Root®
with Centroid™

Masimo

For Sale in the USA

These operating instructions provide the necessary information for proper operation of all models of the Centroid. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Centroid are prerequisites for its proper use. Do not operate Centroid 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.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings and precautions.

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MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
Conforms to ANSI/AAMI ES 60601-1, CAN/CSA C22.2 No. 60601-1, and applicable Particular (IEC 60601-2-49, ISO 80601-2-56) and related Collateral (IEC 60601-1-8:2006) Standards for which the product has been found to comply by Intertek.

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

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Contents

Addendum, Root Operator's Manual: Centroid™

This addendum provides updates to the following:

Operator's Manual, Root®

- 37365/LAB-8425 and equivalent translations

Operator's Manual, Root® with noninvasive blood pressure and temperature

- 38280/LAB-9274 and equivalent translations

This addendum covers Centroid™ operation with Root. For all other information, refer to the *Operator's Manual, Root®* or *Operator's Manual, Root® with noninvasive blood pressure and temperature.*

Product Description, Features, and Indications for Use

The following information is an addendum to be used with the content in *Product Description and Features, Intended Use and Indications for Use* chapter of the *Operator's Manual, Root®* or *Operator's Manual, Root® with noninvasive blood pressure and temperature.*

Product Description and Features

The Centroid System, which consists of the Centroid Sensor and connected Masimo device, is a noninvasive position and activity monitor designed to continuously monitor patient movement and activity, including patient falls. The Centroid System can be used in any hospital and hospital-type facility where patients may be at risk for pressure ulcers. The Centroid System can provide Respiration Rate (RR) for informational purposes only.

Indications for Use

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.

Safety Information, Warnings, and Cautions

The following information is an addendum to be used with the content in *Safety Information, Cautions and Warnings* chapter of the *Operator's Manual, Root®* or *Operator's Manual, Root® with noninvasive blood pressure and temperature.*

CAUTION: Centroid is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use. Refer to Operator's Manuals for Root for additional safety information, warnings, and cautions.

Safety Warnings and Cautions

WARNING: Centroid sensors are to be used with specific monitors. Verify compatibility before use to ensure the sensors function properly.

WARNING: 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.

WARNING: Do not modify or alter the Centroid sensor in any way. Alteration or modification may affect performance and/or accuracy.

WARNING: Avoid contact with the Centroid sensor during defibrillation.

WARNING: Do not use the Centroid sensor during surgical procedures.

WARNING: Do not use Centroid sensors 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.

WARNING: Do not use the Centroid sensor during MRI scanning or in a MRI environment as it may result in physical harm.

Performance Warnings and Cautions

WARNING: 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.

WARNING: The respiration rate feature available on the Centroid system does not provide alarms therefore it should be used for informational purposes only.

WARNING: Do not use Centroid as an apnea monitor. Root with Centroid does not have alarms to alert patients you when patients are not breathing properly.

WARNING: 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.

WARNING: Do not place 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.

WARNING: 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.

WARNING: Check the sensor site to ensure skin integrity and to avoid damage or irritation to the skin.

WARNING: The site must be checked frequently or per clinical protocol to ensure adequate circulation, skin integrity and correct alignment.

WARNING: Exercise caution with poorly perfused patients. Assess site frequently and move the sensor if there are signs of tissue ischemia.

WARNING: Misapplied sensors or sensors that become partially dislodged may cause incorrect readings.

WARNING: Inaccurate readings may be caused by misaligned sensor and/or EMI interference.

WARNING: Inaccurate RR readings may be caused by:

- Motion Induced Artifact.
- Improper Placement or Alignment.

WARNING: Periodically check the sensor site for proper adhesion to minimize the risk of inaccurate Respiration Rate (RR) readings or no readings.

CAUTION: In order to maintain Bluetooth connectivity with Root, ensure that Centroid is within specified distance and line of sight of Root. See the Specifications chapter.

Cleaning and Service Warnings and Cautions

WARNING: Do not attempt to reuse on multiple patients, reprocess, recondition or recycle Centroid sensors as these processes may damage the electrical components, potentially leading to patient harm.

CAUTION: To prevent damage, do not soak or immerse the Centroid sensor in any liquid solution.

CAUTION: Do not attempt to sterilize by irradiation, steam, autoclave or ethylene oxide as it will damage the Centroid sensor.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

CAUTION: Disposal of Product: Comply with local laws in the disposal of the instrument and/or its accessories.

Note: Use Centroid in accordance with the Environmental Specifications section in the *Operator's Manuals* for *Root*.

Note: The Centroid should be placed on the chest on the same relative plane as the patient's head when using the head of bed feature. The angles may vary slightly from the actual head of bed angle if the chest application site falls outside the plane of the head (e.g. due to the contour of the chest or postural deformities), as the reference plane is the device flat in the horizontal position.

