection status. From this screen you can also view detailed connected device information, remove connected devices or add additional Stork devices from this screen.

View information about the device - Select a device to view the following:

- Device information
- Wireless information (Wi-Fi network can be changed from this screen)
- Tutorials for setting up and using the device.
- Remove the device.
- For the Stork Sensor, the battery charge percentage displays (also shown on the device tile).
- Baby Position Alert (Face Down Notification) of when the baby is laying face down, can be turned off. Open the *Side Menu*, select *Devices*, then *Sensor*, and choose to turn the alert **On** or **Off**.
- Update device firmware (when available).
- For the Stork Hub, make changes to the notifications for the ambient measurements (*Room Settings*).

Add a Stork device - Select the add device "+" button at the bottom of the screen and select the Stork device to add. Follow the in-app instructions to add the device. Make sure you have the device you want to add with you for ease of adding to Stork.

Remove a Stork device - Swipe left on a device and select the remove icon. Follow the in-app instructions to remove the device. The device can also be removed from the *Device Info* screen.

Settings

Units of Measurement

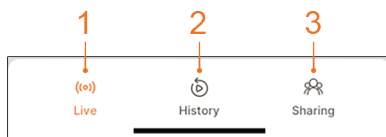
Select the units of measurement for temperature, length or weight.

Alert Sounds

Sounds are on by default. This feature allows the ability to turn the alarm sounds and visual alerts on the Stork Hub off, so as to not disturb the baby. The app alarms cannot be disabled.

Bottom Menu

The *Bottom Menu* provides access to the following functions and features of Stork:

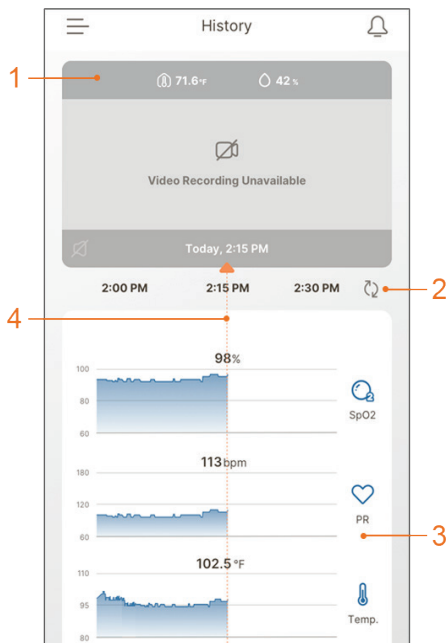


1 Live - Displays the current data, room conditions and health data. See *Step 3: View Live Data* on page 28.

2 History - Review history data recorded by Stork. See *History* on page 38.

3 Sharing - Access to view other Stork Systems that have been shared with you or share your system with other caregivers. See *Sharing* on page 38.

History



When *History* is selected, health data history displays. Up to 7 days (168 hours) of history can be recorded by Stork.

1 Ambient Readings - History of room temp and humidity levels.

2 Refresh History Data - Touch to refresh to the latest recorded data.

3 Health Data History - Displays the recorded health data.

4 Health Data History Cursor - Drag left or right to scroll through health data and video recording. A play/pause button displays in the video window when scrubbing through recording to play or pause the recording playback.

Sharing

When you have accepted to be a caregiver, downloaded the app and created a profile, the baby you have been granted access to appears when on the *Sharing* screen. Select the baby's name to see live health data as well as access history data.

Reject invitation - Select Deny on the invitation from the *Sharing* screen.

More than one baby - If you have been invited to be, or are the caregiver for more than one baby, invitations and other babies are shown on the *Sharing* screen.

Stop being a Caregiver - Swipe left on the baby and select the remove icon.

Note: *Private Mode* can be enabled by the person who invited you to be a caregiver to stop sharing health data at anytime, without revoking your caregiver access.

How to Turn Stork On and Off

Once the Stork System is connected to power during setup, and the sensor is charged, the system is on. Neither the Stork Hub nor Stork Sensor have an On/Off switch or controls to turn On or Off.

To turn the system Off:

1. Unplug the hub power adapter from the wall socket.

2. Remove the Stork Boot and sensor from the baby's foot. After a while, the sensor goes into stand-by power mode.
3. Close the Stork app.

