

rainbow[®] RAS-45 Inf/Neo rainbow[®] RAS-125c Adult/Pediatric



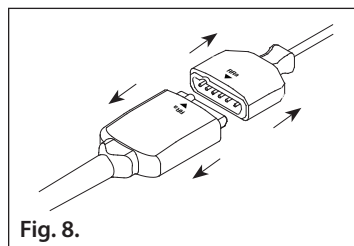
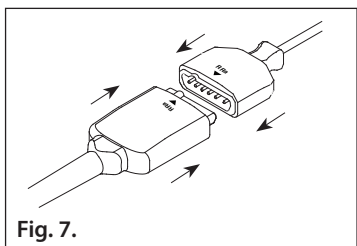
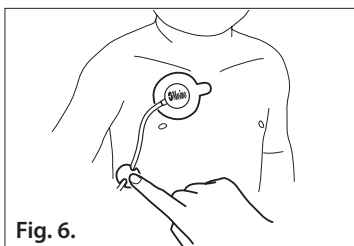
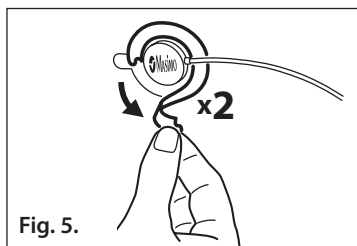
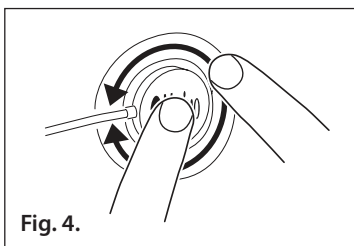
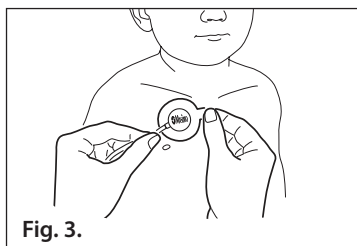
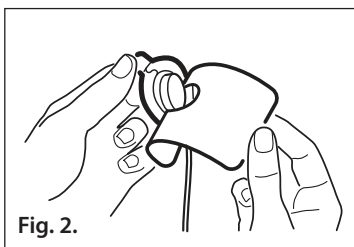
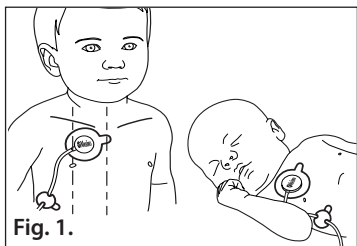
Acoustic Respiration Sensor for Infants/Neonates/Adult/Pediatric



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rainbow® RAS-45/RAS-125c

Acoustic Respiration Sensor for Infants/Neonates/Adult/Pediatric



DIRECTIONS FOR USE Do Not Re-Use 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, monitor and this Directions for Use.

INDICATIONS

The Masimo® Acoustic Respiration Sensor RAS-45/RAS-125c is indicated for continuous, noninvasive monitoring of respiratory rate (RRa®). The Masimo Acoustic Respiration Sensor RAS-45/RAS-125c is intended for use with infant and neonatal patients, in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The rainbow Acoustic Monitoring® sensors are not indicated for Apnea monitoring.

CONTRAINDICATIONS

The Masimo Acoustic Respiration Sensor RAS-45/RAS-125c is contraindicated for patients who exhibit allergic reactions to foam rubber products and/or adhesive tape.

DESCRIPTION

The RAS-45/RAS-125c sensor is for use only with devices containing Masimo rainbow SET® technology.

RAS-45/RAS-125c Sensors are compatible with Masimo rainbow technology V7.14.9.4 and above.

