

Stork Vitals+ Smart Home Baby Monitor



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 product, please notify the competent authority in your country and the manufacturer.

Wireless Radio:

Masimo Stork Camera:

- FCC ID:VKF-STORKC

- IC: 7362A-STORKC

Masimo Stork Sensor:

- FCC ID: VKF-STORK

- IC: 7362A-STORK



Manufacturer:

Masimo Corporation

52 Discovery

Irvine, CA 92618, USA

www.masimostork.com

Patents: www.masimo.com/patents.htm

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About This Manual

Not intended for use as a medical device or to replace a medical device. Do not use it to diagnose, cure, treat, alleviate, or prevent any disease or health condition.

This Manual provides an overview of the Stork System and how to set up and use the Stork 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 35. 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 Camera 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.

Product Description

Masimo Stork™ is a smart home baby monitoring system designed for parents to track health data for a healthy baby at home. Masimo Stork Vitals+ consists of a sensor, boot, camera, cloud, and app, which combine to allow parents to stay connected with their baby via video, 2-way audio, and continuous health data on the app.

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

- **Stork App:** A smart phone application that provides high-resolution video, room conditions, baby health, and audio controls.
- **Stork Camera:** Capable of providing 2K QHD video resolution so that you can see your baby in the app regardless of time of day or room lighting. Additionally, the Stork Camera provides 2-way audio, room condition monitoring, and connect to the cloud so that you can get the data on your phone no matter where you are.
- **Stork Sensor:** A wireless sensor that slots into the bottom of the Stork Boot. The sensor uses Masimo SET® technology to track baby's health data, including oxygen saturation, pulse rate, and temperature. 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, with a large size sold separately. The boot is designed for babies aged 0-18 months old.
- **Masimo Cloud:** A server accessed over the internet that securely gathers and stores the health data, video and audio communicated wirelessly from the Stork Sensor and the Stork Camera.

Meet the Stork System

Stork System

The Stork System consists of the following:



1 Stork Camera

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 Camera 12W AC power adapter
- Stork Sensor charge cable and cable clip
- Stork Camera power cable and cable covers
- Stork Camera wall mounting bracket (and hardware)

Components of Stork

Stork Camera Overview

The Stork Camera supports the communication between the Stork System parts, captures audio and video, provides room ambient temperature and humidity, supports 2-way audio communication, and provides lullaby playback.



| | |
|---|--|
| 1 Speaker | Used for 2-way communication and to play lullabies. |
| 2 Status Light | Shows notifications, camera operation and connection status. See <i>Stork Camera Notifications</i> on page 26 and <i>Camera Status Light</i> on page 49. |
| 3 Ambient Light Sensor | Measures ambient light in the room. |
| 4 Microphone | For listening to the baby. |
| 5 Temperature and Humidity Sensors | Measures ambient temperature and humidity of the room. |
| 6 Power Connector | Located on the bottom of the camera. Power is provided by the AC adapter and the power cable. The cable is routed through the opening in camera base. |

Note: A hole to access the factory reset button is located on the bottom of the camera.

Stork Sensor Overview

The Stork Sensor is for use with the Stork System.



A Rear of Sensor (Faces the boot)

| | |
|-----------------------------|---|
| 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. |

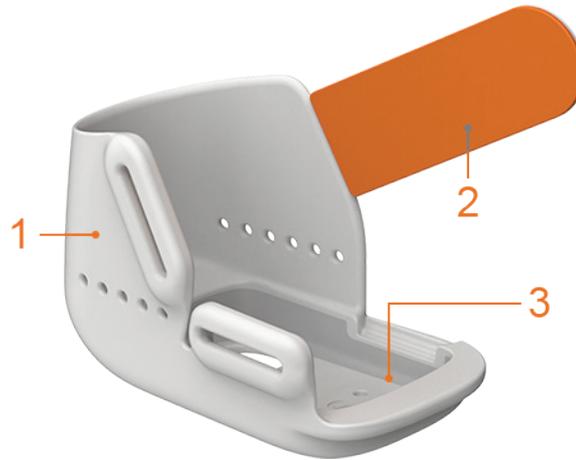
B Front of Sensor (Faces the baby's foot)

| | |
|------------------------------|---|
| 4 Sensor Status Light | Displays the sensor status. See <i>Sensor Status Light</i> on page 41. |
| 5 Charging Contacts | Charge the sensor battery using the charging cable and AC power adapter. See <i>Charging the Stork Sensor</i> on page 18. |

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. |

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 Camera to the app using local Wi-Fi.
 - Install the camera.
 - Charge the Stork Sensor.
 - Pair the sensor using the 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 27.

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 27.

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 28.

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 28 to connect Stork devices.

- Connect the Stork Camera to the app and local Wi-Fi network, and set up the camera viewing location.
- 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 setup, monitoring of the baby's health data begins.

Stork Camera Setup

See *Device Management* on page 28 to connect the Stork Camera and follow the app instructions to:

- Pair the camera to the Stork app using Bluetooth.
- Connect the camera to the wireless network (Wi-Fi).
- Install the camera. The camera can be set on a flat surface (such as a dresser) or mounted to the wall (preferred).

