Operator's Manual

SedLine® Sedation Monitor

Masimo

These operating instructions intend to provide the necessary information for proper operation of the SedLine® Sedation Monitor (SedLine). General knowledge of electroencephalograph (EEG) monitoring and an understanding of the features and functions of SedLine are prerequisites for proper use. Do not operate SedLine without completely reading and understanding these instructions.

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.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

Masimo Corporation
52 Discovery
Irvine, CA 92618, USA
Tel.: 949-297-7000
Fax.: 949-297-7001
www.masimo.com

CE 0123

EU authorized representative for Masimo Corporation:

EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

3149433

MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005/A1, CAN/CSA C22.2 No. 60601-1:2014, and applicable Particular (EN/ISO 60601-2-26:2012) Standards for which the product has been found to comply by Intertek.

Patents: www.masimo.com/patents.htm

Contents

About This Manual

This manual explains how to set up and use the SedLine® Sedation Monitor. Important safety information relating to general use of SedLine appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Indications, and Contraindications

Product Description

SedLine® Sedation Monitor is a patient-connected, 4-channel processed electroencephalograph (EEG) monitor designed specifically for intraoperative or intensive care use. It can display electrode status, EEG waveforms, Density Spectral Array (DSA), Patient State Index (PSi), EMG Index, Suppression Ratio (SR) and Artifact (ARTF).

The operator controls the unit via the host device. See the host device's operator's manual or user's guide for information and instructions. The system consists of 4 major components: a host device, SedLine Module, SedLine Patient Cable, and SedLine Sensors.

Indications for Use

The SedLine® Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSi), a proprietary computed EEG variable that is related to the effect of anesthetic agents. The agents include: Alfentanil, Desflurane, Fentanyl, Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane. The SedLine® Sedation Monitor is intended for use with adult patients (18 years of age and older) in the operating room (OR), intensive care unit (ICU), and clinical research laboratory.

Contraindications

This device is not intended for use in children less than 18 years of age*.

* Applicable to FDA/US Markets only.

Safety Information, Warnings and Cautions

CAUTION: SedLine is to be operated by, or under the supervision of, qualified personnel only. Read this Operator's Manual, accessories directions for use, all precautionary information, and specifications before use. Refer to the host device operator's manual or user's guide for additional safety information, warnings and cautions.

Safety Information Warnings and Cautions

WARNING: Do not start or operate the SedLine Module unless the setup was verified to be correct. Improper set-up of the device may result in degraded performance and/or patient injury.

WARNING: Always use the SedLine Module and SedLine Sensor in conjunction with an appropriate host device. Do not use parts from other systems. Injury to personnel or equipment damage could occur.

WARNING: All sensors and cables are designed for use with specific devices. Verify the compatibility of the device, cable and sensor before use; otherwise degraded performance and/or patient injury can result.

WARNING: Do not use the SedLine Module if it appears or is suspected to be damaged. Damage to the module enclosure can result in exposed electrical circuits that may cause patient harm.

WARNING: Do not adjust, repair, open, disassemble, or modify the SedLine Module. Damage to the module may result in degraded performance and/or patient injury.

WARNING: Do not use the SedLine Module in the presence of flammable anesthetics or other flammable substance in combination with air or oxygen-enriched environments.

WARNING: Do not use SedLine during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: To protect against Electrical Shock Hazard, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Use cleaning solutions only as instructed in this Operator's Manual.
- Do not attempt to clean the SedLine Module while monitoring patient.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Performance Warnings and Cautions

WARNING: The SedLine Module is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Use Patient State Index (PSi) information in conjunction with other indicators of patient state in the delivery of anesthetics.

WARNING: Abnormal PSi values may be present when SedLine detects artifactual electrical pacing signals (e.g., pace makers).

WARNING: The SedLine Module may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: The SedLine Module may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: SedLine performs continuous impedance measurements (at the sensor) in order to check that the electrodes are firmly in place. The 83.33 Hz and 125 Hz impedance measurement signals could interfere with other electronic monitoring equipment connected to the patient.

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the SedLine Module.

CAUTION: Do not place the SedLine Module on electrical equipment that may affect the instrument, preventing it from working properly.