Setting Up

The following information is an addendum to be used with the content in **Setting Up** chapter of the **Operator's Manual, Root®** or **Operator's Manual, Root® with noninvasive blood pressure and temperature.**

Centroid

To connect Centroid to the Masimo device for patient monitoring, perform the following:

1. Pair the Centroid sensor to the Masimo device. See **Basic Setup and Use** on page 15.
2. Attach the Centroid sensor to the Patient. Refer to the sensor Directions for Use for proper instructions.

Operation

The following information is an addendum to be used with the content in **Operation** chapter of the **Operator's Manual, Root®** or **Operator's Manual, Root® with noninvasive blood pressure and temperature.**

The following provides necessary information for proper operation of the Centroid sensor with a Masimo device. Do not operate the Masimo device with the Centroid sensor without completely reading and understanding these instructions and the Centroid sensor Directions for Use. The information in this section assumes that the Centroid sensor is set up and ready for use, and the user understands how to operate both the Centroid sensor and the Masimo device.

Accessing Main Menu Options

To access the Main Menu options at the bottom right corner of the Root touchscreen, press/select the **Main Menu** icon.

With Centroid connected to the Masimo device, the *Main Menu* options change and are reflected below.

Layout

See **Chapter 3: Operation** of the **Operator's Manual, Root®.**

Centroid Settings*

See **Centroid Settings** on page 12.

**Device Settings**

See **Device Settings** on page 13.


About

See **About** on page 14.

* Centroid settings can also be accessed directly by pressing/selecting anywhere on the Centroid window, with the exception of the trend area.

Layout with Centroid

When Centroid is connected to Root, the user will have the option to select from several pre-configured layouts. Image below shows possible layout options available on Root with Centroid connected and Radical-7 docked.
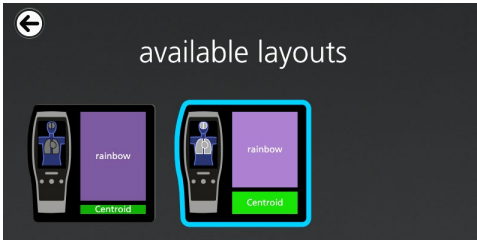
Centroid Settings
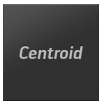
From the *Centroid Settings* screen, access the following screens:

- *Alarms* on page 12.
- *Sensor Settings* on page 13.

Alarms

From the *Centroid Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Position Duration	Maximum amount of time patient should be in one position.	Low	2 hours	1, 1.5, 2, 2.5, 3, 3.5, or 4 hours
Fall Detection Alarm	Alarms when a fall-like movement occurs.	High	On	On or Off

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Positions Allowed	A user set configuration for indicating that a certain patient position is allowed or not allowed. When On, position is allowed, when Off, position is not allowed.	Low	On (All)	• Right: On or Off • Supine: On or Off • Left: On or Off

Sensor Settings

From the *Centroid Sensor Settings*, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Stand By Monitoring	Allows Centroid sensor to be placed on standby to prevent unintentional alarms.	NA	Standby or Resume
Clear Sensor History	Clears sensor data and trend history.	NA	Select to clear history

Device Settings

The **Device Settings** menu allows the user to view and customize settings for the Masimo device.

The **Device Settings** options are:

Bluetooth

See *Bluetooth* on page 14.

Bluetooth

Use the *Bluetooth* screen to enable or disable Bluetooth connectivity, connect devices to the Masimo device using a Bluetooth connection or view connected device information. For complete information on the Masimo device Bluetooth menu, see the Operator's Manual for the Masimo device.

Option	Description	Factory Default Setting	Configurable Settings
Centroid	Pairs the Centroid sensor to Root.	NA	Pair, Info*

* After paring, the Centroid Info screen can be accessed through the *Bluetooth* screen. See **Accessing the Centroid Info Screen** on page 21.

About

Use the *About* screen to view the software version, MAC address, and signal strength information for Centroid. These details may be helpful during troubleshooting.

Option*	Description
SW Version	Displays software version number.**
MAC address	Displays the Centroid Bluetooth MAC address.
Signal Strength	Displays the Centroid Bluetooth received signal strength indicator (RSSI).**

* These fields are read-only and cannot be configured by the user.
** Displays when Centroid is on and connected to the Masimo device.

Centroid Operation

Centroid Overview

The Centroid™ System, which consists of the Centroid Sensor and connected Masimo device, is a noninvasive position and activity monitor designed to continuously monitor patient movement and activity, including patient falls. The Centroid System can be used in any hospital and hospital-type facility where patients may be at risk for pressure ulcers. The respiration rate feature available on the Centroid system does not provide alarms therefore it should be used for informational purposes only.

Basic Setup and Use

The following information describes basic setup and use of Centroid.

Pairing Centroid

To pair Centroid with a Masimo device:

Note: Only one (1) Centroid sensor can be paired to a Masimo device at one time. If a Centroid sensor is already paired and a different sensor needs to be paired, the currently paired sensor needs to be disconnected before a new sensor can be paired. See ***Disconnecting Centroid from the Masimo Device*** on page 26.