Connecting the Stork Camera

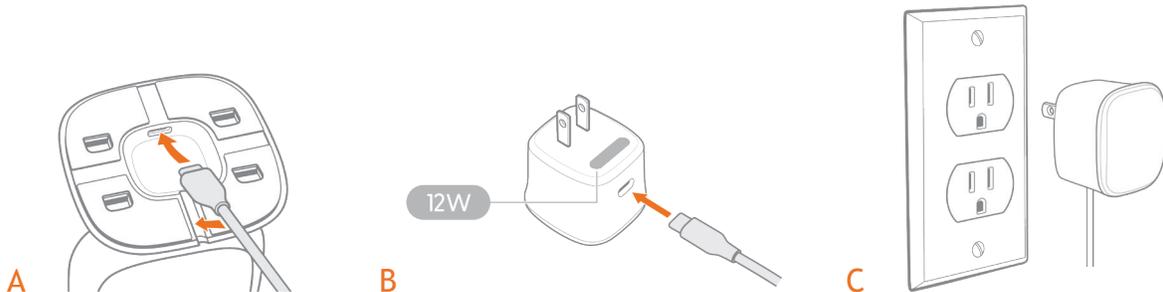
The Stork Camera is connected in two (2) steps.

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

Step 2: Connect the camera to the wireless network (Wi-Fi).

1. Plug the power cable into the camera (A), the power cable into the 12W AC power adapter (B) and plug the power adapter into a wall socket (C).

Note: The camera Indicator is white when powered on. See *Camera Status Light* on page 49.



2. Follow the app instructions to pair the camera. Hold your smart phone near the camera 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 camera from a list.

Note: If the Bluetooth connection fails, hold the smart phone closer to the camera and try to reconnect. If the camera cannot connect, see *Troubleshooting* on page 31.
3. Next, 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**.
4. Select the wireless *Network* and enter the *Password*. Select **Continue**.

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

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

Note: If the camera cannot connect, follow the app instructions to verify the network and try again or view *Troubleshooting* on page 31.

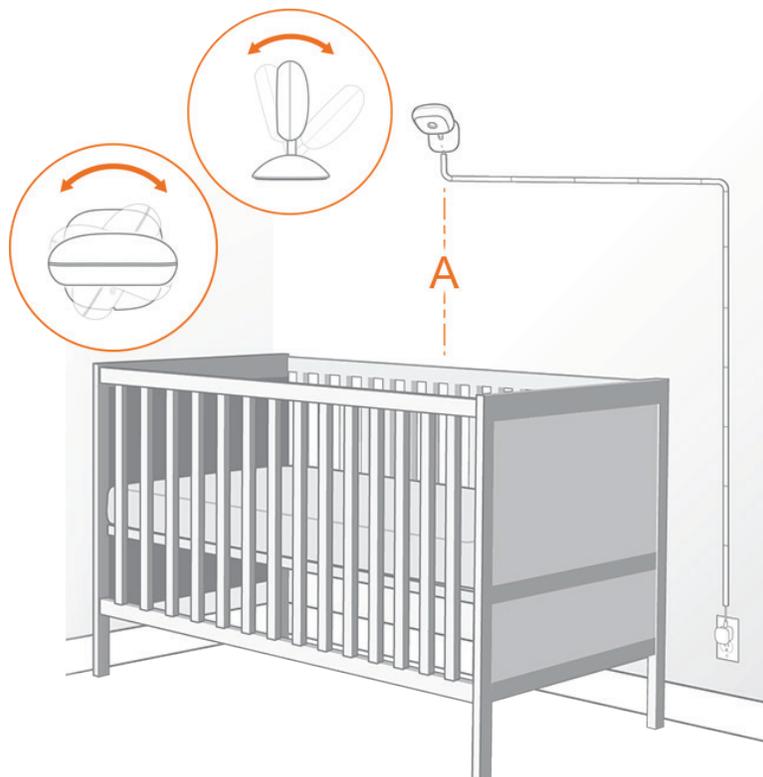
Choosing a Location for the Stork Camera

The Stork Camera can be set on a flat surface (for example: a dresser or a nightstand) or mounted to the wall (preferred). When set on a flat surface, place the camera in a safe location near the crib that is 4 to 5 feet above the mattress and so as not to fall on anyone, get damaged, or where communication is not muffled and notification sounds can be heard.

For wall mounting, pick a spot on the wall near the crib that is 4 to 5 feet above the mattress. Ideally, the camera should be located somewhere near the middle of the crib (A). At this height, the camera will be able to monitor the whole crib. The camera needs to be located within reach of a wall outlet using the included power cable.

WARNING: Do not place or mount the camera inside or on the edge of the crib to prevent the camera from falling on the baby or the baby pulling on the power cable.

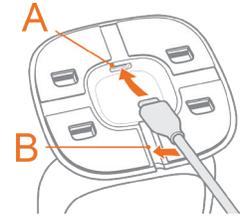
No matter the camera location, the camera can be adjusted for the perfect view of the baby.



