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stork™ Replacement Sensor

USER'S 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.

Download the Stork App before using this product. For help, go to www.masimostork.com for additional tips and tutorials, a full list of supported devices, warranty, trouble shooting, and customer support. Follow the in app instructions for device pairing and general set up.

DESCRIPTION

Stork™ is a smart home baby monitoring system designed for parents to monitor a healthy baby at home. The Stork Sensor is a wireless sensor that fits into the bottom of the Stork Boot. It uses Masimo SET® technology to track baby's health data, including oxygen saturation, pulse rate, and temperature. It is also capable of determining baby's position and notifying you in-app if baby is face up or face down.

Use as a Stork replacement sensor or as an extra sensor that will allow you to continuously track your baby's health data without charging downtime.

Contents:

A. Stork Sensor **B.** Magnetic Charge Cable & Cord Clip **C.** 5W Power Adapter

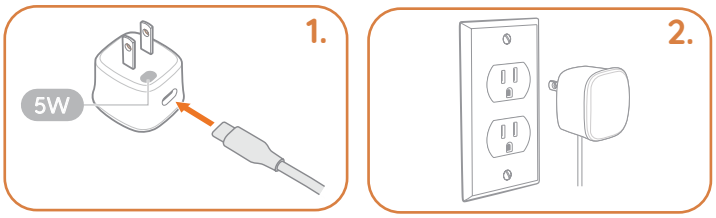
Not included: Boot, Boot Straps, Camera, or Hub (all sold separately).

INSTRUCTIONS

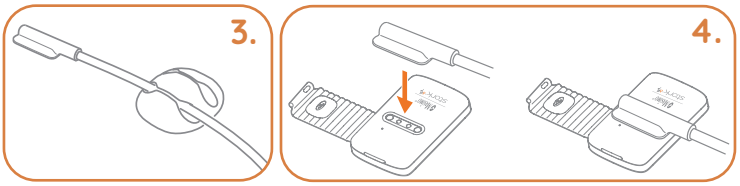
a) Charge the sensor

CAUTION: Make sure the sensor is fully changed before use.

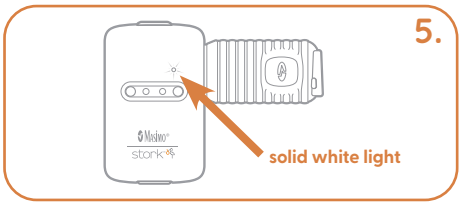
1. Refer to **Fig. 1.** Plug in the USB-C cable to the 5W power adapter.
2. Refer to **Fig. 2.** Plug in the power adapter into a wall socket.



3. Refer to **Fig. 3.** Peel and stick the cord clip to secure the sensor charge cord.
4. Refer to **Fig. 4.** Connect the magnetic charger to the sensor.



5. Refer to **Fig. 5.** The sensor is fully changed when the LED light turns solid white.

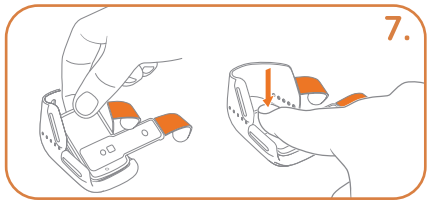


b) Pair the Sensor with your device (phone not included)

1. Refer to **Fig. 6.** Open the Stork App and click on Sensor.
2. Follow the on screen instructions to pair the sensor.

c) Insert the Sensor into the Boot

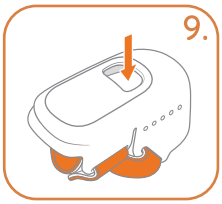
1. Refer to **Fig. 7.** Insert the sensor into the boot at an angle, toe end first, with the Masimo logo facing down and press down to secure the sensor. The sensor should sit flush in the boot.



2. Refer to **Fig. 8.** WARNING: Follow the instructions from your Stork system, boot and/or in the app to ensure the boot fits properly and the straps are not too tight to avoid injury.

d) Remove the Sensor

1. Refer to **Fig. 9.** Gently push the sensor through the opening on bottom of the boot to remove the sensor from the boot.



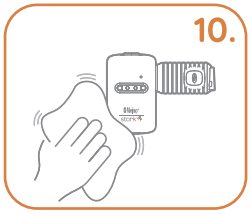
CLEANING

CAUTION:

- Do not use undiluted bleach or any cleaning solution other than those recommended here because permanent damage to the sensor could occur.
- Do not immerse the connector of the sensor or cable in any liquid solution.
- Using excessive force when removing the saensor may damage it.

To clean the sensor

1. Remove the sensor from the baby and the boot.
2. Refer to **Fig. 10.** Clean the sensor by wiping it with a 70% isopropyl alcohol pad or mild detergent.
3. Allow the sensor to dry completely prior to charging or use.



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

stork™ Replacement Sensor

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SAFETY PRECAUTIONS

- Stork is 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.
- Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor.
- Periodically check the areas where the user's skin contacts with the sensor to prevent potential issues, since there are skin-contacting components, there is a risk of skin irritation, pressure injury, and general discomfort while a sensor is applied to a user.
- Before using Stork, read the safety precautions 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. For safe use, do not use any component of the Stork System if it appears damaged.
- Do not adjust, repair, open, disassemble, or modify Stork. Such changes may lead to injury and/or incorrect readings.
- Misapplied sensors may cause incorrect readings.
- Do not leave the sensor components unattended, small items may become choking hazards.
- Carefully position any cables to avoid entanglement.
- Remove the Stork Sensor before bathing to prevent damage.
- Avoid strapping the boot too tightly around the foot to avoid injury.
- To avoid skin injury, consider alternating feet after it has been used for more than 12 hrs.
- Only use the AC power supply and cable included with your Stork Sensor to prevent damage to the device.
- Do not monitor more than one person at a time with Stork.
- The Stork Sensor is to only be used with Masimo Stork authorized devices.
- Do not use the Stork Sensor if it has visible defects, appears damaged, or seams discolored. Otherwise the sensor may not work properly.
- Check the sensor for proper securement and alignment frequently and adjust the sensor as necessary.
- Do not use additional tape to secure the sensor to the site. This can restrict blood flow and cause incorrect readings. Use of additional tape can also cause skin damage, and/or pressure injury or damage the sensor.
- Avoid placing the sensor directly under bright lights (e.g. fluorescent lights, infrared heating lamps, and direct sunlight) as they can interfere with the performance of the sensor. Cover the sensor site with opaque material, if required.
- Check pairing before use to ensure proper wireless connection.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance.