1. Remove the Centroid sensor from the packaging.
2. Pull the plastic battery tab as shown to turn the sensor on. Refer to the sensor Directions for Use for proper instructions.
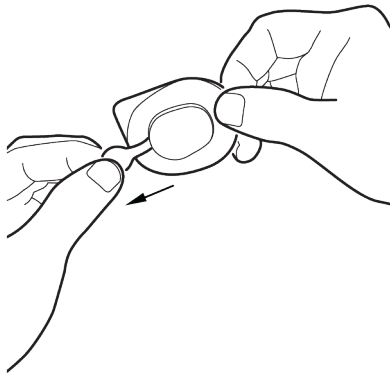

3. On the Masimo device, at the bottom right corner of the screen, press/select the *Main Menu* icon ⚙.
4. Swipe left or right and press/select the *Device Settings* menu icon.
5. Swipe left or right and press/select the *Bluetooth* menu icon.
6. On the *Bluetooth* screen, press/select the Centroid *Pair* button. The Centroid sensor appears under *Devices Found*.

Note: If a Centroid sensor is already paired to the Masimo device, this sensor must be disconnected before a new sensor can be paired. See ***Disconnecting Centroid from the Masimo Device*** on page 26.
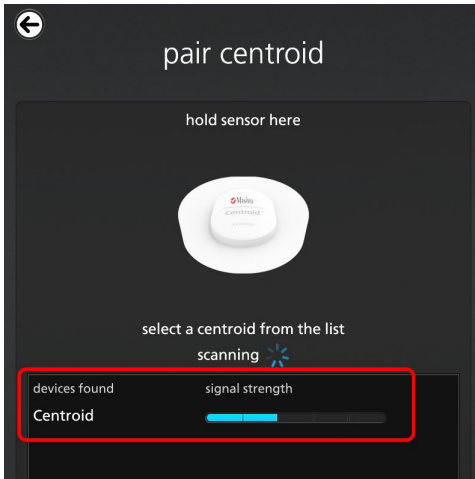

CAUTION: Multiple sensors may be detected and displayed under the *Devices Found* list as shown. To identify the Centroid sensor that requires pairing at this time, see ***Identifying Centroid Sensor for Pairing*** on page 16.
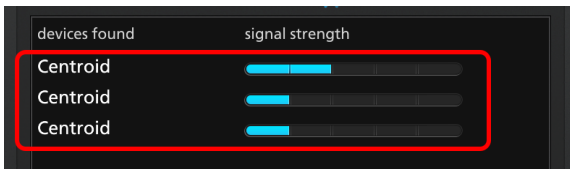
7.   After identifying the correct Centroid sensor, press/select the sensor under the *Devices Found* list on the screen. If only one (1) sensor is displayed on the screen, press/select that sensor.

8.   Press/select the *Pair* button. The Centroid sensor will pair with the Masimo device.

9.   After successfully pairing, Centroid data displays in the Centroid window of the Masimo device. See ***Centroid Window*** on page 18.

Identifying Centroid Sensor for Pairing

When attempting to pair a Centroid sensor with multiple active Centroid sensors within Bluetooth range of the Masimo device, all detected sensors appear in the *Devices Found* list on the *Bluetooth* Screen.
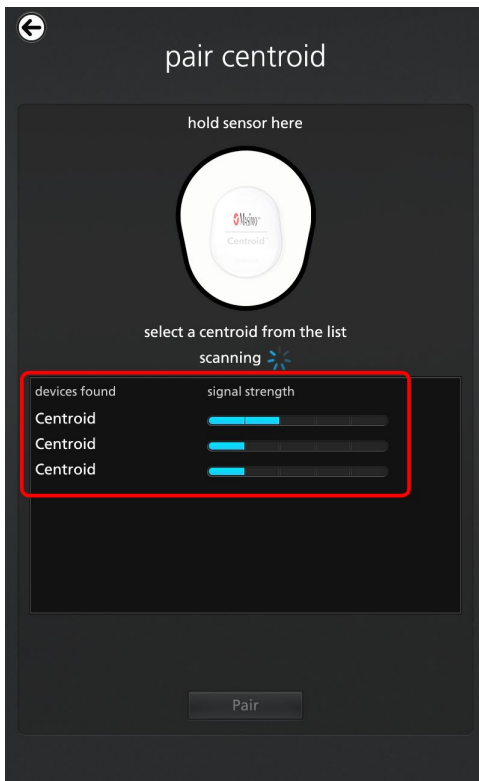
To properly identify the sensor that is to be paired for patient monitoring, perform the following:
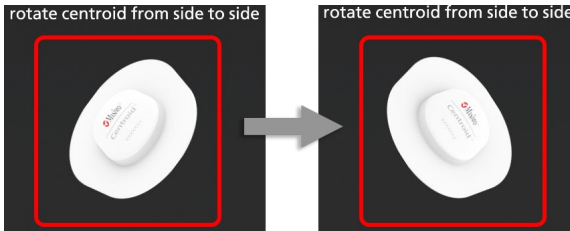
1. Hold the Centroid sensor to be paired, in front of the Masimo device.
2. Press/select the top sensor displayed in the *Devices Found* list.
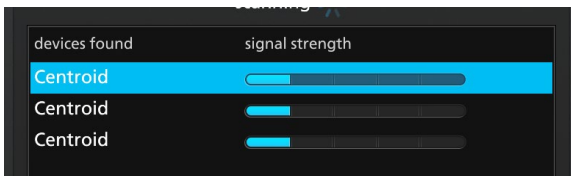
3. While watching the image of the Centroid sensor at the top of the Masimo device *Bluetooth* screen, move the sensor as instructed on the screen.

