

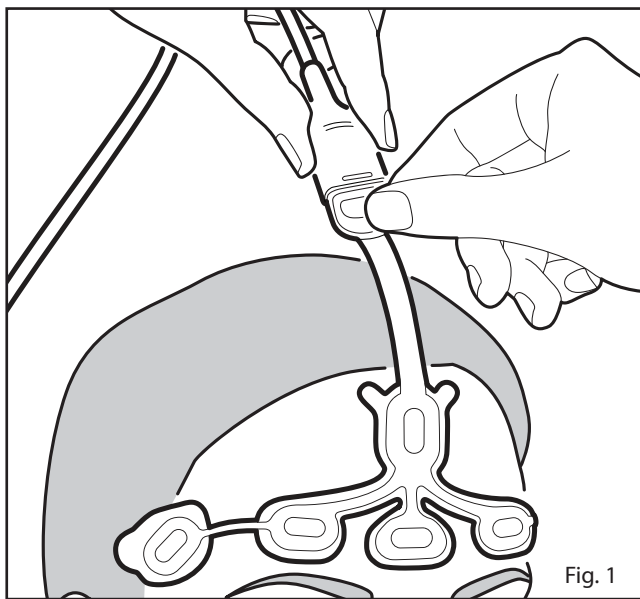
RD SedLine® Patient Cable



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RD SedLine® Patient Cable



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DIRECTIONS FOR USE

Reusable



Not made with natural rubber latex



Non-sterile

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

DESCRIPTION

The RD SedLine® Patient Cable transfers analog EEG signals collected from the Sensor to the Module for processing. The Patient Cable is a reusable cable and may be used from patient to patient.

Always refer to the operator's manual for complete instructions or additional instructions.

The RD SedLine Patient Cable is compatible with the RD SedLine EEG Sensor.

WARNINGS, CAUTIONS, AND NOTES

- Ensure the cable is physically intact, with no broken or frayed wires or damaged parts. Visually inspect the cable and discard if cracks or discoloration are found.
- Carefully route patient cable to reduce the possibility of patient entanglement or strangulation.
- Masimo sensors and cables are designed for use with instruments licensed to use Masimo sensors.
- 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.
- Failure to properly connect the sensor or the module to the cable will result in intermittent readings, inaccurate results, or no reading.
- To avoid damage to the cable, always hold it by the connector rather than the cable when connecting or disconnecting either end.
- Always refer to the module operator's manual for complete instructions or additional instructions.
- Do not attempt to reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- **Caution:** Replace the cable when a replace cable message is displayed, or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing the low SIQ troubleshooting steps identified in the monitoring device operator's manual.
- **Note:** The cable is provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. The cable will provide up to 17,520 hours of patient monitoring time. Replace the cable when the patient monitoring time is exhausted. Some legacy monitoring devices do not distinguish between the cable and the sensor. In these devices, a replace sensor or similar message could pertain either to the sensor or the cable.

INSTRUCTIONS

A) Connecting

To connect the Patient Cable to the Module

1. Align the ridged Patient Cable connector end with the available Module connector end.
2. Push to insert.

To connect the Patient Cable to the Sensor

1. Align the yellow indicator connector on the end of the RD SedLine Patient Cable with the yellow indicator on the Sensor Connector.
2. Refer to Fig. 1. Push together until the connections fit securely.

B) Disconnecting the Sensor

To disconnect the Patient Cable from the Module

- Gently pull the Patient Cable out of the Module by grasping the patient cable connector end.

To disconnect the Patient Cable from the Sensor

- Gently pull the Sensor out of the Patient Cable connector from the Sensor's connector end.

CLEANING

1. Remove the sensor from the patient and disconnect it from the patient cable.
2. Clean the surface of the cable by wiping it with a 70% isopropyl alcohol pad, quaternary ammonium chloride solution, or a 10% (1:10) chlorine bleach to water solution.
3. Wipe all surfaces of the cable.
4. Saturate another cloth or gauze pad with sterile or distilled water and wipe all surfaces of the cable.
5. Dry the cable by wiping all surfaces with a clean cloth or dry gauze pad.

The surface of the cable has been tested to be chemically resistant to the following solutions: Quaternary Ammonium Chloride solution wipe, Accelerated Hydrogen Peroxide, Chlorhexidine, Cidex, 70% and 90% Isopropyl Alcohol, and 10% (1:10) chlorine bleach to water solution.

CAUTION

- Do not immerse the connector on the cable in any liquid solution.
- Do not sterilize by irradiation, steam, autoclave, or ethylene oxide.
- Do not clean with chemicals not approved above.

SPECIFICATIONS

Cable length	3 feet (0.9 meters)
Patient module connector	9 pin proprietary
Sensor connector	Custom connector

ENVIRONMENTAL

Storage/Transport Temperature	-40° C to +70° C, ambient humidity
Operating Temperature	+5° C to +40° C, ambient humidity
Storage/Transport Humidity	10% to 95%, non-condensing
Operating Humidity	10% to 95%, non-condensing

WARRANTY

Masimo warrants to the initial buyer only that this product, 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

Purchase or possession of this patient cable does not carry any expressed or implied license to use this cable with any device that is not an authorized device or separately authorized to use SedLine cables.

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.

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
	Date of manufacture YYYY-MM-DD		Masimo reference number		Body weight
	Caution		Storage humidity limitation		Storage temperature range
	Do not discard		Do not use if package is damaged		Keep dry
	Fragile, handle with care		Greater than		Less than
	Non-sterile		Not made with natural rubber latex		Atmospheric pressure limitation
	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eIFU is not available for CE mark countries.				

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

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9501D-eIFU-1217