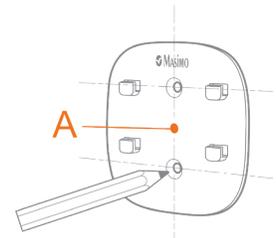
Installing the Stork Camera on a Wall

Note: Ensure the power adapter is unplugged from the wall socket before installing the camera to the wall.

1. Plug the power cable into the bottom of the camera (A).
Press the cable down to secure it in the built-in channel (B).



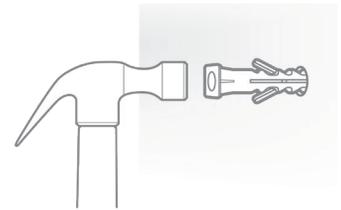
2. Place the camera on wall with the center of the mount (A) 4-5 feet above the crib mattress, near the center of the crib.
Make sure it is level and the 4 hooks are facing up, then mark the locations of the screw holes.



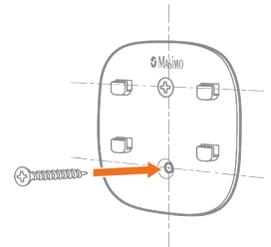
3. Drill the 2 marked locations using a 1/4" (6.35 mm) drill bit.



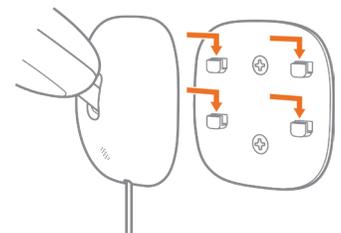
4. Gently tap the two wall anchors into the holes until they are flush with the wall.



5. Hold the mounting plate against the wall. Secure the mounting plate onto the wall with the included screws.



6. Align the 4 holes on the camera base with the hooks on the mounting plate, and then slide the camera down to snap it in place.



7. Peel off the sticky pad liners on the back of the cable cover(s) to apply, starting at the camera.

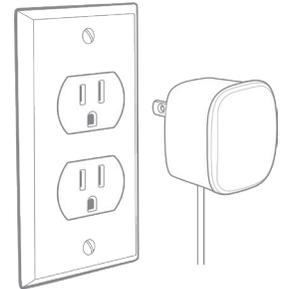
Add more covers as needed to fully protect the cable from being pulled on by the baby while in the crib.



8. Ensure the wall socket being used is within reach of the camera power cable. Plug the power cable into the 12W AC adapter. Plug the power adapter into the wall socket to power on the camera.

The camera will automatically connect to the Stork app when powered on if previously connected.

Adjust the camera angle as necessary for the best view.



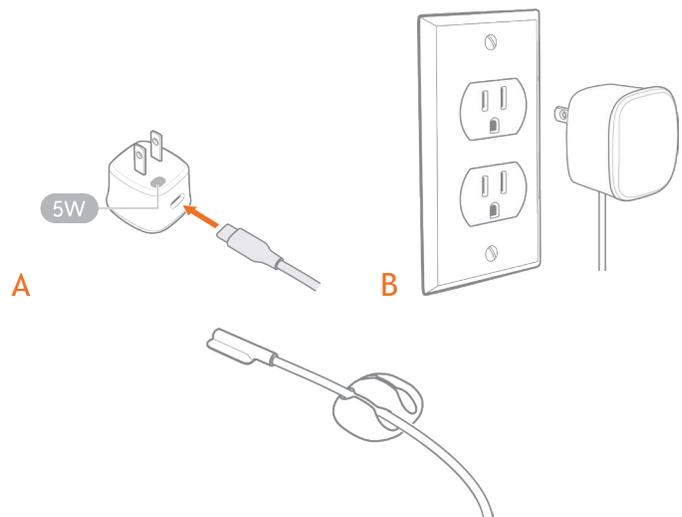
Stork Sensor Setup

See *Device Management* on page 28 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

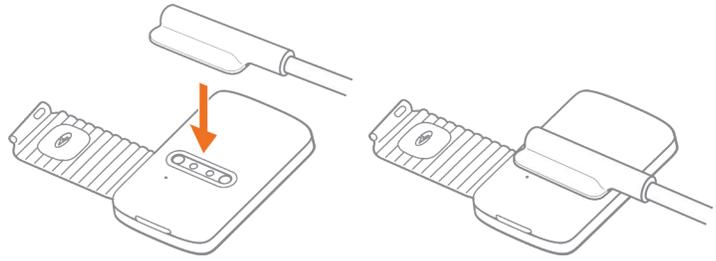
1. To charge the Stork Sensor, plug the charge cable into the 5W AC power adapter (A) and plug the power adapter into a wall socket (B).



2. 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.

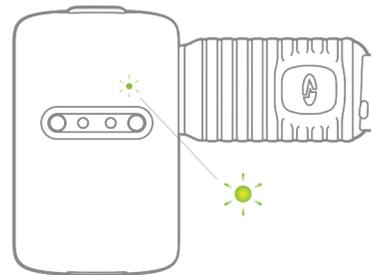
Note: If the sensor is in the boot, remove it from the Stork Boot to charge.



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 31.

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 31.