-   If the image of the sensor responds to the movement of the Centroid sensor and the image moves accordingly, this indicates the Centroid sensor selected in the *Devices Found* list is the same one being held, and can be paired.

-   If the image of the sensor does not respond to the movement of the Centroid sensor, press/select the next sensor displayed in the *Devices Found* list and repeat until the correct sensor is identified.

4. Once the correct Centroid sensor is identified, press/select the *Pair* button at the bottom of the screen to pair the Centroid sensor to the Masimo device.

Attach Centroid to Patient

After pairing the Centroid sensor, attach the sensor to the patient. Refer to the sensor Directions for Use for proper instructions. Ensure the location of the sensor on the patient matches the sensor site location in the Masimo device settings. See **Sensor Settings** on page 13.

Centroid Window

Parameters and measurements display in the *Centroid* window. Patient position is shown as a graphical representation, and parameters display as numeric values.

When multiple technologies are connected to the Masimo device, each technology's parameters are displayed in an individual window. On Root, the relative size of each window can be configured using the Layout feature, which is accessible though the Layout icon in the Main Menu. For additional information, see the **Operator's Manual, Root®** or **Operator's**

Manual, Root® with noninvasive blood pressure and temperature. The image below is an example of the Root *Centroid* window.
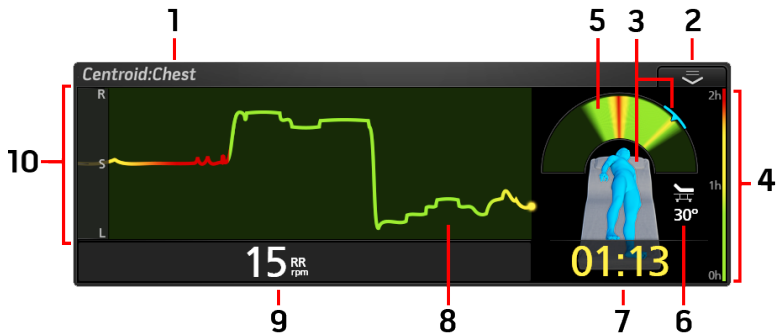
| Ref.	Feature
1	**Sensor Location** Location of the sensor on the patient. See **Sensor Settings** on page 13.
2	**Action Menu** Shortcuts to Centroid functions and features. See **About the Action Menu** on page 20.
3	**Patient Current Position** Shows patient current position. If patient is sitting or standing/walking, a message is displayed at the top of the Centroid window.
4	**Time in Position Color Key** Color key for length of time in position vs. severity. See **Time in Position** on page 20.
5	**Time in Position Color Chart** Color chart for length of time in each position. See **Time in Position** on page 20.
6	**Head of Bed Angle** Patient's current incline angle.
7	**Time in Current Position** Elapsed time in hours and minutes (HH:MM) patient is in current position. See **Time in Position** on page 20.
8	**Trend Graph** Displays time in position over a period of time. See **Time in Position** on page 20.
9	**Respiration Rate** Breathing rate as measured by Centroid.
10	**Patient Position in Trend** R = Right Side, S = Supine, L = Left. See **Centroid Settings** on page 12.

About the Action Menu
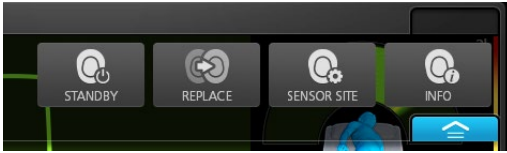
The Centroid *Action Menu* provides access to the following settings:

- **Standby** - Places the Centroid sensor in Standby monitoring. See ***Centroid Standby*** on page 27.

- **Replace** - Displays the *Replace Centroid* screen for sensor replacement. See ***Replace Centroid Sensor*** on page 22.

- **Sensor Site** - Displays the *Centroid Sensor Settings* screen for the sensor location on the patient. See ***Sensor Settings*** on page 13.

- **Info** - Displays the *Centroid Info* screen with sensor information. See ***Centroid Info*** on page 21.