Troubleshooting

Stork Messages

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>	Sensor not making good contact.	<ul style="list-style-type: none"> • Please ensure that sensor is properly inserted into the Boot and the Boot is properly placed on the foot. • If you still experience issues, please contact Masimo Customer Support. See <i>Customer Support</i> on page 54.
<i>"Replace your sensor"</i>	Sensor is not working.	Replace sensor.
<i>"Wireless sensor disconnected during a notification"</i>	<ul style="list-style-type: none"> • Sensor became disconnected during audible notifications for including: • Physiology notification or technical notification • Low SpO₂ • Sensor off • Obstructed battery • Low battery • Depleted battery 	<ul style="list-style-type: none"> • Press the notification silence button on the Stork Hub. Follow the instructions and attempt to pair the sensor again. See <i>Pairing the Stork Sensor</i> on page 25. • If you still experience issues, please contact Masimo Customer Support. See <i>Customer Support</i> on page 54.
<i>"No Internet Connection"</i>	<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.
<i>"Battery low Warning"</i>	Sensor battery is low.	Charge sensor.
<i>"Depleted Battery"</i>	Sensor battery is depleted.	Charge sensor.
<i>"Wireless Sensor Disconnected"</i>	Sensor is not monitoring.	Ensure sensor placement steps are completed and you are obtaining readings.
<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 <i>Customer Support</i> on page 54.

Troubleshooting Stork

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

Symptom	Potential Causes	Next Steps
<i>Stork app does not communicate with Stork Hub</i>	<ul style="list-style-type: none"> Stork Hub is not powered on. Smart phone is not in close proximity to 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 Stork Hub is plugged into the AC power supply. Ensure the smart phone is in close proximity with Stork Hub. Ensure Bluetooth on the smart phone is turned on. Check smart phone compatibility. See <i>Specifications</i> on page 42. Update the smart phone software. Refer to the smart phone's Operator's Manual or Directions For Use. Contact Masimo Customer Support. See <i>Customer Support</i> on page 54.
<i>Stork Hub does not connect to Wi-Fi or Masimo Cloud</i>	<ul style="list-style-type: none"> Stork Hub is not connected to power. Incorrect Wi-Fi network selected. Incorrect Wi-Fi password in entered. Wi-Fi network is not correctly configured. Masimo Cloud may be down. 	<ul style="list-style-type: none"> Ensure Stork Hub is plugged in to a working power outlet and not to an outlet controlled by a dimmer or switch. Ensure smart phone is connected to correct Wi-Fi network. See <i>Stork Hub Setup</i> on page 23. Ensure correct Wi-Fi network is selected. See <i>Stork Hub Setup</i> on page 23. Ensure correct Wi-Fi password is entered. See <i>Stork Hub Setup</i> on page 23. 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 <i>Customer Support</i> on page 54.
<i>Stork Sensor does not pair with Stork Hub</i>	<ul style="list-style-type: none"> Stork Hub is not connected to power. Sensor is not inserted into boot. Sensor is not in close proximity with Stork Hub during pairing. Incorrect user logged into the app. Stork Hub has been registered with another account. Depleted sensor battery. 	<ul style="list-style-type: none"> Ensure Stork Hub is plugged in to a working power outlet and not to an outlet controlled by a dimmer or switch. Ensure the sensor is firmly inserted into the boot. See <i>Attaching the Stork Sensor to the Boot</i> on page 26. Ensure the sensor is in close proximity with Stork Hub during pairing. Ensure correct user is logged into the app. Contact Masimo Customer Support. See <i>Customer Support</i> on page 54.

Symptom	Potential Causes	Next Steps
<i>NO user data is displayed</i>	<ul style="list-style-type: none"> • Incorrect user logged into the app. • Wi-Fi is not correctly configured. • Smart phone settings are incorrect. • Sensor is not connected to the Stork Hub. • No previous sessions have been recorded. 	<ul style="list-style-type: none"> • Ensure the correct user is logged into the app. • Restart 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 <i>Customer Support</i> on page 54.