WARNINGS, CAUTIONS AND NOTES

- Always refer to the operator's manual for the connected monitor, along with these instructions for use for complete instructions.
- When monitoring acoustic respiration (RRa), monitoring oxygenation (functional oxygen saturation of arterial hemoglobin, SpO₂) is required.
- All sensors and cables are designed for use with specific monitors. Verify the compatibility of the monitor, cable and sensor before use, otherwise degraded performance and/or patient injury can result.
- Do not use sensors that appear to be damaged or discolored, otherwise degraded performance and/or patient injury can result.
- Do not use sensors during magnetic resonance imaging (MRI) or in an MRI environment.
- Carefully route all patient cables to reduce the risk of patient entanglement or strangulation.
- Do not cover the sensor or apply additional adhesives to the sensor, this may result in inaccurate or no readings.
- Do not place the sensor where it may cover the patient's nose or mouth.
- Avoid exposing sensors to liquids during use to avoid possible patient harm.
- Do not use tape to secure the sensor to the site; this can cause inaccurate readings. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the sensor.
- Only use the adhesive film provided on the sensor to secure it to the patient. Excessive pressure can cause skin damage or patient discomfort.
- Check the sensor site (every 8 hours) 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.
- Periodically check the sensor site for proper adhesion to minimize the risk of inaccurate or no readings.
- Ensure that the placement of the Anchor pad does not tightly stretch the cable to prevent accidental detachment of the sensor due to patient movement.
- The Anchor pad needs to be attached directly to the patient's skin in order to ensure correct readings.
- Properly apply/place the sensor. Incorrect application or placement may result in inaccurate or no readings.
- Ensure that the cable is not tightly stretched, to prevent accidental detachment of the sensor due to patient movement.
- Avoid placing sensor on patients exposed to environments with excessive noise. This may result in inaccurate or no readings.
- Properly connect the sensor or the oximeter module to the cable to avoid intermittent readings, inaccurate results, or no reading.
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize the sensor.
- Do not attempt to reuse, reprocess, recondition or recycle Masimo sensors as this may damage the electrical components, potentially leading to patient harm.

- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.
- If the sensor has been stored in a cold environment, it will need to be brought to room temperature to ensure a correct reading.
- The sensor may not adhere well on extremely diaphoretic patients.
- The RAM® dual cable must be connected to a compatible monitor with Masimo rainbow SET technology with the RRA feature enabled.
- RAS-45/RAS-125c is not for Apnea monitoring or Apnea alarm.
- **Caution:** Replace the sensor when a replace sensor message is displayed, or when a low SIQ message is consistently displayed after completing the low SIQ troubleshooting steps identified in the monitoring device operator's manual.
- **Note:** The sensor is provided with X-Cal® technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. The sensor will provide up to 120 hours of patient monitoring time. After single-patient use, discard sensor.

INSTRUCTIONS

A. Site Selection:

Site should be hair-free, cleaned of debris and dry prior to sensor placement. Use an alcohol swab to clean the application site, if needed.

1. Refer to **Fig. 1**. The measuring site is the upper chest. It is recommended that the center of the sensor pad is placed sub clavicular, at the 2nd intercostal towards the right of the patient's chest.

B. Applying the Sensor:

1. Refer to **Fig. 2**. Gently pull the small tab away from the liner to expose the sensor adhesive.
2. Refer to **Fig. 3**. Gently place the sensor onto the application site so that the "Masimo" label is visible.
3. Refer to **Fig. 4**. Apply pressure all around the perimeter of the sensor to ensure the adhesive is secure to the patient's skin. Avoid contact with the exposed sensor adhesive.
4. Ensure that the skin of the patient is relaxed and not stretched in any way and that there are no skin folds under the sensor pad.
5. Refer to **Fig. 5**. Remove the two piece sensor liner from the top of the sensor.
6. Refer to **Fig. 6**. Remove the anchor liner and attach the anchor pad to the patient's chest at the level of the armpit.
7. Route and secure the sensor cable to reduce the risk of patient entanglement or strangulation.

C. Connecting the RAS-45 Inf/Neo Sensor to the Acoustic Respiration Patient Cable:

1. Refer to **Fig. 7**. Insert the sensor connector into the cable connector, until it locks in place.
2. Confirm that the RAS-45/RAS-125c sensor is properly applied to the patient's application site and also connected to the patient cable.
3. Confirm that the monitor is able to detect a signal (refer to device manual).

Note: If the signals are not detected, select another site on the chest using a new sensor.


D. Disconnecting and Removing the RAS-45/RAS-125c Sensor:

Warning: Disconnect the cable from the sensor prior to removing the sensor from the patient.

1. Refer to **Fig. 8**. Grasp the cable connector and the sensor connector and pull to disconnect.
2. Gently pull on the sensor adhesive tab to stretch and release the sensor from the application site.
3. Gently pull on the anchor pad to lift and remove the adhesive from the patient.

Note: When the RAS-45 Inf/Neo sensor is off the patient and is still connected to the system, the sensor may pick up background noise and report a measurement. The sensor should only be connected to the cable while performing patient monitoring. If the patient is not being monitored, the sensor should be disconnected from the cable.