Time in Position
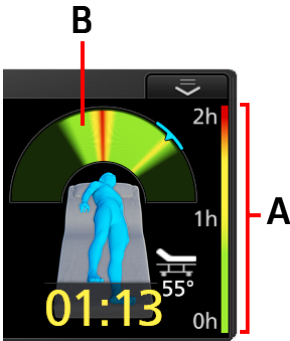
The Time In Position Color Key (A) and Time In Position Color Chart (B) are related to the patients positions. Alarms can be set for the Masimo device to notify the clinician based on a selected elapsed time the patient can be in any one position. See ***Alarms*** on page 12.

- The scale in the Time In Position Color Key (A) changes based on the Position Duration settings (2 hours is shown in the example).

- The colors in the Time in Position Color Chart (B) changes from Green > Yellow > Red as the elapsed time a patient is in one position increases.

Accessing the Centroid Info Screen

Centroid information as well as the ability to replace the current sensor with a new sensor, and disconnecting (un-pairing) from the Masimo device are available through this screen.

To access the Centroid Info screen through Bluetooth settings:

1. On the Masimo device, press/select the Bluetooth icon on the main screen, or navigate to the *Bluetooth* screen. See **Device Settings** on page 13.

2. Press/select the information icon ![info icon] next to *Centroid*. The Centroid Info screen displays.

To access the Centroid Info screen through the Action Menu**:**

1. On the Masimo device, press/select the Action Menu in the *Centroid Window*.

2. Press/select the **INFO** icon ![info icon]. The Centroid Info screen displays.

Centroid Info

The Centroid Info screen displays the following information for Centroid:

Option	Description
FW Version*	Displays the Centroid firmware version number.**
MAC address*	Displays the Centroid Bluetooth MAC address.
Signal Strength*	Displays the Centroid signal strength indicator.**
Battery Status*	Displays the Centroid battery status.**
Replace	Press/select to replace the current sensor with a new sensor. See **Replace Centroid Sensor** on page 22.
Forget	Press/select to disconnect the Bluetooth connection between the sensor and the Masimo device. See **Disconnecting Centroid from the Masimo Device** on page 26.

* These fields are read-only and cannot be configured by the user.
** Displays when Centroid is on and connected to the Masimo device.

Replace Centroid Sensor

When the Centroid sensors battery life is depleted, a new sensor can be paired and used to monitor the patient without interrupting the trend data.
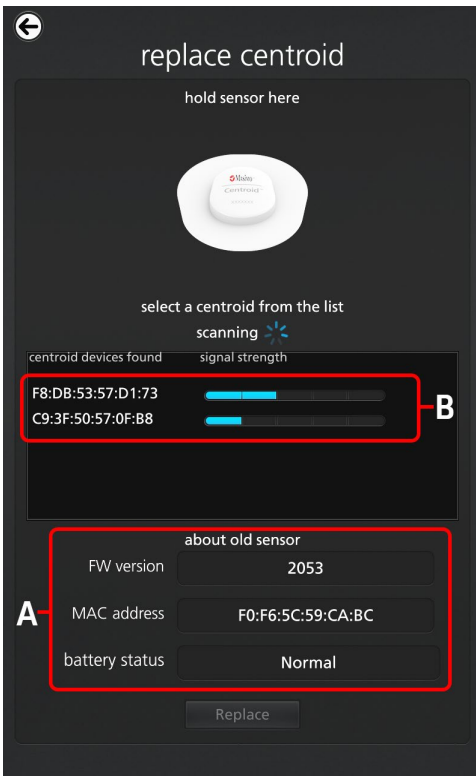
Access the *Replace Centroid* sensor screen:

From the Centroid Window:

1. Press/select the **Action Menu**. See *About the Action Menu* on page 20.
2. Press/select the **Replace** option. The *Replace Centroid* screen displays.

While viewing the Centroid Info screen:

1. Access the Centroid Info Screen. See *Accessing the Centroid Info Screen* on page 21.
2. Press/select the **Replace** button. The *Replace Centroid* screen displays.

The *Replace Centroid* screen displays the following information for the old sensor **(A)**:

Option*	Description
FW Version	Displays the Centroid firmware version number.**
MAC address	Displays the Centroid Bluetooth MAC address.
Battery Status	Displays the Centroid battery status.**

* These fields are read-only and cannot be configured by the user.
** Displays when the old Centroid is on and connected to the Masimo device.

Above the information about the old sensor are possible sensors to replace the old sensor **(B)**.
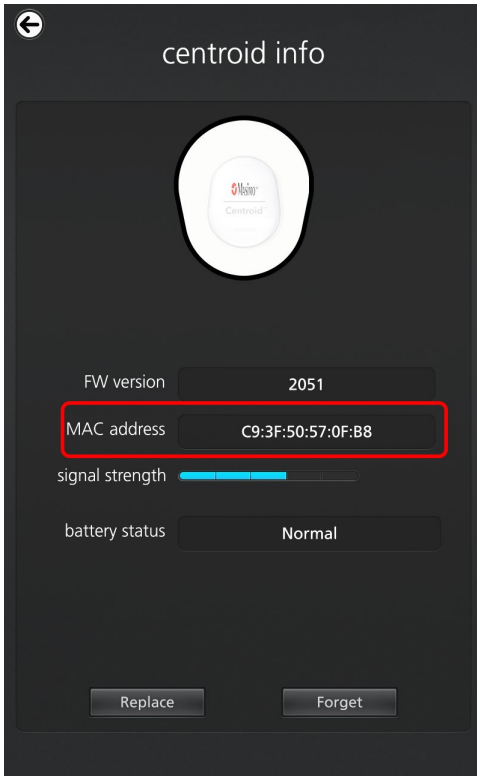
To Replace the Centroid Sensor:

1. Pull the tab on the replacement Centroid sensor to turn the sensor on. Refer to the sensor Directions for Use for proper instructions.
2. Hold the replacement Centroid sensor as instructed on the Masimo device screen until the replacement sensor appears under *Devices Found*.

    CAUTION: Multiple sensors may be detected and display under the *Centroid Devices Found* list as shown. To identify the Centroid sensor that requires pairing at this time, see **Identifying Centroid Sensor for Replacement** on page 25.

3. After identifying the correct sensor, press/select the sensor under the *Centroid Devices Found* list on the screen. If only one (1) sensor is displayed on the screen, press/select that sensor.
4. Press/select the *Replace* button. The replacement Centroid sensor will pair with the Masimo device.

5.   After successfully sensor replacement, the replacement sensor information is shown.

6.   Data now displays in the Centroid window of the Masimo device using the replacement sensor information. See **Centroid Window** on page 18.

Identifying Centroid Sensor for Replacement

When attempting to replace a Centroid sensor with multiple Centroid sensors within Bluetooth range of the Masimo device, all detected sensors appear in the *Centroid Devices Found* list on the *Replace Centroid* Screen.
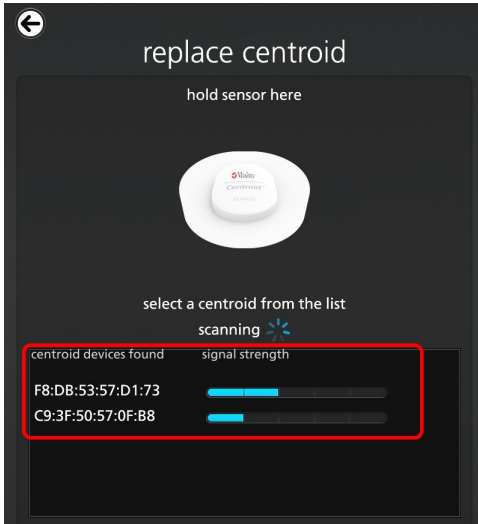
To properly identify the sensor that is to be paired as a replacement for the existing sensor, perform the following:

1. Hold the Centroid sensor to be paired, in front of the Masimo device.
2. Press/select one of the Centroid sensors displayed in the *Centroid Devices Found* list.

3. While watching the image of the Centroid sensor at the top of the Masimo device *Replace Centroid* screen, move the sensor as instructed on the screen.

- If the image of the sensor responds to the movement of the Centroid sensor and the image moves accordingly, this indicates the Centroid sensor selected in the *Centroid Devices Found* list is the same one being held, and can be paired as a replacement for the existing sensor.
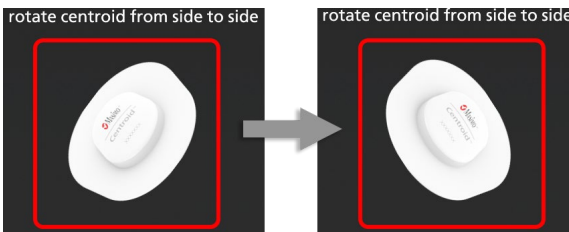
- If the image of the sensor does not respond to the movement of the Centroid sensor, press/select the next sensor displayed in the *Centroid Devices Found* list and repeat until the correct sensor is identified.

4. Once the correct Centroid sensor is identified, press/select the *Replace* button at the bottom of the screen to replace the current Centroid sensor with a different sensor.

Disconnecting Centroid from the Masimo Device

To disconnect Centroid from the Masimo device, perform the following:

1. Access the Centroid Info Screen. See ***Accessing the Centroid Info Screen*** on page 21.
2. Press/select the **Forget** button.
3. On the *Forget Device* pop-up window, press/select the **Forget** button to confirm.
    Note: Press/select the **Cancel** button to leave Centroid paired to the Masimo device.

Centroid Standby

Standby allows the Centroid sensor to be placed in standby monitoring to prevent unintentional alarms during activities such as patient movement, walking, or transport, or when the patient may move out of Bluetooth range. Monitoring is not performed during standby and there will be a gap in the trend data.

Note: The Centroid is still On and communicating with the Masimo device. Placing Centroid into standby DOES NOT increase battery life of the sensor.

Activate Standby

To activate standby monitoring through the Centroid window:

1. Press/select the **Action Menu**. See *About the Action Menu* on page 20.
2. Press/select the **Standby** option.
3. When prompted, press/select *Confirm* to place in standby or *Cancel*.