Troubleshooting Measurements

The following section lists possible measurement symptoms, potential causes, and next steps. For more information, see *Safety Information* on page 7.

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/Stork Hub is not plugged into AC power supply. 	<ul style="list-style-type: none"> • Check the placement and alignment of the sensor on the foot. Re-apply the sensor. • Allow time for the parameter measurement to stabilize. • Check if blood flow to the sensor location is restricted. Warm the foot where the sensor is placed. • Minimize or eliminate motion at the monitoring location. • Shield the sensor from excessive or strobing light. • Charge/connect to AC power supply • Replace sensor. • Contact Masimo Customer Support. See <i>Customer Support</i> on page 54.
<i>Low SIQ message displayed (Low signal quality confidence).</i>	<ul style="list-style-type: none"> • Incorrect placement of sensor on user. • Misalignment of sensor components. • Excessive user motion. • Low perfusion (blood flow). • Sensor is damaged or not functioning. 	<ul style="list-style-type: none"> • Check the placement and alignment of the sensor on the foot. Re-apply the sensor. • Minimize or eliminate motion at the monitoring site. • Check if blood flow to the sensor location is restricted. Warm the foot where the sensor is placed. • Replace sensor. • Contact Masimo Customer Support. See <i>Customer Support</i> on page 54.

Appendix

Specifications

Stork App

Measurement Display Range

Measurement	Display Range	Unit of Measure
Oxygen Level (SpO ₂)	0 to 100	%
Pulse Rate (PR)	25 to 240	bpm
Temperature	77.0 to 109.4 (25.0 to 43.0)	°F (°C)
Ambient Temperature	59 to 113 (15 to 45)	°F (°C)
Ambient Humidity	10 to 100	%

Smart Phone Compatibility

Item	Specification*
Operating System	Android 8.0 (Marshmallow) (minimum)
	iOS 15.0 (minimum)

* For complete specifications, refer to www.masimostork.com.

Stork Sensor

Sensor Status Light

The status light on the Stork Sensor shows the status of the sensor, its connection and battery.

Color/Behavior	What does it mean?
No LED	Sensor is not connected
Blinking Green	Sensor is on and waiting to be paired
Solid Blue	Sensor is paired
Blinking Blue	Software is updating
Blinking Orange	Sensor battery is low
Blinking White	Sensor battery is charging
Solid White	Sensor battery is fully charged
Blinking Red	Sensor battery is very low/depleted
Solid or Blinking Red in a pattern to indicate a number code	Sensor has a problem (non-battery related). <i>Customer Support</i> on page 54

Measurement Site

Population	Age Range	Measurement Site
Infant and Neonate	0 to 18 months	Foot

SpO₂ and PR Specifications

Display Range and Display Resolution

Measurement	Display Range	Resolution
SpO ₂ (Functional Oxygen Saturation)	0% to 100%	1%
PR (Pulse Rate)	25 bpm to 240 bpm	1 bpm

The emitted wavelengths range from 600 nm to 1000 nm and the peak optical power is less than 15 mW. Information about the wavelength range can be especially useful to clinicians.

Accuracy (ARMS*)

Oxygen Level (SpO ₂)		
Range	70% to 100%	
No Motion [1]	Infants, Neonates	1.5%
Motion [2]	Infants, Neonates	1.5%
Low perfusion [3]	Infants, Neonates	2%
Pulse Rate (PR)		
Range	25 bpm to 240 bpm	
No motion	Infants, Neonates	3 bpm
Motion	Infants, Neonates	5 bpm
Low Perfusion [4]	Infants, 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 provide the A_{RMS} (Accuracy Root Mean Square) values for the Stork as compared to Masimo RD SET Adhesive sensors under no motion clinical testing. A total of 30 subjects, 14 dark skinned and 16 light skinned, were tested.

Measurement A_{RMS} Values for Masimo Stork to RD SET Adhesive Sensor	
SpO ₂ Accuracy Range (%)	A_{RMS} (%)
90-100	0.75
80-90	1.04
70-80	1.75
70-100	1.24

The below Bland-Altman plot represents the distribution of points in the difference between the Masimo Stork and the RD SET Adhesive reference ($SpO_2 - SpO_{2Ref}$) versus the reference (SpO_{2Ref}) under no motion with an upper 95% and lower 95% limits of agreement.

