

RD SET™ MP Series

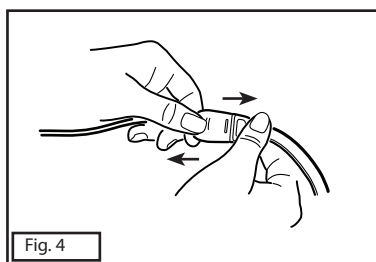
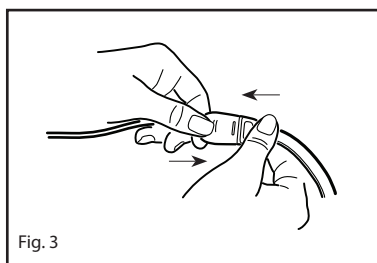
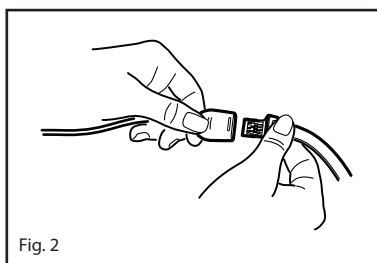
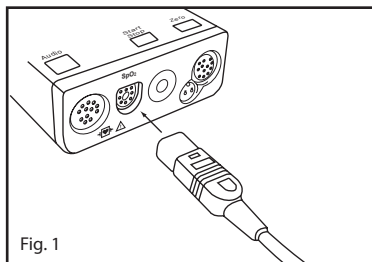
Patient Cables



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DIRECTIONS FOR USE

Reusable

 Not made with natural rubber latex

 Non-Sterile

INDICATIONS

The RD SET™ MP Series patient cables and Masimo RD SET sensors are indicated for the continuous, noninvasive monitoring of arterial saturation (SpO2) and pulse rate for adult, pediatric, infant and neonatal patients.

DESCRIPTION

The RD SET MP Series patient cables are for use on Philips modules with Masimo SET® Technology and devices with Philips FAST-SpO2 Technology.

On Philips modules with Masimo SET Technology, RD SET MP Series patient cables are for use with RD SET disposable sensors.

On devices with Philips FAST-SpO2 Technology, RD SET MP Series patient cables are for use with RD SET disposable sensors. Masimo SET Technology is not available on devices with Philips FAST-SpO2 Technology.

WARNING: Masimo sensors and cables are designed for use with devices containing Masimo SET® oximetry or licensed to use Masimo sensors.

WARNINGS, CAUTIONS, AND NOTES

- Always refer to the oximeter module operator's manual for complete instructions or additional instructions.
- 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.
- 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.
- Carefully route patient cable to reduce the possibility of patient entanglement or strangulation.
- Failure to properly connect the sensor or the oximeter module to the cable may 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.
- To prevent damage, do not soak or immerse the sensor or cable in any liquid solution. Do not attempt to sterilize the cable or sensor.
- 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.

INSTRUCTIONS

A) Attach the RD SET MP Series patient cable to the Device

1. Refer to **Fig. 1**. Orient the connector of the cable to mate with the patient cable connector on the Module.

Caution: Ensure you are connecting a RD SET MP patient cable to either a Masimo SET or Philips FAST-SpO2 cable connector on the Module. There are a number of similar connectors with different colors and different mechanical keying. Never force a patient cable connector into the module. Failure to use a RD SET MP patient cable may result in damage to the module, inaccurate readings, or no readings.

Note: There is a difference in color shade between the RD SET MP Patient Cable and the Philips Module patient cable connector. However, this is an acceptable configuration. Masimo SET performance is not available when connected to a device with Philips FAST-SpO2 Technology.

B) Attaching the RD SET MP Series patient cable connector to an RD SET disposable sensor connector

1. Refer to **Fig. 2**. Orient the sensor connector to the patient cable connector as shown.
2. Refer to **Fig. 3**. Insert the sensor connector completely into the patient cable connector until it locks in place as shown.

C) Disconnecting the RD SET MP Series patient cable connector from the RD SET disposable sensor connector

1. Refer to **Fig. 4**. Pull firmly on the sensor connector to remove it from the patient cable.

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.
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.

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

The RD SET MP Series Patient Cable is indicated for use with the following sensors:

RD SET MP Patient Cable Compatibility:

When used with Masimo SET Technology:

Sensors	Weight Range	Saturation Accuracy (70 - 100% SpO ₂)		Pulse Rate Accuracy (25 - 240 bpm)		Low Perfusion Accuracy (70 - 100% SpO ₂)	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
RD SET Adt	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
RD SET Pdt	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
RD SET Inf	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
RD SET Neo	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
RD SET NeoPt	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm

When used with Philips FAST-SpO₂ Technology:

Sensors	Weight Range	Saturation Accuracy (70 - 100% SpO ₂)	Pulse Rate Accuracy (25 - 240 bpm)
		No Motion	No Motion
RD SET Adt	> 30 kg	± 2%	± 3 bpm
RD SET Pdt	10 - 50 kg	± 2%	± 3 bpm
RD SET Inf	3 - 20 kg	± 2%	± 3 bpm
RD SET Neo	< 3 kg	± 3%	± 3 bpm
	> 40 kg	± 2%	± 3 bpm
RD SET NeoPt	< 1 kg	± 3%	± 3 bpm

RD SET MP Series Patient Cables and the above Masimo RD SET Sensors have been tested with Masimo SET technology and Philips FAST-SpO₂ technology. The saturation accuracy of the neonatal sensors were validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.

ENVIRONMENTAL

Operating Temperature	41°F to 104°F (5°C to 40°C)
Storage Temperature	-40°F to 158°F (-40°C to 70°C)
Relative Humidity	10% to 95% noncondensing

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


Purchase or possession of these patient cables does not carry any express or implied license to use these cables with any device that is not an authorized device or separately authorized to use RD SET MP Patient Cable.

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
	Consult Instructions for Use		Separate collection for electrical and electronic equipment (WEEE).
 (blue background)	Follow Instructions for Use		Lot code
	Manufacturer		Catalogue number (model number)
	Date of Manufacture		Masimo reference number
	Use By YYYY-MM		Body weight
	Do not discard	>	Greater than
	Non-Sterile	<	Less than
	Not made with natural rubber latex		Storage Humidity Limitation
R _x Only	Federal law (USA) restricts this device to sale by or on the order of a physician	 +1060 hPa - +500 hPa 795 mmHg - 375 mmHg	Storage Temperature Limitation, Pressure Limitation
	Mark of Conformity to European Medical Device Directive 93/42/EEC		Keep Dry
	Authorized representative in the European community		Do not use if package is damaged
	Light Emitting Diode (LED) LED emits light when current flows through		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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