To activate standby monitoring through the Centroid Settings Screen:

1. Access the *Sensor Settings* screen. See *Sensor Settings* on page 13.
2. Press/select the *Standby* button and *OK* to activate standby monitoring.

When standby is activated, the Centroid window displays that the sensor is in Standby.

Resume Monitoring

To cancel standby and resume monitoring, press/select the icon in the Centroid window to resume monitoring.

Monitoring can also be resumed though the Action Menu or *Sensor Settings* screen. See *Sensor Settings* on page 13.

- **Action Menu -** Press/select the *Standby* button to resume monitoring.

- **Sensor Settings -** Press/select the *Resume* button and *OK* to resume monitoring.

Alarms and Messages

The following information is an addendum to be used with the content in **Messages** chapter of the **Operator's Manual, Root®** or **Operator's Manual, Root® with noninvasive blood pressure and temperature.**

Alarms

The following section lists Centroid alarms, priority, potential cause, and next steps.

Message	Alarm Priority	Potential Causes	Next Steps
Fall Detected	High	A fall-like movement has occurred.	Physically check patients condition.
Turn Due	Low	Allowed time in one position has lapsed.	Move patient to a different position.
Restricted Position	Low	Patient is in a position not allowed.	Move patient to an allowed position.

Messages

The following section lists messages related to Centroid, the potential cause, and next steps.

Message	Potential Causes	Next Steps
Standby	User has set Centroid sensor in standby mode, via Root Display, to suspend monitoring.	To resume monitoring, follow on-screen instructions on the Masimo device screen.
Head of Bed Angle displays "--"	Patient's head of bed angle is not valid because sensor is either off the patient or patient is currently in walking state.	In the event of sensor off, reattach the sensor. Otherwise, physically check the patient's condition.
Turn Due	Patient has overstayed in a given position beyond the time limit set forth by user.	Physically check patient's condition and move the patient to a new position.
Patient Current Position does not display	Patient's body angle is not valid because sensor is either off the patient or patient is currently in upright or walking state.	In the event of sensor off, reattach the sensor. Otherwise, physically check the patient's condition.

Message	Potential Causes	Next Steps
Position Left, Position Right, Position Supine	Patient is currently violating one of two possible restricted zones.	Physically check patient's condition and move the patient to an allowed position.
Sensor Off	Sensor is off the patient.	Reattach the sensor.
Fall Detected	Centroid sensor has detected a fall-like movement.	Physically check patient's condition, and acknowledge the alarm on Masimo device screen.
Time in Current Position displays "--"	Elapsed timer is not valid because sensor is either off the patient or the patient is in upright or walking state.	Physically check patient's condition.
Upright Detection	Patient is either sitting up in bed or standing without movement.	Physically check patient's condition.
Walking Detection	Patient is in walking state.	Physically check patient's condition.
RR displays "--"	Respiration rate cannot be measured, either due to low signal confidence or sensor is off the patient.	Physically check patient's condition. In the event of sensor off, reattach the sensor.
Low Battery	Centroid sensor battery charge is low.	Replace the Centroid sensor using "Replace" functionality in drop down menu. See **Replace Centroid Sensor** on page 22.
Centroid Disconnected	• Centroid sensor is out of Bluetooth range. • Centroid sensor has lost communication with the Masimo device. • Centroid sensor battery is depleted. • Centroid internal failure.	• Ensure the Centroid sensor is within Bluetooth range of the Masimo device. • Forget and pair the Centroid sensor to the Masimo device again. See **Disconnecting Centroid from the Masimo Device** on page 26 and **Pairing Centroid** on page 15. • Replace the Centroid sensor. • Contact Masimo Service.

Troubleshooting

The following information is an addendum to be used with the content in **Troubleshooting** chapter of the **Operator's Manual, Root®** or **Operator's Manual, Root® with noninvasive blood pressure and temperature.**

Troubleshooting Centroid

The following section lists possible Centroid symptoms, potential causes, and next steps.

Symptom	Potential Causes	Next Steps
Sensor does not turn on	• Centroid battery depleted. • Centroid internal failure.	• Replace Centroid. • Contact Masimo Service.
Sensor does not communicate to Masimo devices through Bluetooth connection	• Masimo device is not compatible. • Bluetooth is not turned on and/or properly configured. • The sensor has lost communication with the Masimo device. • Centroid internal failure.	• Check Masimo device compatibility. • Check that the Bluetooth feature on the Masimo device is on and correctly configured. Refer to the Operator's Manual for the Masimo device. • Forget and pair the Centroid sensor to the Masimo device again. See **Disconnecting Centroid from the Masimo Device** on page 26 and **Pairing Centroid** on page 15. • Contact Masimo service.
Parameter readings displayed as dashes.	• Parameter may not have stabilized. • Low signal quality. • Sensor off patient.	• Allow time for parameter reading to stabilize. • Physically check the patient's condition. • Reattach the sensor.
Head of Bed Angle displays "--"	• Sensor off patient. • Patient is walking.	• Reattach the sensor. • Physically check the patient's condition.
Time in Current Position displays "--"	• Sensor off patient. • Patient is in upright position or walking.	• Reattach the sensor. • Physically check the patient's condition.