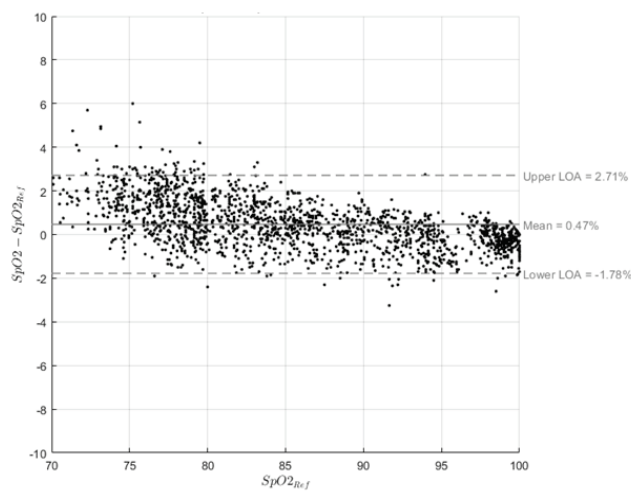


Figure 1: Masimo Stork (70-100%)

The tables below provide the A_{RMS} (Accuracy Root Mean Square) values for the Masimo RD SET Adhesive sensors to Arterial Blood References (SaO_2) under no motion clinical testing.

Measurement A_{RMS} Values for RD SET Adhesive Sensors to Arterial Blood References (SaO_2)	
SpO ₂ Accuracy Range (%)	A_{RMS} (%)
90-100	0.83
80-90	1.11
70-80	1.53
70-100	1.16

The below Bland-Altman plot represents the distribution of points in the difference between the RD SET Adhesive Sensor and the reference SaO₂ (SpO₂ – SaO₂) versus the reference (SaO₂) under no motion with an upper 95% and lower 95% limits of agreement.

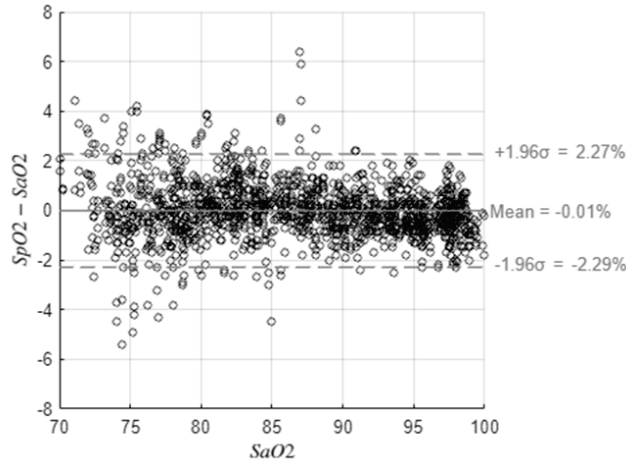


Figure 2: RD SET Adhesive Sensor (70-100%)

Temperature Specifications

Display Range and Display Resolution

Measurement	Display Range	Resolution
Temperature	25°C to 43°C (77°F to 109.4°F)	0.1 °C (0.1 °F)

Stork provides a surface temperature of the skin where the Stork Sensor is applied. The displayed temperature may require time to equilibrate after initial application (up to 7 minutes).

Accuracy

Temperature	
Laboratory	25°C to 43°C (77°F to 109.4°F) ±0.3°C (±0.54 °F)
Application Site	Foot

Electrical

Battery - Stork Sensor	
Type	Li-ion Rechargeable
Run Time	16 hours [5]
Charging Time	2 Hours [6]

Physical Characteristics

Stork Sensor

Dimensions 2.5" x 1.9" x 0.30" (6.35 cm x 4.8 cm x 0.76 cm)

Weight 0.03 lbs. (12g)

Wireless Specifications

Communication (Bluetooth) - Stork Sensor

Type	Bluetooth LE 5.0
Frequency	2402-2480 MHz
Classification of Output Power Rating	Conducted
Max Peak Output Power	6.13 dBm
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

Radio Compliance - Stork Sensor

USA FCC ID: VKF-STORK

Canada IC: 7362A-STORK

Stork Hub

Hub Status Light

The indicator on the Stork Hub shows the connection, operation, and notification status.

