# RD SedLine Tester

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## DIRECTIONS FOR USE

Reusable  Not made with natural rubber latex  Non-sterile

### PURPOSE

The RD SedLine™ Test Tool connects in place of the RD SedLine EEG sensor and allows testing of basic function and patient safety of the SedLine® system.

**The SedLine® system consists of 3 distinct components:**

- A base monitor and display device (e.g. The Masimo® Root® Monitor).
- The SedLine Module, which connects to the monitor.
- The RD SedLine patient cable, which connects the SedLine module to the RD SedLine EEG Sensor.

Safety testing of the base monitor should be performed in accordance with the maintenance or service procedures for that device. These instructions describe the additional tests required to verify the functional and safety characteristics of the SedLine Module and RD SedLine patient cable.

### WARNINGS, CAUTIONS AND NOTES

- The Tester should be free of visible defects. Never use a damaged product, or one with an open enclosure shell or exposed electrical contacts.
- Failure to properly connect the Tester to the device or patient cable will result in intermittent readings, inaccurate results or no reading.
- Functional Testers cannot be used to assess accuracy.
- The Tester is not to be used as a calibration tool.

### INSTRUCTIONS

**A. Functional Test**

1. Connect the SedLine Module to the base monitor and attach the RD SedLine Patient Cable to the SedLine Module.
2. Set the monitor to display SedLine monitoring window on Root® or alternative monitoring device (consult the monitor instruction manual if necessary).
3. Connect the RD SedLine Test Tool to the patient cable. Verify the following:
   a. All electrodes show good connected status, and impedance in the range of 4.5 to 5.5 kΩ.
   b. Adjust the EEG amplitude to 1 µV/mm observe for flat trace signals with approximately 2 mm peak-to-peak baseline noise.

***Failure to achieve these results may indicate a defect in the SedLine Module or patient cable.***

**B. Safety Test (Leakage Current)**

1. Verify that the base monitor itself has passed safety testing in accordance with its maintenance/service documentation.
2. Connect the SedLine Module to the base monitor, and attach the RD SedLine Patient Cable.
3. Connect the RD Sedine Test Tool to the patient cable.
4. The wire terminal on the RD SedLine Test Tool represents the "Applied Part". For purposes of this safety test, the RD SedLine EEG Sensor is considered to be a single applied part. Connect the wire terminal to an appropriate "Applied Part" terminal of a medical safety analyzer or leakage tester. (On many testers, this may be an ECG electrode terminal, such as RL. Consult the analyzer/tester instruction manual if required.)
5. Follow the operating instructions for the analyzer/tester to perform a patient applied part leakage current test.
   **The following power conditions should be tested:**
   a. Normal Polarity: Normal, Open Neutral, Open Earth (Ground)
   b. Reverse Polarity: Normal, Open Neutral, Open Earth (Ground)
   **Verify that the leakage current is less than 10 µA for all cases.**
6. Follow the operating instructions for the analyzer/tester to perform a mains on applied part leakage current test. The following power conditions should be tested:
   a. Normal Polarity
   b. Reverse Polarity
   **Verify that the leakage current is less than 20 µA for all cases.**
7. Remove the tester from the device or cable.

## CLEANING

Clean the Tester by wiping with 70% isopropyl alcohol and allowing it to dry thoroughly.

**CAUTION**

Do not use petroleum-based or acetone solutions, or other harsh solvents for cleaning. These substances affect the devices materials and device failure can result.

## ENVIRONMENTAL

| Characteristic | Specification |
|---|---|
| Storage/Transport Temperature | -40°C to +70°C, ambient humidity |
| Storage/Transport Humidity | 5% to 95% humidity, non-condensing |
| Operating Temperature | 5°C to 50°C, ambient humidity |
| Operating Humidity | 5% to 95% humidity, non-condensing |

## 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 or a period of six (6) months from the date of purchase. The manufacturer's sole obligation under this warranty is to replace any product that it deems to be covered under warranty with a replacement Tester.

## WARRANTY EXCLUSIONS

This warranty does not extend to any product that has been subject to misuse, neglect or accident; that has been damaged by causes external to the product; or that has been used in violation of the operating instructions supplied with the product. The warranty does not extend to any product that has been connected to an unlicensed device system, modified accessories, or any unit that has been disassembled or reassembled by anyone but an authorized agent.

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 WITH 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 TESTER DOES NOT CARRY ANY EXPRESS OR IMPLIED LICENSE TO USE THIS DEVICE WITH ANY DEVICE THAT IS NOT AN AUTHORIZED DEVICE OR SEPARATELY AUTHORIZED TO USE THE TESTER.

**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 |
|---|---|---|---|
|  | Caution |  | Authorized representative in the European community |
|  | Follow instructions for use |  | Separate collection for electrical and electronic equipment (WEEE). |
|  | Manufacturer |  | Lot code |
|  | Date of manufacture YYYY-MM-DD |  | Catalogue number (model number) |
| **Rx ONLY** | **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician |  | Storage humidity limitation |
|  | Non-Sterile |  | Storage temperature range |
|  | Not made with natural rubber latex |  | Keep dry |
| CE | Mark of conformity to European Medical Device Directive 93/42/EEC |  | Fragile, handle with care |
|  | Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note: eIFU is not available in all countries.** | | |

Patents: www.masimo.com/patents.htm

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