Specifications

The following information is an addendum to be used with the content in the ***Specifications*** chapter of the ***Operator's Manual, Root®*** or ***Operator's Manual, Root® with noninvasive blood pressure and temperature.***

Display Range

Measurement	Display Range
Respiration Rate (RR)	0 rpm to 45 rpm
Patient Recline Angle	-180° to 180° [1]
Time in Current Position	0 to 65,535 minutes

Resolution

Parameter	Resolution
Respiration Rate (RR)	1 rpm

Accuracy Range*

Respiration Rate (RR) [2]		
Range of 8 rpm to 35 rpm	Adults	+/- 3 rpm

* 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 +/- A_{RMS} of the reference measurements in a controlled study.

Medical Conditions

Medical Conditions from clinical study of hospitalized patients

	N
Cardiovascular	
Atrial Fibrillation	3
Coronary Artery Disease	4
Hypertension	17
Acute Hypotension	1
Anasarca	2
Ischemic Cardiomyopathy	3
Heart Failure (Systolic/Diastolic/Congestive)	10
Non ST Elevation Myocardial Infarction	3
Supraventricular Tachycardia	1
Cardiac Arrest	1
Endocrine/Metabolic	
Diabetes	12
Hyperlipidemia	7
Hypoalbuminemia	2
Hyponatremia	3
Hypernatremia	1
Hyperkalemia	2

	N
Infections	
Sepsis and Septic Shock	9
Granulomatosis with polyangiitis	1
Human Immunodeficiency Virus	1
Hemorrhagic Shock	1
Muscular	
Inguinal Hernia	1
Musculoskeletal and Connective Tissue	
Ischemic Limb	1
Metabolic Bone Disease	1
Rheumatoid Arthritis	2
Fibromyalgia	1
NA	
None Reported	1
Neoplasm	
Non-Hodgkin's lymphoma	1
Circulatory	
Deep Vein Thrombosis	2

Hyperthyroidism	3	Venous Stasis Dermatitis	1
Hyperglycemia	1	Coagulopathy	1
Morbid Obesity	2	**Neurological**	
Hyperammonemia	1	Cerebrovascular Accident	5
Diabetic Ketoacidosis	1	Encephalopathy	9
High Cholesterol	1	Ischemic Stroke	2
Chronic Pancreatitis	1	Acute Embolic Stroke	1
Pancreatic Cancer	1	Ruptured Brain Aneurysm	1
Gastrointestinal		Brain Tumor	2
Gastrointestinal Bleeding	3	Seizure Disorder	4
Gastrointestinal Reflux	1	Epilepsy	1
Diarrhea	1	Neurosarcoidosis	1
Diverticulitis	1	Basilar meningitis	1
Genitourinary		Parkinson's Disease	1
Breast Cancer/Breast Cancer History	1	**Renal**	
Neurogenic bladder	1	Kidney Disease	5
Herpes zoster	1	Kidney Failure	2
Fournier gangrene	1	Kidney Injury	9
Urinary tract infection	5	Elevated Creatinine level	1
Hematology		**Respiratory**	

Anemia	3		Asthma	1
Leukocytosis	1		Cytomegalovirus pneumonia	1
Dyslipidemia	1		Pleural Effusion	1
Thrombocytopenia	1		Interstitial Lung Disease	1
Hypoglycemia	1		Respiratory Failure	21
Pancytopenia	1		Small Cell Lung Cancer	1
Acute Blood Loss	1		Pulmonary Hypertension	1
Hepatobiliary			Chronic Obstructive Pulmonary Disorder	7
Acidosis	4		Shortness of Breath	2
Hepatitis C	2		Aspiration Pneumonia	4
Cirrhosis	2		Placed on Mechanically assisted Ventilator	4
Liver Mass	1		Pneumoperitoneum	1

Compatible Masimo Devices

The following Masimo devices and systems are compatible with Centroid:

Device or System	Minimum Software Level Requirement
Root	V2.1.2.0 or above

Electrical

Battery	
Capacity	Approx. 4 days
Storage Life	Approx. 2 Years

Environmental

Environmental	
Operating Temperature	10°C to 40°C (50°F to 104°F)
Storage/Transport Temperature	-20°C to 50°C (-4°F to 122°F)
Operating Humidity	15% to 95%, non-condensing
Storage/Transport Humidity	15% to 90%, non-condensing

Physical Characteristics

Physical Characteristics (Sensor)	
Dimensions	12.7cm x 12.7cm x 1.27cm (5" x 5" x 0.5")
Weight	30g (0.07 lbs.)

Citations

[1] Angle determined based upon a reference plane where the device is flat in the horizontal position. No calibration required.

[2] 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.

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