Color/Behavior	What does it mean?
Slowly Blinking White	The sensor is not actively monitoring
Solid White	The sensor is actively monitoring with a successful connection to the Masimo Cloud.
Blinking Green	The hub is ready for pairing to the smart phone/Stork app or to be connected to the wireless network.
Slowly Blinking Blue	The hub software is currently updating. Readings from the sensor may be unavailable at this time.
Solid Blue	A Stork app user is actively listening through the hub.
Solid Yellow	<ul style="list-style-type: none"> A low priority notification is active. A low or medium priority notification has been acknowledged.
Blinking Yellow*	A medium priority notification is active.

Color/Behavior	What does it mean?
Solid Red	A high priority notification has been acknowledged and silenced.
Blinking Red*	A high priority notification is active.
Blinking Red in a pattern to indicate a numbered code	A fault has been detected. <i>Customer Support</i> on page 54

* An audible notification may also sound.

Electrical

Stork Hub	
AC Power Requirements	100 to 240 VAC, 50 to 60 Hz, 0.2A
Power Consumption	1W

Physical Characteristics

Stork Hub	
Dimensions	2.39" x 2.39" x 2.0" (6.07 cm x 6.07 cm x 5.08 cm)
Weight	0.13 lbs. (61g)

Wireless Specifications

Communication (Bluetooth) - Stork Hub	
Type	Bluetooth
Frequency	2402-2480 MHz
Classification of Output Power Rating	Conducted
Max. Peak Output Power	9 dBm
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) - Stork Hub	
Type	WLAN Radio: IEEE 802.11 b/g/n
Frequency	802.11b/g/n(HT20): 2412-2462 MHz 802.11n(HT40): 2422-2452 MHz
Classification of Output Power Rating	Conducted
Max. Peak Output Power	26.62 dBm

Communication (Wi-Fi) - Stork Hub

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 - Stork Hub

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 - Stork Hub

USA Contains FCC ID: 2AC7Z-ESP32WROVERE

Canada Contains IC: 21098-ESPWROVERE

Environmental

Environmental Conditions

Operating Temperature 41 °F to 95 °F (5 °C to 35 °C)

Storage Temperature -4 °F to 140 °F (-20 °C to 60 °C)

Operating Humidity 10% to 95%, non-condensing

Storage Humidity 10% to 95%, non-condensing

Atmospheric Pressure 540 to 1060 mBar

Expected Service (Useful) Life

Item	Description
Expected Service Life for Stork System Components	3 Years

Compliance

EMC Compliance

IEC 60601-1-2

Safety Standards Compliance

IEC 60601-1

IEC 60601-1-2

IEC 60601-1-11

IEC 62304

EN ISO 80601-2-61

Equipment Classification per IEC 60601-1

Type of Protection

Stork Sensor	Internally powered (Battery power)
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Stork Hub	Class II (AC Power)
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Degree of Protection against Electrical Shock (Stork Sensor)	Type BF-Applied Part
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Protection against harm from Water and Particulate Matter

Stork Hub	IP22 (Protection from solid foreign objects ≥ 12.5 mm diameter and against ingress from vertically falling water drops when enclosure is tilted up to 15°)
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Stork Sensor	IP44 - Protection from solid bodies larger than 1 millimeter and protection against small splashes of water coming from all directions
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Mode of Operation	Continuous
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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%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 1 kV for input/ output 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)	+/- 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 6 Vrms	3 Vrms 6 Vrms	Performed over 0.15-80 MHz 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.
Voltage dips on power supply input lines IEC 61000-4-11	0% UT ¹ , 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°; 0% UT 1 cycle, and 70% UT 25/30 cycles at 0°	0% UT ¹ , 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°; 0% UT 1 cycle, and 70% UT 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% UT, 250/300 cycle	0% UT, 250/300 cycle	
Radiated RF IEC 61000-4-3	10 V/m	10 V/m	Performed over 80 MHz to 2.7 GHz

Electromagnetic Immunity

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.

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.