Stork Boot Setup

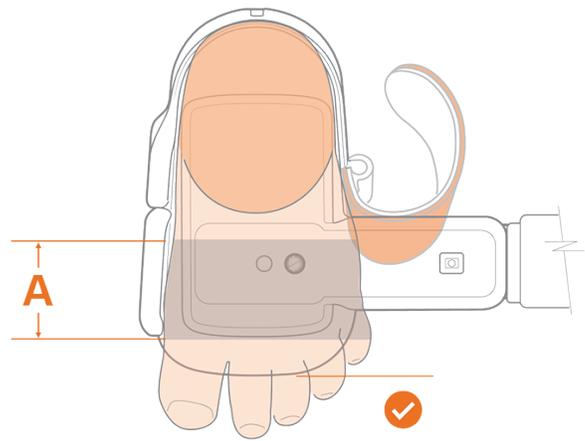
Follow the app instructions to:

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

Boot Size Selection

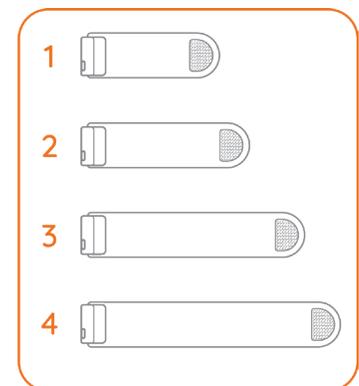
When sizing, your baby's heel should be all the way back against the boot. It is acceptable if the baby's toes overhang a little, as shown.

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

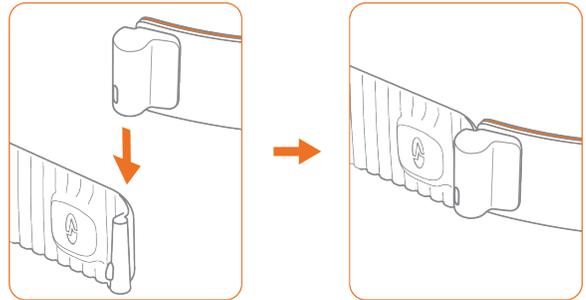
Straps come in 4 sizes. The small and medium boots come preattached with strap sizes 3 and 4. Size 1 and 2 come in separate packaging.



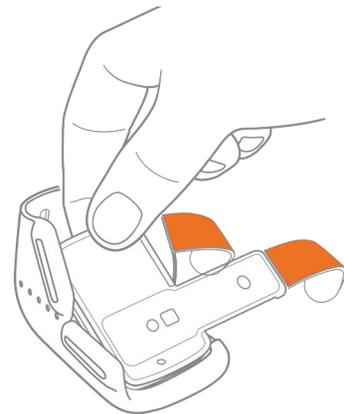
Attaching the Stork Sensor to the Boot

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.

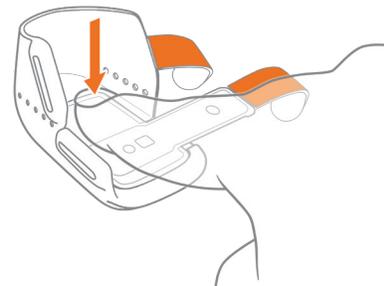
To remove the strap, simply slide back off.



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

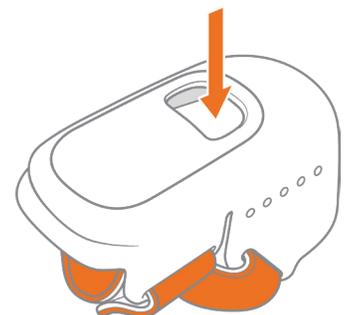


3. Press down to secure the sensor. The sensor should sit flush in the boot.



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

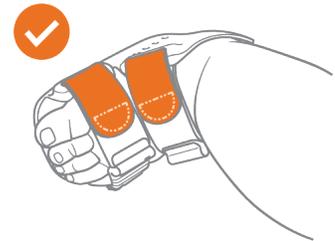
1. Place the boot to either foot. Check for proper alignment. The boot should be snug, but not tight.



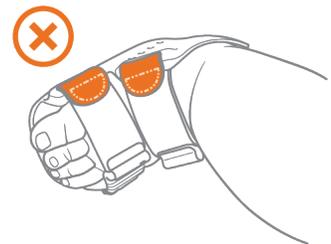
2. Wrap the cloth straps for the boot and the sensor around the foot and feed the straps through the openings in the boot.



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.

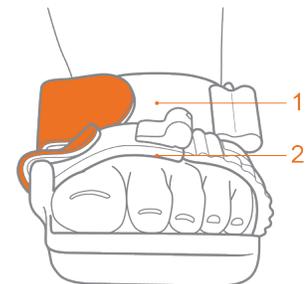


When sizing the straps for proper fit, for example, a small newborn will most likely require the Size 2 strap at the ankle and the Size 1 strap at the sensor.



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.



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 27.

2 Notifications - Provides device, account, and environmental notifications. Notifications are available when an orange dot appears on the icon. Touch the icon to open the *Notifications* screen. See *App Notifications* on page 25.

