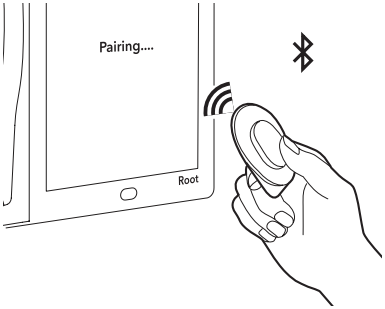
Centroid™

Patient Position Tracker



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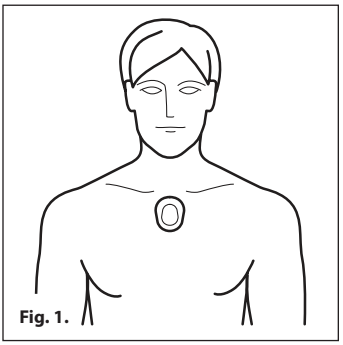

Fig. 1.

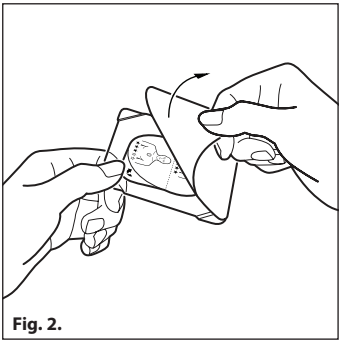

Fig. 2.

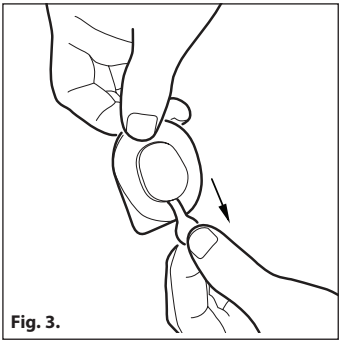

Fig. 3.

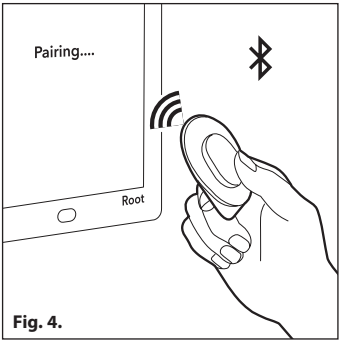

Fig. 4.

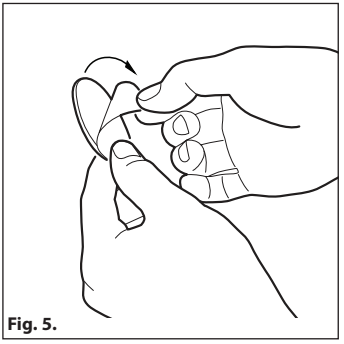

Fig. 5.

Centroid™

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Patient Position Tracker

DIRECTIONS FOR USE

Single patient use only | Not made with natural rubber latex | Non-sterile

Prior to using this sensor, the user should read and understand the Operator's Manual for the Device and this Directions for Use.

INDICATIONS

The Centroid™ System is intended for monitoring the orientation and activity of patients. The Centroid System is intended to provide alerts when patient orientation or activity deviates from parameters set by healthcare providers. The Centroid System is indicated for monitoring the orientation and activity of patients including those susceptible to pressure ulcers. The Centroid System is intended for use in healthcare environments.

The Centroid System is also indicated for the measurement of respiration rate of adults in healthcare environments.

CONTRAINDICATIONS

Centroid sensors are contraindicated for patients who exhibit allergic reactions to adhesive tape.

DESCRIPTION

Centroid sensors are battery powered, disposable sensors that can track the patient's posture, orientation and activity. The sensors are intended to transmit data wirelessly via Bluetooth to the paired Masimo® device.

Note: Centroid sensors are designed to be compatible with specific Masimo devices. See Compatibility section.