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
710 745 780	704-787	LTE Band 13, 17	Pulse modulation (b) 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation (b) 18 Hz	2	0.3	28
1720 1845 1970	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
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 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation (b) 217 Hz	0.2	0.3	9

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)
	$d = 0.6 * \text{sqrt}(P)$
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.




















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
IC Model:	Innovation, Science and Economic Development Canada (ISED)		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°	IP44	Protection from solid bodies larger than 1 millimeter and protection against small splashes of water coming from all directions
	Federal Communications Commission (FCC) Licensing		ETL Intertek certification
FCC ID:	Identifies unit has been registered as a radio device		MR Unsafe. Not appropriate for use in MR environment (i.e.: inside the MR magnet room)
	Recyclable		Non-Sterile

Symbol	Description	Symbol	Description
	Product contains no PVC (polyvinyl chloride) material		Not made with natural rubber latex
	Warning		Caution
	Manufacturer		Date of manufacture YYYY-MM-DD
	Serial number		Catalog number (model number)
	Storage temperature range		Masimo reference number
	Keep dry		AC current
	Storage humidity limitation		Do not use if package is damaged
	Atmospheric pressure limitation		Wireless Symbol level
	Less Than		Greater Than
	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 specifications reflect the representative accuracy of the RD SET Adhesive sensor using Masimo SET Technology that 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 specifications reflect the representative accuracy of the RD SET Adhesive sensor using 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 Stork has been validated for low perfusion accuracy in bench top testing against a simulator with signal strengths as low as 0.02% for the simulated saturation range of 70% to 100%.

[4] The Masimo Stork has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a simulator and Masimo's simulator with signal strengths of greater than 0.02%.

[5] This represents the approximate run time when it is continuously operating with the Bluetooth active after a fully charged battery.

[6] The battery recharge time shall be no longer than 2 hours to reach 80% charge capacity at operating temperature of 25°C (77°F) ambient temperature and might not charge completely under elevated ambient temperature.

Service and Maintenance

Cleaning

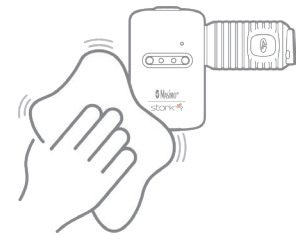
The Stork Sensor, the Stork Boot and the straps should be cleaned daily or before each use or when they appear soiled or dirty.

⚠ WARNING: Before cleaning, remove the Stork Sensor from the Stork Boot. Do not put the sensor in the washing machine.

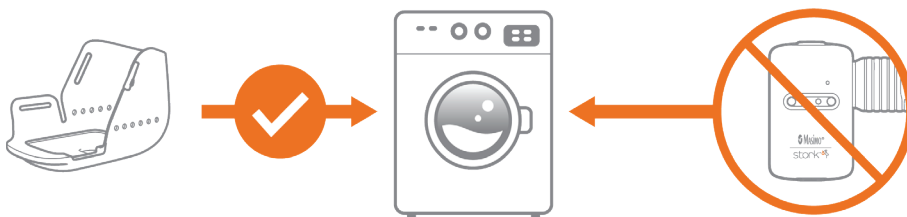
⚠ CAUTION: Do not clean the sensor with undiluted bleach, petroleum-based products, acetone, or other harsh solvents. Clean only with the solutions specified to prevent damage to the device.

Dampen a cloth with water and mild detergent (dish soap) to wipe the sensor or boot of the Stork System (sensor is shown). Disinfectant wipes or 70% isopropyl alcohol (IPA) can also be used.

Air dry when cleaning is done.



You can also place the boot (and the straps if desired) in the washing machine. It is recommended to place the boot and straps into a delicates bag and wash with the baby's clothes.



⚠ WARNING: Ensure the baby's foot and the Stork Boot are completely dry before putting the boot and sensor back on the baby's foot.

Note: The Stork Hub does not require cleaning with the exception of wiping the surface with a damp cloth.

Customer Support

For product support, along with troubleshooting for your Stork product, please go to the Stork Support page www.masimostork.com/en-us/support/contact-us.html.

For warranty information for your Stork product, please go to the Stork warranty page www.masimostork.com/en-us/support/warranty.html.



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