CAUTION: Close proximity to high frequency interference may cause display artifacts. As a mitigation, consider moving the SedLine Module away from the source of radiation, changing the location of the host device, or plugging the host device into a different outlet if potential artifacts are displayed.

CAUTION: Train-of-Four stimulation on a patient's face is not recommended. Doing so may create EEG artifact, preventing calculation of PSi values.

CAUTION: The PSi value may be elevated in the following situations:

- Due to the use of nitrous oxide or ketamine. These agents may present an EMG-like pattern that may result in increased EEG activity at higher frequencies in the band > 12 Hz.
- On patients with non-typical EEG patterns such as seizure activity.
- When there is significant EMG activity interfering with the EEG waveform.

CAUTION: Inaccurate PSi values may be caused by:

- Elevated artifact and other sources of electromagnetic interferences.
- Patients with neurological disorders such as stroke, tumor, metabolic disease or traumatic brain injury.

CAUTION: To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time SedLine is used.

CAUTION: Disabling impedance monitoring may lead to decreased signal quality and decreased PSi reliability due to the user not being notified of inadequate electrode contact.

Note: The SedLine electrodes detect electrical activity primarily EEG. Similar to other EEG devices, electrical signals artifacts, such as ECG, EOG etc., may also be displayed when present.

Note: Use and store the SedLine Module in accordance with specifications. See the Specifications chapter in this manual.

Note: The anesthetic agents listed below were used in the comparison study* to evaluate the improved performance of the current PSi on the SedLine Sedation Monitor:

- Alfentanil
- Desflurane
- Fentanyl
- Isoflurane
- Nitrous Oxide
- Propofol
- Remifentanil
- Sevoflurane

*All data is based on the retrospective analysis of clinical data in Masimo Corporation's files.

Note: Not all host devices implement all parameters and displayable values. Consult the host device operator's manual or user's guide for more details on a specific implementation.

Cleaning and Service Warnings and Cautions

WARNING: Do not attempt to remanufacture, recondition or recycle the SedLine Module as these processes may damage the electrical components, potentially leading to patient harm.

WARNING: To avoid electric shock, always turn off SedLine and physically disconnect the AC power and all patient connections before cleaning.

WARNING: Service of the SedLine Module should be done by qualified personnel only.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the SedLine Module for servicing.

CAUTION: To avoid permanent damage to the SedLine Module, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the SedLine Module. These substances affect the device's materials and instrument failure can result.

CAUTION: Do not submerge the SedLine Module in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

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

Compliance Information 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 SedLine in accordance with the Environmental Specifications chapter of this manual.

Note: For FCC compliance information, refer to the host device's operator's manual or user's guide.

Note: For EMC compliance information, refer to the host device's operator's manual or user's guide.

Chapter 1: Technology Overview

Theory of Operation

The Patient State Index (PSi) formula was constructed based upon multivariate combinations of quantitative electroencephalogram (QEEG) variables found to be sensitive to changes in the level of anesthesia but insensitive to the specific substances producing such changes. The PSi is the result of a complex computation that combines weighted quantitative values reflecting many dimensions of brain electrical activity, such as: (1) changes in power in various EEG frequency bands, (2) changes in symmetry and synchronization between critical brain regions, and (3) the inhibition of regions of the frontal cortex.

The PSi is computed from continuously monitored changes in the QEEG during surgery, using statistical analysis to estimate the likelihood that the patient is anesthetized. The SedLine performs these computations automatically on the continuously recorded EEG after automatic removal of data contaminated with artifact from physiological and environmental signals. The computed PSi is periodically updated and displayed in numeric form for monitoring the effect of certain anesthetics on the state of the brain.

Chapter 2: System Descriptions

The SedLine system is comprised of the following components:

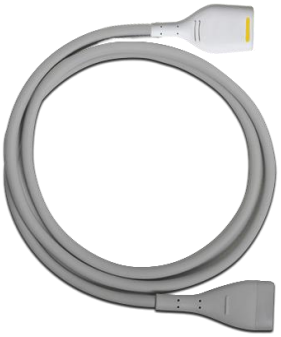
- SedLine Module
- SedLine Patient Cable
- SedLine Sensor(s)

SedLine Module

The SedLine Module computes and calculates PSi and additional parameters using the EEG signals acquired from the SedLine Sensor. The module connects the host device to the SedLine Patient Cable and receives its power from the host device.