Things that interfere with the light can affect your SpO2 accuracy. Some things can be controlled, while others need awareness:

- **Controllable things:**
  - Keeping feet dry and free of foreign objects.
  - Not blocking the light through your foot.
  - Avoiding direct exposure to bright lights, including direct sunlight.
  - Keeping the foot still.
  - Warming the baby's 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.
  - Skin conditions that may affect the ability to comfortably wear the boot (e.g.: eczema).
  - Foot deformities (e.g. extreme club foot).
  - 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 the blood.
  - Age and medical history.

SENSOR STATUS LIGHT

Light Indicator Color	What does it mean?
Blinking Green	Sensor is on and waiting to be paired.
Solid Blue	Sensor is paired.
Blicking Orange	Sensor battery is low.
Blinking Red	Sensor battery is very low/depleted.
Blinking White	Sensor battery is charging.
Solid White	Sensor battery is fully charged.
Blinking Red in a pattern to indicate a number code	Sensor has a problem (non-battery related)

BATTERY

Battery type:	Li-ion rechargable	**Battery run time:**	16 hours*	**Charging Time:**	2 hours

* Minimum of 16 hours in typical continuous usage until fully discharged.

ENVIRONMENTAL

Storage Temperature	-20°C to + 60°C @ ambient humidity
Operating Temperature	5°C to + 35°C @ ambient humidity
Storage/Transport Humidity	10–95% RH (non-condensing) @ ambient temperature
Operating Humidity	10–95% RH (non-condensing) @ ambient temperature
Atmospheric Pressure	540 to 1060 mBar at ambient temperature and humidity

PERFORMANCE SPECIFICATIONS

The Stork Sensor has the following specifications:

Stork Sensor	
Application Site:	Foot
Age/Baby Size:	0-18 months
Measurements:	2.5" (L) x 1.9" (W) x .03" (H) (6.35 cm x 4.83 cm x 0.76 cm
Weight:	0.03 lbs. (13g)
Oxygen level SpO_2 performance (Arms) specifications (70-100%)SaO_2	
SpO_2 Accuracy, No Motion, Arms [1]	1.5 %
SpO_2 Accuracy, Motion, Arms [2]	1.5 %
SpO_2 Accuracy, Low Perfusion, Arms [3]	2 %
Pulse Rate (Arms) specifications from 25-240 BPM	
Pulse Rate No Motion, Arms [4]	≤ 3 BPM
Pulse Rate, Motion, Arms	≤ 5 BPM
Pulse Rate, Low Perfusion, Arms	≤ 3 BPM
Temperature Measurement Accuracy	
±0.3°C (±0.54°F) in the range of 25°C to 43°C (77°F to 109.4°F)	
Position	
The sensor will distinguish if the baby changes postion to face down.	

Note: Arms accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- Arms of the reference measurements in a controlled study.

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

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

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

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

WIRELESS TECHNOLOGY INFORMATION

Communication (Bluetooth)	
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
Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 b/g/n
Frequency	802.11b/g/n(HT20): 2412-2462 MHz 802.11n(HT40): 2422-2452 MHz
Classification of Output Power Rating	Conducted
Max. Peak Output Power	20 dBm
Output Power Type	Fixed at the Factory

Modulation Types	802.11b: DSSS 802.11g/n(HT20/HT40): OFDM
Modulation Signals	Analog and Digital
Available Data Rates	802.11b - 1, 2, 5.5, 11 Mbps. 802.11g - 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11n- MCS0 – MCS7
Security and Authentication	
Encryption	64/128-bit WEP, Dynamic WEP, WPA-TKIP, WPA2-AES
Authentication	Open System, Shared Key, Pre-Shared Key (PSK), 802.1X: LEAP, PEAP, TTLS, TLS, EAP-FAST
Radio Compliance	
USA	FCC ID: VFK-STORK
Canada	IC ID: 7362A-STORK

WARNING: Changes or modifications not expressly approved by the party responsible for compliance could 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.

GUIDANCE AND MANUFACTURER'S DECLARATION- 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	The ME Equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
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	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 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
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% UT1, 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% UT1, 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]UT: Rated voltage for the equipment

ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATION EQUIPMENT

TEST FREQUENCY	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	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 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)	
	d = 0.6*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.

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

SYMBOL	DEFINITION	SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Follow instructions for use		Separate collection for electrical and electronic equipment (WEEE).		Consult instructions for use
	Manufacturer	REF	Catalogue number (model number)		Do not use if package is damaged and consult instructions for use
	Date of manufacture YYYY-MM-DD	####	Masimo reference number		Atmospheric pressure limitation
	Keep dry		Fragile, handle with care		Storage temperature range
NON STERILE	Non-Sterile		Not made with natural rubber latex		Storage humidity limitation
	Caution		Do not discard		Bluetooth
	UL LLC certification		AC Currant		Wireless Symbol level
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	FCC ID:	Identifies unit has been registered as a radio device

Patents: http://www.masimo.com/patents.htm