WARNINGS, CAUTIONS, AND NOTES

- Centroid sensors are to be used with specific monitors. Verify compatibility before use to ensure the sensors function properly.
- The Centroid sensor should be free of visible defects, discoloration and damage. If the sensor is discolored or damaged, discontinue use. Never use a damaged sensor or one with exposed electrical circuitry.
- Avoid contact with the sensor during defibrillation.
- Do not modify or alter the Centroid sensor in any way. Alteration or modification may affect performance and/or accuracy.
- Do not use the Centroid sensor during surgical procedures.
- Do not use the Centroid sensor in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments or nitrous oxide to avoid risk of exposure.
- Do not use the sensor during MRI scanning or in a MRI environment as it may result in physical harm.
- The Respiration Rate (RR) feature available on the Centroid system does not provide alarms therefore it should be used for informational purposes only.
- The Respiration Rate (RR) feature should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- Do not use Centroid as an apnea monitor. The Centroid system does not have alarms to alert you when patients are not breathing properly.
- Always ensure settings including alarms are appropriate for each patient and facility's protocols prior to use. Centroid has not been validated for ambulatory use or for use on pediatric populations.
- Do not place the Centroid sensor on garments. Apply directly to the skin. Choose a site on the chest where the skin is clean and dry prior to sensor placement.
- Do not use additional tape to secure the sensor to the site. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the sensor.
- Check the sensor site to ensure skin integrity and to avoid damage or irritation to the skin.
- The site must be checked frequently or per clinical protocol to ensure adequate circulation, skin integrity and correct alignment.
- Exercise caution with poorly perfused patients. Assess site as frequently and move the sensor if there are signs of tissue ischemia.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect readings.
- Inaccurate readings may be caused by misaligned sensor and/or EMI interference.
- Inaccurate or no Respiration Rate (RR) readings may be caused by: improper placement; motion induced artifact.
- Periodically check the sensor site for proper adhesion to minimize the risk of inaccurate Respiration Rate (RR) readings or no readings.
- Do not attempt to reuse on multiple patients, reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not attempt to sterilize by irradiation, steam, autoclave or ethylene oxide as it will damage the sensor.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.

INSTRUCTIONS

A) Site Selection

- Chose a site on the chest where the skin is clean of debris and dry prior to sensor placement.
- Ensure orientation and location of the sensor on the patient matches the sensor site location in the Masimo device settings.

Chest

Refer to **Fig. 1.** The preferred site is on the patients chest.

B) Applying the sensor

1. Refer to **Fig. 2.** Open the package and remove the sensor.

   Note: Do not remove the release liner at this point.
2. Refer to **Fig. 3.** Pull to remove the plastic battery tab.
3. Refer to **Fig. 4.** Move the sensor close to the Masimo device (such as Root®), to enable Bluetooth pairing.

   Note: Refer to the Masimo device Operators Manual for complete instructions.
4. Clean and dry the sensor application site.
5. Refer to **Fig. 5.** Pull off the release liner from the sensor.
6. Apply the sensor on to the selected application site.

Note: Centroid sensor is designed for removal and reapplication for no more than two (2) times over the life of the product.

C) Removing the Sensor

1. Peel gently to remove the sensor from the patient.

   Note: Disposal of Product: Comply with local laws in the disposal of the Centroid sensor, host device and/or its accessories.

SPECIFICATIONS

The sensors have the following specifications:

Centroid Sensor:	
Weight Range	approximately 30 g
Application Site	Chest
Sensor Life	96 hours
Respiratory Rate Range*	8 – 35 breaths/min
Respiratory Rate Accuracy[1]	3 rpm

**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]*Respiration rate performance has been validated against manual scored capnogram respiratory measurements on 40 healthy volunteer subjects and 34 hospitalized adults. The clinical testing results may not be generalized to all patient conditions.*

ENVIRONMENTAL

Centroid Sensor:	
Storage/Transport Temperature	-20°C - 50°C @ ambient humidity
Shelf Life	2 years
Operating Temperature	10°C - 40°C @ ambient humidity
Storage/Transport Humidity	15% RH - 90% RH (non-condensing) @ ambient temperature
Operating Humidity	15% RH - 95% RH (non-condensing) @ ambient temperature
Protection against harm from liquid ingress	IP24, Protection from ingress of particulates and water spray from any direction

WIRELESS SPECIFICATIONS

Communication (Bluetooth)	**Configurable Settings**
Type	Bluetooth Low Energy

CAUTION: In order to maintain Bluetooth connectivity with Root, ensure that Centroid is within specified distance and line of sight of Root. See Root with Centroid Operator's Manual.