SedLine Patient Cable

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



SedLine Sensor(s)

The SedLine Sensor is comprised of six (6) gelled electrodes, including four (4) active channels (R1, R2, L1, L2), one reference channel (CT), and one ground channel (CB). The sensor is a single-use, non-sterile product that does not contain natural rubber latex.

Chapter 3: Setting Up the System

Unpacking and Inspecting the System

To unpack and inspect the system

1. Remove the components from the shipping carton and examine them for signs of shipping damage.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
3. If anything is missing or damaged, contact Masimo Technical Service.

Preparation for Use

Prior to using SedLine for monitoring

1. The following system components are required:
   - Host device
   - SedLine Module
   - SedLine Patient Cable
   - SedLine Sensor
2. Host device operator's manual or user's guide.
3. SedLine Sensor DFU for sensor application.

Connecting the Module and Patient Cable

The image below shows the SedLine system components connected as one unit for patient monitoring.

To connect the module to the patient cable

1. Identify the SedLine module connector end.

2. Align the ridged patient cable connector end with the module connector end.

3. Push to insert.
4. For additional details, See the Directions for Use (DFU) for the patient cable.

Connecting to the Host Device

1. Identify the host device connector on the end of the SedLine Module cable.
2. Identify the appropriate port on the host device.
3. Connect the SedLine Module cable to the host device.

For directions on how to connect the SedLine Sensor, See the Directions for Use (DFU) for SedLine Sensors.

Chapter 4: Operation

The information in this chapter assumes that SedLine is set up and ready for use. This chapter describes how SedLine information is provided to the host monitor. For additional information, See the host monitor Operator's Manual to identify supported features. Do not operate SedLine without completely reading and understanding these instructions.

SedLine Operation

Electrode Status

This feature is used to monitor electrode impedance. The Electrode Status display provides electrode connectivity status of the sensor.

EEG Waveforms

The EEG display reflects electrical activity of the frontal and pre-frontal cortex of the brain.

PSi (Patient State Index)

The Patient State Index (PSi) is related to the effect of certain anesthetic agents on a patient. PSi is represented by a numeric value that ranges from 0 to 100.

DSA (Density Spectral Array) Display

The Density Spectral Array (DSA) display contains left and right spectrograms that represents the power of the EEG on both sides of the brain within specific frequency ranges.

Asymmetry

The Asymmetry value visualizes and quantifies the difference in the brain activity between the left and the right sides of the brain. Higher values indicate greater difference in EEG activity between the two hemispheres.

EMG (Electromyography)

Electromyography (EMG) feature on the SedLine is a measure of the detected interference due to muscle activity, such as grimacing or jaw clenching. EMG interference is represented by a numeric value that ranges from 0-100%.

SR (Suppression Ratio)

Suppression Ratio (SR) is a measure of how much the electrical activity of the frontal and pre-frontal cortex of the brain is suppressed as a percentage of time. SR is represented by a numeric value that ranges from 0 to 100%.

ARTF (Artifact)

Artifact (ARTF) is a measure of how much physiological (non-brain related) and environmental noise the system detects. ARTF is represented by a numeric value that ranges from 0 to 100%.

SEFL and SEFR (Spectral Edge Frequencies)

Spectral Edge Frequency (Left and Right) identifies the frequency below which 95% of the total power of the patient's EEG is located. SEFL and SEFR are represented by numeric values that range from 0-30Hz.

Chapter 5: Troubleshooting

Troubleshooting SedLine

To troubleshoot issues with the SedLine Sensor, See the Directions for Use (DFU) for the sensor. If a problem persists, contact an Authorized Masimo Representative.