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

4 Camera Display - Displays the camera live view. Adjust the camera angle to get the best view of the baby.

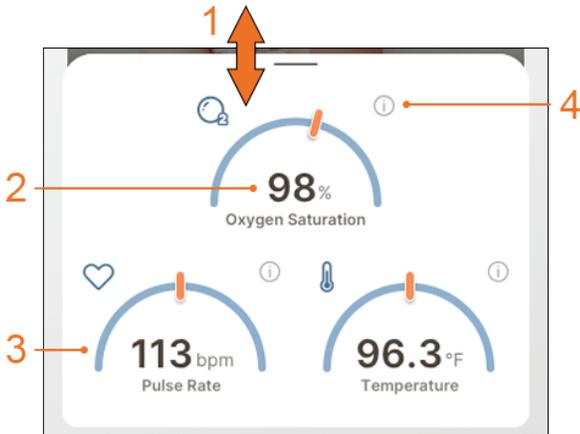
5 Live Controls - Touch the screen and the *Live Controls* appear. See *Live Controls* on page 27.

6 Health Data Dashboard - Swipe up to view health data readings. See *Health Data Dashboard* on page 24.

7 Bottom Menu - Shortcuts to additional app functions and features. See *Bottom Menu* on page 29.

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 - Touch the icon to see a description about the reading.

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

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

Advanced Use

Notifications

App Notifications

Pop-Up Notifications

Notifications appear on the Stork app screen for notifications related to the Stork Camera or Stork Sensor. In many cases, an notification also appears on the Stork Camera.

Notification 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. Touch the icon to open the *Notification Center* screen. Touch a notification to view additional information and acknowledge. Any "next steps" to address the notification are also shown (when available).

Baby Notification - When the sensor detects that the baby changes its position from laying face up to laying face down.

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 28.

Acknowledge and Clear Notifications

Pop-Up Notifications

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

Notifications Screen

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 Camera Notifications

Notifications are also communicated through the camera status light and speaker. Medium and high priority notifications are available. See *Camera Status Light* on page 49. When a low or medium priority notification is present, the camera status light flashes Yellow, and in some cases, an audible notification sounds. When a high priority notification is present, the camera status light flashes Red and an audible notification sounds. The app also shows pop-up notifications and some notifications appear on the *Notifications* 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.
- The ambient room temperature is too low.*

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.
- The ambient room temperature is too high.*

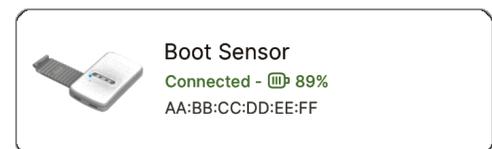
* Can be enabled through Room Settings for the device. See *Device Management* on page 28.

How to Silence and Acknowledge Notifications

Touch the Dismiss button in the pop-up message on the app to acknowledge and silence the notification.

Sensor Battery Charge Status

Battery charge status for the Stork Sensor is viewed through the *Side Menu* under *Devices*. See *Device Management* on page 28. Current battery charge status is shown on the sensor device tile next to the sensor connection status.



Live Controls



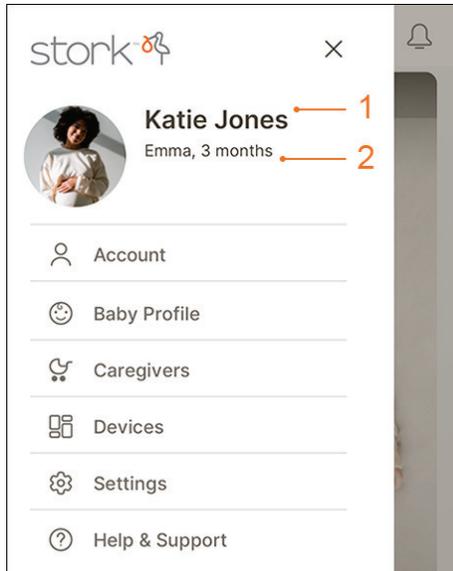
- 1 **Background Audio** - Touch to toggle the sound from Stork between off to "on with app open" or "on with another app displayed or phone locked".
- 2 **Two Way Talk** - Touch to toggle the Stork app microphone on or off (shown as off). Microphone volume controls display on the screen above the *Health Data Dashboard* when on.
- 3 **Lullaby** - Touch to display the lullaby player. See *Lullaby Player* on page 27.
- 4 **Snapshot** - When selected, a photo button appears at the bottom of the live feed to take a picture. The picture is saved to the smart phone.

Lullaby Player

Lullaby music can be played over the Stork Camera speaker. When selected, controls to play and pause the lullaby displays.

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 28.

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 28.

Caregivers - Invite trusted people to view Stork health data. See *Caregivers* on page 29.

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 28.

Settings - Select the units of measurement.

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.

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 tile 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). The sensor can also be set to notify when the baby is laying face down.
- Update device firmware (when available).
- For the Stork Camera, 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 the 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.

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 29.