COMPATIBILITY

This sensor is intended for use only with devices containing Masimo technology. Each sensor is designed to operate correctly only on the systems from the original device manufacturer. Use of this sensor with other devices may result in no or improper performance.

For Compatibility Information Reference: www. Masimo.com

WARRANTY

Masimo warrants to the initial buyer only that these products, when used in accordance with the directions provided with the Products by Masimo, will be free of defects in materials and workmanship for a period of six (6) months. Single use products are warranted for single patient use only.

THE FOREGOING IS THE SOLE AND EXCLUSIVE WARRANTY APPLICABLE TO THE PRODUCTS SOLD BY MASIMO TO BUYER. MASIMO EXPRESSLY DISCLAIMS ALL OTHER ORAL, EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. MASIMO'S SOLE OBLIGATION AND BUYER'S EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY SHALL BE, AT MASIMO'S OPTION, TO REPAIR OR REPLACE THE PRODUCT.

WARRANTY EXCLUSIONS

This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product, or has been subject to misuse, neglect, accident or externally created damage. This warranty does not extend to any product that has been connected to any unintended instrument or system, has been modified, or has been disassembled or reassembled. This warranty does not extend to sensors or patient cables that have been reprocessed, reconditioned or recycled.

IN NO EVENT SHALL MASIMO BE LIABLE TO BUYER OR ANY OTHER PERSON FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION LOST PROFITS), EVEN IF ADVISED OF THE POSSIBILITY THEREOF. IN NO EVENT SHALL MASIMO'S LIABILITY ARISING FROM ANY PRODUCTS SOLD TO BUYER (UNDER A CONTRACT, WARRANTY, TORT OR OTHER CLAIM) EXCEED THE AMOUNT PAID BY BUYER FOR THE LOT OF PRODUCT(S) INVOLVED IN SUCH CLAIM. IN NO EVENT SHALL MASIMO BE LIABLE FOR ANY DAMAGES ASSOCIATED A PRODUCT THAT HAS BEEN REPROCESSED, RECONDITIONED OR RECYCLED. THE LIMITATIONS IN THIS SECTION SHALL NOT BE DEEMED TO PRECLUDE ANY LIABILITY THAT, UNDER APPLICABLE PRODUCTS LIABILITY LAW, CANNOT LEGALLY BE PRECLUDED BY CONTRACT.

NO IMPLIED LICENSE

This single-patient sensor is licensed to you under the patents owned by Masimo for single-patient use only. By acceptance or use of this product, you acknowledge and agree that no license is granted for use of this product with more than a single patient.

After single-patient use, discard sensor.

Purchase or possession of this sensor confers no express or implied license to use the sensor with any device which is not separately authorized to use Masimo sensors.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

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).	Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician
	Consult instructions for use	LOT	Lot code		Non-sterile
	Manufacturer	REF	Catalogue number (model number)		Not made with natural rubber latex
	Date of Manufacture YYYY-MM-DD	####	Masimo reference number		Body weight
	Use By YYYY-MM-DD		Storage humidity Limitation		Storage temperature range
	Do not re-use/Single patient use only		Do not use if package is damaged and consult instructions for use		Keep dry
	Caution		Bluetooth	IP24	Protection from ingress of particulates and water spray from any direction
FC	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device		Single patient - multiple use
MD	Medical device	UDI	Unique device identifier		Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note: eIFU is not available in all countries.**

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

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Manufacturer:
Masimo Corporation
52 Discovery
Irvine, CA 92618
USA

www.masimo.com

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