- Verify that the SedLine Module is connected to the host device.
- Verify that the SedLine Patient Cable is securely inserted into the SedLine Module.
- Verify that the SedLine Sensor is securely inserted into the SedLine Patient Cable. For more information about connecting the SedLine Sensor to the SedLine Module, ***See Chapter 3: Setting Up the System*** on page 17.
- If the SedLine Sensor is properly connected, replace the SedLine Sensor and/or SedLine Patient Cable and See if the issue persists.
- If the host device is displaying any error messages with regards to the SedLine module, refer to the host device operator's manual or user's guide for more information about troubleshooting or correct set up of the SedLine measurement.
- If a signal is noisy or high in amplitude and appears different from the other channels, this may indicate an issue with electrodes or cabling. After making any electrode or cable adjustments, wait two (2) to three (3) seconds for SedLine parameters to update.

Troubleshooting PSi

The following table lists potential causes and corrective action for PSi errors.

Observation	Potential Cause	Next Steps
No PSi reading in the absence of an EEG waveform	The SedLine sensor, patient cable or module may not be connected, may be defective, or may have passed its expiration date.	See Directions for Use (DFU) for the Sensor and ensure that adequate impedance has been achieved.
No PSi reading in the presence of an EEG signal	Insufficient data available or artifact is above 50%.	Follow the troubleshooting steps to correct artifact. ***See Troubleshooting in the Presence of Artifact*** on page 22

Troubleshooting Unexpected Changes in PSi

The following table lists potential causes and corrective action for unexpected changes in PSi values.

Observation	Potential Cause	Next Steps
EEG appears corrupted	Proximity of the SedLine module to other devices can cause high frequency interference or artifact.	Position the source of interference away from the SedLine module.
EMG level is high	There is significant EMG activity interfering with the EEG.	If possible, reduce patient movement or surgical stress. See EMG Interferences below.
The EEG display does not display waveforms for electrodes.	The electrode failed to pass the initial impedance check.	1. To improve electrode-patient contact, push and wiggle the white lining around the electrodes. Do not press directly on the electrode, otherwise the gel may leak out. 2. Remove the sensor from the patient. 3. Wipe the patient's forehead with alcohol and dry. 4. Apply a new sensor. **Note**: For details on applying the sensor, See the Directions for Use (DFU) for the sensor.

Troubleshooting in the Presence of Artifact

The following may assist in troubleshooting in the presence of artifact.

Symptom	Potential Cause	Next Steps
Interference during Electrocautery	The SedLine Module may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.	1. Check that the electrosurgical generator and cables are physically separated from the Host monitor and the SedLine module and sensors. 2. Verify that the patient is not in contact with potentially grounded metal objects, such as bed rails, patient positioning devices, etc. 3. Ensure reliable grounding and avoid using power strips. Verify that the electrosurgical generator and Host monitor are plugged directly into the same wall outlets. 4. Verify that the path of electrosurgical current, from the cutting side to the return pad, is directed away from the SedLine electrodes. This should be ensured through appropriate placement of the return pad and electrodes. **Note:** If the recommended steps do not appear to resolve the artifact, it is advisable to read the PSi when electrocautery is temporarily not in use.
Electromagnetic Interference	Sources of electromagnetic interferences may cause inaccurate PSi readings.	1. Ensure that devices with electrical motors, such as patient beds with pneumatic positioners, blood warmers, and heating blankets (such as Bair Hugger™), are positioned away from the SedLine module and sensor. 2. Ensure that cables are not positioned across the patient body and that surplus cable length is not coiled around limbs or metal objects.

Symptom	Potential Cause	Next Steps
Electromyography (EMG) Interference	• Confirm that the elevation in the EMG parameter corresponds to the change in the PSi. • The elevation in EMG may be associated with patient movement and/or surgical stress.	1. Take action to reduce surgical stress, which could decrease EMG interference. 2. Check for patient movement and wait until patient movement has stopped for more representative PSi estimation. 3. Verify if the patient is being moved by the OR team. Wait until patient adjustment/ manipulation is complete for more representative PSi estimation.