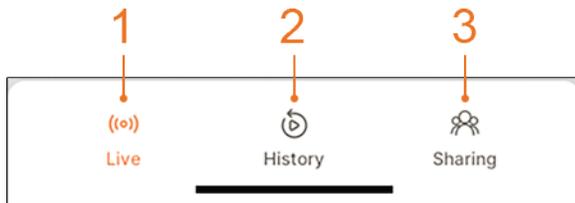
Remove caregiver access - Swipe left on the caregiver and select the remove icon.

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 27.

Bottom Menu

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

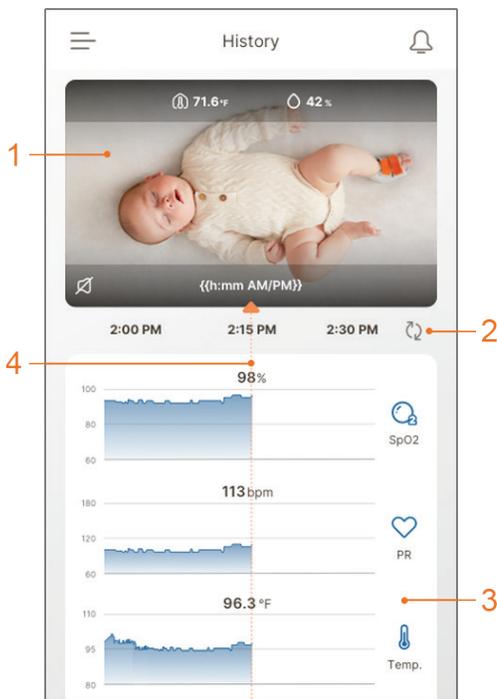


1 Live - Displays the current data, room conditions and vitals. See *Step 3: View Live Data* on page 23.

2 History - Review history data recorded by Stork. See *History* on page 30.

3 Sharing - Access to view other Stork Systems that have been shared with you. See *Sharing* on page 30.

History



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

1 Camera View/Ambient History - Displays the recorded camera view and room temperature 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 on the video 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 Camera nor Stork Sensor have an On/Off switch or controls to turn On or Off.

To turn the system Off:

1. Unplug the camera 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 |
|---|---|--|
| "Difficulty in obtaining a reading" | 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 55. |
| "Replace your sensor" | Sensor is not working. | Replace sensor. |
| "Wireless sensor disconnected during an notification" | <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 19. • If you still experience issues, please contact Masimo Customer Support. See <i>Customer Support</i> on page 55. |

| Displayed Messages | Potential Causes | Next Steps |
|--|---|---|
| "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. |
| "Battery low Warning" | Sensor battery is low. | Charge sensor. |
| "Depleted Battery" | Sensor battery is depleted. | Charge sensor. |
| "Wireless Sensor Disconnected" | Sensor is not monitoring. | Ensure sensor placement steps are completed and you are obtaining readings. |
| "Something unexpected happened. Please try again later." | 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 55. |

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 Camera</i> | <ul style="list-style-type: none"> Stork Camera is not powered on. Smart phone is not in close proximity to Stork Camera. 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 Camera is plugged into the AC power supply. Ensure the smart phone is in close proximity with Stork Camera. Ensure Bluetooth on the smart phone is turned on. Check smart phone compatibility. See <i>Specifications</i> on page 40. 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 55. |
| <i>Stork Camera does not connect to Wi-Fi or Masimo Cloud</i> | <ul style="list-style-type: none"> Stork Camera is not connected to power. 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 Stork Camera 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 Camera Setup</i> on page 15. Ensure correct Wi-Fi network is selected. See <i>Stork Camera Setup</i> on page 15. Ensure correct Wi-Fi password is entered. See <i>Stork Camera Setup</i> on page 15. 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 55. |

| Symptom | Potential Causes | Next Steps |
|---|---|---|
| <i>Stork Sensor does not pair with Stork Camera</i> | <ul style="list-style-type: none"> Stork Camera is not connected to power. Sensor is not inserted into boot. Sensor is not in close proximity with Stork Camera during pairing. Incorrect user logged into the app. Stork Camera has been registered with another account. Depleted sensor battery. | <ul style="list-style-type: none"> Ensure Stork Camera 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 21. Ensure the sensor is in close proximity with Stork Camera during pairing. Ensure correct user is logged into the app. Contact Masimo Customer Support. See <i>Customer Support</i> on page 55. |
| <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 Camera. 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 55. |

Troubleshooting Measurements

The following section lists possible measurement symptoms, potential causes, and next steps. For more information, see *Safety Information* on page 35.

| 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 Camera 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 55. |

Appendix

Safety Information

Before using Stork, read the following safety information carefully. Always consult a physician if you have concerns about your baby's well-being. Call emergency services if you believe your baby is having a medical emergency.

Do not rely on Stork for a clinical assessment. Stork is not intended to be used as a medical device or to replace a physician or health care professional. 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:** Carefully position the power cable to avoid possible strangulation or entanglement.

 **WARNING:** Secure the Stork Camera where it will not fall on anyone.

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

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

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

 **WARNING:** To avoid skin injury, consider alternating feet after it has been used for more than 12 hrs.

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

 **CAUTION:** Place the Stork Camera 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 Camera to prevent damage 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 as an apnea or as a sudden infant death syndrome (SIDS) monitor. Oxygen changes may be delayed from when breathing actually stops.