SPECIFICATIONS

| Sensor | RAS-45 Inf/Neo/RAS-125c Adt/Ped |
|--|--|
|  Body Weight | RAS-45 Inf/Neo: Infant and Neonate < 10 kg RAS-125c Adt/Ped: Infant and Neonate > 10 kg |
| Application Site | Chest |
| Breaths per Minute, Accuracy Range* | 4 to 120 ± 1 breath per minute |

* Respiration rate accuracy for the RAS-45/125c sensor has been validated for the range of 4 to 120 breaths per minute in bench top testing. Clinical validation was performed with the RAS-45/125c sensor and monitoring device for up to 82 breaths per minute in infant and neonatal subjects.

MEDICAL CONDITIONS

Medical Conditions from clinical study of hospitalized patients.

| Condition | |
|---------------------------------|--|
| Acquired | Fetal Alcohol Syndrome |
| Cardiovascular | Atrial Septal Defect, Bicuspid Aortic Valve, Chronic Systolic Congestive Heart Failure, Congenital Heart Disease, Ostium Secundum, Patent Ductus Arteriosus, Patent Foramen Ovale, Right Ventricular Hypertrophy, Tricuspid Valve Regurgitation, Ventricular septal defect |
| Congenital | Cleft palate |
| Congenital Anatomic Deformities | Bilateral Club Feet, Congenital Hand Deformity, Dysmorphic Craniofacial Features, Polydactyly (Both Hands or Feet), (Syndactyly (Fingers or Toes |
| Dermal | Congenital Melanocytic Nevus, Dermoid Cyst of Eyebrow |
| Gastrointestinal | Colostomy, Congenital Atresia of Colon, Congenital Gastroschisis, Gastroesophageal Reflux Disease, Imperforate Anus, Intestinal Malrotation, Laparoscopic Gastrostomy, Meckel's Diverticulum, Omphalocele, Rectal Fistula, Short Gut Syndrome |
| Genetic/Hereditary | Congenital Birth Defect, Digeorge Syndrome, High Arched Palate, Williams Syndrome |
| Genitourinary | Labial Abscess, Scrotal Abscess, Undescended Testicles, Phimosis, Ureteropelvic Junction Obstruction, Meatal Stenosis, Posterior Urethral Valves, Ureterocele, Vesicoureteral Reflux |
| Hematology | Anemia |
| Hepatology | Total Parental Nutrition Induced Cholestasis |
| Immunodeficiency | T-cell deficiency |
| Infectious | Methicillin-Resistant Staphylococcus Aureus, Rhinovirus |
| Metabolic | Malnutrition |
| Musculo-Skeletal | Umbilical Hernia |
| Renal | Chronic Kidney Disease, Hydronephrosis, Renal Agenesis, Renal Stone |
| Neurological | Neuromuscular Disease, Sensorineural hearing loss |
| Ophthalmology | Astigmatism, Dacryostenosis |
| Other | Prematurity, Intrauterine Growth Retardation |
| Otology | Bilateral Hearing Loss |
| Skeletal-Congenital Deformities | Congenital Absence of Both Tibias, Congenital Lower Limb Shortening, Klippel-Feil Syndrome, Microcephalus (HCC), Saggital Craniosynostosis |

COMPATIBILITY

 This sensor is intended for use only with rainbow Acoustic Monitoring® enabled devices containing Masimo rainbow SET technology or pulse oximetry monitors licensed to use rainbow Acoustic™ compatible sensors.  Each sensor is designed to operate correctly only on the pulse oximetry 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

SOFTWARE REQUIREMENT

RAS-45 Inf/Neo Sensors are compatible with Masimo rainbow technology V7.14.9.4 and above.

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 device 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.

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NO IMPLIED LICENSE

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
















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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 | Caution: Federal law (USA) restricts this device to sale by or on the order of a physician |
|  | Consult instructions for use |  | Lot code |  | Mark of conformity to European Medical Device Directive 93/42/EEC |
|  | Manufacturer |  | Catalogue number (model number) |  | Authorized representative in the European community |
|  | Use-by YYYY-MM-DD |  | Masimo reference number |  | Body weight |
|  | Do not re-use/Single patient use only |  | Greater than |  | Storage temperature range |
|  | Non-Sterile |  | Less than |  | Keep dry |
|  | Not made with natural rubber latex |  | Storage humidity limitation |  | Do not use if package is damaged and consult instructions for use |
|  | Caution |  | Fragile, handle with care |  | Light Emitting Diode (LED) LED emits light when current flows through |
|  | Medical device |  | Unique device identifier |  | Importer |
|  | Distributor |  | Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eFU is not available in all countries. | | |

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

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