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

⚠ WARNING: Stork may be used during defibrillation. This may affect the accuracy or availability of the parameters and readings.

⚠ WARNING: Stork is not intended for use during electrocautery.

⚠ 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 message is provided. Clinicians should consider additional information to supplement values to completely understand the patient's condition.

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

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

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

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

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

SpO₂ and PR Features

⚠ WARNING: Things that interfere with the light can affect your SpO₂ accuracy. 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.
- 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.

⚠ WARNING: The temperature readings may not reflect skin temperature due to the following:

- Obstructed access to skins surface (e.g. clothing, perspiration, excess oil, hair, paint, heavy make-up).
- 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 40 for details. Moving outside of this range may cause a loss in connection.

⚠ WARNING: Do not place anything on top of the Stork Camera 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 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: 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 Camera is within the specified distance and in line-of-sight of the Stork Sensor. See *Specifications* on page 40.

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

Cybersecurity

⚠ WARNING: If you expect 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 phone should be located with the responsible users.
- Smart phone should not be left unattended.
- Security features on smart phone 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 Camera to prevent harm or damage to the system.

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

⚠ CAUTION: Do not clean the Stork Sensor or Stork Camera 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 55.

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

Radio Compliance

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

⚠ 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: 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 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: Stork Sensor 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: To satisfy RF exposure requirements, the Stork Camera 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.

Note: Stork Camera has been tested to FCC 15 Subpart B.

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 55 |

Weight Range and 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.

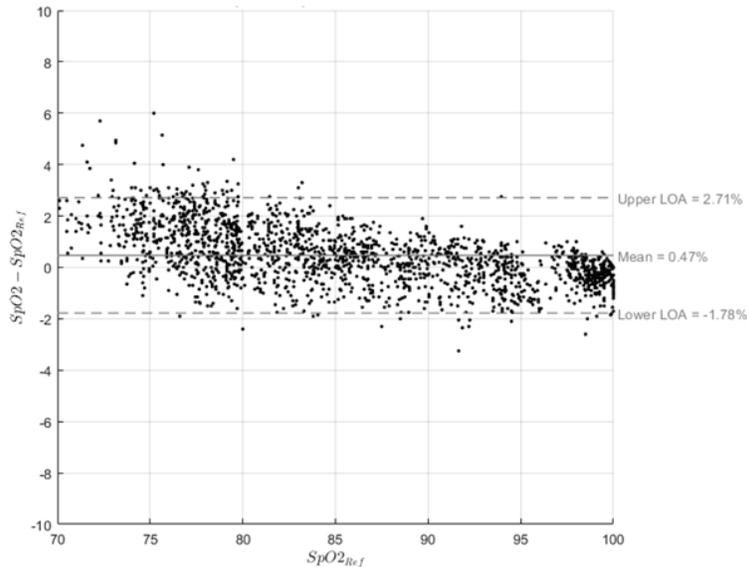


Figure 1: Masimo Stork (70-100%)

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 Masimo Stork to RD SET Adhesive Sensor | |
|---|---------------|
| 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.

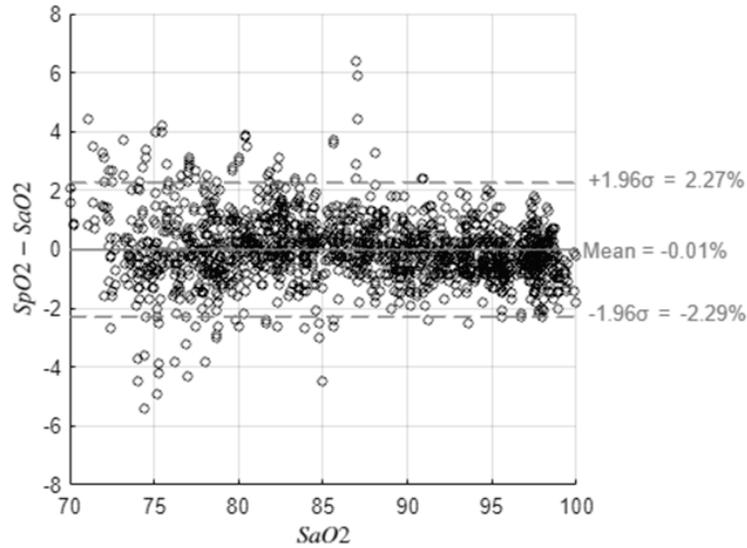


Figure 2: RD SET Adhesive Sensor (70-100%)

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 |

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 | 3 Vrms | 3 Vrms | Performed over 0.15-80 MHz |

| Electromagnetic Immunity | | | |
|--|---|---|--|
| IEC 61000-4-6 | 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. |
| 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 |

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) | |
|---|---|--|
| | $d = 0.6 \cdot \sqrt{P}$ | |
| 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.

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.

Stork Camera

Camera Status Light

The indicator on the Stork Camera shows the connection and operational 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 camera is ready for pairing to the smart phone/Stork app or to be connected to the wireless network. |
| Slowly Blinking Blue | The camera 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. |
| Solid Red | A high priority notification has been acknowledged and silenced. |

| Color/Behavior | What does it mean? |
|---|---|
| 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 55 |

* An audible notification may also sound.

Electrical

| Stork Camera | |
|-----------------------|-----------------------------------|
| AC Power Requirements | 100 to 240 VAC, 50 to 60 Hz, 2.4A |
| Power Consumption | 12W |

Physical Characteristics

| Stork Camera | |
|---------------------|---|
| Dimensions | 3.1" (L) x 3.0" (W) x 4.8" (H) (7.95 cm x 7.95 cm x 12.21 cm) |
| Weight | 0.70 lbs. (312g) |
| Resolution | 5 Megapixels |
| Viewing Angle | 130 degrees |
| Rotation adjustment | 252 degrees |
| Tilt Forward | 55 degrees |
| Tilt Backward | 16 degrees |

Wireless Specifications

| Communication (Bluetooth) - Stork Camera | |
|--|----------------------|
| Type | Bluetooth |
| Frequency | 2402-2480 MHz |
| Classification of Output Power Rating | Conducted |
| Max. Peak Output Power | 4.28 dBm |
| Output Power Type | Fixed at the Factory |
| Modulation Types | DH5, 2DH5, 3DH5 |
| Modulation Signals | Analog and Digital |
| Available Data Rates | 1, 2, 3 Mbps |

| Communication (Bluetooth LE) - Stork Camera | |
|---|------------------|
| Type | Bluetooth LE 5.0 |
| Frequency | 2402-2480 MHz |

Communication (Bluetooth LE) - Stork Camera

| | |
|---------------------------------------|-----------------------------------|
| Classification of Output Power Rating | Conducted |
| Max. Peak Output Power | 3.88 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 Camera

| | |
|---------------------------------------|---|
| Type | WLAN Radio: IEEE 802.11 ac/a/b/g/n |
| Frequency | 2400 MHz - 24835 MHz (2.4GHz ISM Band) 5.15 - 5.35GHz, 5.47 - 5.725GHz, 5.725 - 5.85GHz (5GHz UNII Band) 802.11b/g/n(HT20): 2412-2462 MHz 802.11n(HT40): 2422-2452 MHz 802.11ac(HT20,HT40 & HT80) |
| Classification of Output Power Rating | Conducted |
| Max Peak Output Power | 2.4 GHz wifi: 22.33 dBm 5 GHz wifi: 18.89 dBm |
| Output Power Type | Fixed at the Factory |
| Modulation Types | 802.11b: DSSS 802.11g: OFDM 802.11gn: OFDM 802.11a: OFDM 802.11an: OFDM 802.11ac: 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 802.11ac- MCS0 - MCS9 |

Security and Authentication - Stork Camera

| | |
|----------------|--|
| 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 Camera

| | |
|--------|--------------------|
| USA | FCC ID: VKF-STORKC |
| Canada | IC: 7362A-STORKC |

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 - Stork Sensor

IEC 60601-1-2

Safety Standards Compliance

IEC 60601-1

IEC 60601-1-11

IEC 62304

EN ISO 80601-2-61

Equipment Classification per IEC 60601-1 - Stork Sensor

| | |
|---|---|
| Type of Protection | Internally powered (Battery power) |
| Degree of Protection against Electrical Shock | Type BF-Applied Part |
| Protection against harm from Water and Particulate Matter | IP44 - Protection from solid bodies larger than 1 millimeter and protection against small splashes of water coming from all directions. |
| Mode of Operation | Continuous |

EMC Compliance - Stork Camera

FCC 15B, Class B (Emissions)

Safety Standards Compliance

IEC 62368-1

Equipment Classification per IEC 62368-1 - Stork Camera

| | |
|--------------------|----------------------|
| Type of Protection | Class III (DC Power) |
| Mode of Operation | Continuous |

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) |
| IP44 | Protection from solid bodies larger than 1 millimeter and protection against small splashes of water coming from all directions |  | ETL Intertek certification |
|  | Federal Communications Commission (FCC) Licensing |  | MR Unsafe. Not appropriate for use in MR environment (i.e.: inside the MR magnet room) |
| FCC ID: | Identifies unit has been registered as a radio device |  | Non-Sterile |
|  | Recyclable |  | Not made with natural rubber latex |
|  | Product contains no PVC (polyvinyl chloride) material |  | Caution |
|  | Warning |  | Date of manufacture YYYY-MM-DD |
|  | Manufacturer |  | Catalog number (model number) |
|  | Serial number |  | Masimo reference number |
|  | Storage temperature range |  | AC current |
|  | Keep dry |  | Do not use if package is damaged |
|  | Storage humidity limitation |  | Wireless Symbol level |
|  | Atmospheric pressure limitation | - | -- |

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 with signal strengths as low as 0.02% for the simulated saturation range of 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%.*

[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.*

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

Service and Maintenance

Cleaning

⚠ 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.

Allow to 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.



Note: The Stork Camera 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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