Chapter 6: Specifications

Display Range

Parameter	Range
PSi	0 to 100
SR	0% to 100%
EMG	0% to 100%
ARTF	0% to 100%
SEFL/SEFR	0 Hz to 30 Hz
DSA Amplitude (Left and Right)	-60 dB to 40 dB
DSA Asymmetry	-100% to +100%
Electrode Impedance	0 Ohms to 65 KOhms

Resolution

Parameter	Resolution
PSi	≤ 1
SR	≤ 2%
EMG	≤ 1%
ARTF	≤ 1%
SEFL/SEFR	≤ 1 Hz
DSA Amplitude (Left and Right)	≤ 1 dB
DSA Asymmetry	≤ 1%
Electrode Impedance	≤ 1 KOhm

Environmental

Environmental Conditions	
Operating Temperature	+41°F to +104°F (+5°C to +40°C)
Storage Temperature	-40°F to +158°F (-40°C to +70°C)
Operating and Storage Humidity	10% to 95%, non-condensing
Operating Pressure	500 to 1060 mbar

SedLine Module Physical Characteristics

Dimension	Measurement
Width	1.3 in (3.3 cm)
Length	4.0 in (10.2 cm)
Thickness	0.8 in (2.0 cm)
Cable Length	12 ft. (3.66 m)
Weight	6.8 oz. (210 g)

Clinical Testing Summary

Clinical Testing Summary	
Study Title	Retrospective Assessment of PSi by Independent EEG Experts
Study Type	Retrospective Study
Study Design	The study compared the performance of two SedLine Patient State Index (PSi) algorithms (proposed vs. predicate) through a review by three independent EEG experts, Board Certified Anesthesiologists.
Patient Information	100 subjects, ages 18 to 77 years including both male and female subjects.
Study Results	See table below.

Expert Review Analysis of overall data	
	PSi V2000 Success rate
Overall	90%
GABA with NMDA	90%

Safety Classifications

Equipment Classification per IEC 60601-1	
Type of Protection	Class II
Degree of Protection of Electrical Shock	Defibrillation proof BF-Applied Part
Protection against harm from liquid ingress	IPX1, Protection against vertically falling water drops.
Mode of Operation	Continuous operation

Safety Compliance

Safety Compliance
IEC 60601-1:2005/AMD1:2012
IEC 60601-1-6:2010/AMD1:2013
IEC 62304:2006/AMD1:2015
IEC 60601-2-26:2012
EN 60601-1:2006/AMD1:2013
ANSI/AAMI ES60601-1:2005/A1:2012
CAN/CSA C22.2 No. 60601-1:2014

EMC Compliance

EMC Compliance
See the host device operator's manual or user's guide.

Symbols

The following symbols may appear on the product or product labeling:

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		ETL Intertek certification ***See Declarations on Page 1*** for certifications
IPX1	Protected against vertically falling water drops.		Non-Sterile
	Defibrillation-proof. Type BF applied part		Separate collection for electrical and electronic equipment (WEEE)
EC REP	Authorized representative in the European community		Recyclable
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician	FC	Federal Communications Commission (FCC) Licensing

Symbol	Description	Symbol	Description
	Non-ionizing electromagnetic radiation	FCC ID:	Identifies unit has been registered as a radio device
	Warning, electricity	IC Model:	Industry Canada Identification
	Electrostatic		Biohazardous Waste
	No parameter alarms	 SpO2	Not for continuous monitoring (No alarm for SpO_2)
	Caution	 LATEX	Not made with natural rubber latex
	Manufacturer	REF	Catalog number (model number)
	Date of manufacture YYYY-MM-DD	####	Masimo reference number
	Storage temperature range	SN	Serial number
	Keep dry		Fragile, handle with care
	Storage humidity limitation		Do not use if package is damaged
	Atmospheric pressure limitation	>	Greater than
<	Less than		China Restriction of Hazardous Substances
 eIFU indicator	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Chapter 7: Service and Maintenance

Cleaning Procedures

Cleaning of SedLine should be performed at regular intervals in accordance with hospital, as well as local and governmental regulations.

See Safety Information, Warnings and Cautions on page 9.

SedLine is a reusable instrument. The instrument is supplied non-sterile.

To clean the module

- The outer surface of the module can be cleaned with a soft cloth dampened with a mild detergent and warm water solution.
- Do not allow liquids to enter the interior of the module.
- The outer surface of the module can also be wiped down using any of the following solvents or cleaning agents:
  - Cidex Plus (3.4% glutaraldehyde)
  - 10% bleach solution
  - ≤ 70% isopropyl alcohol solution
  - Oxivir® Tb Wipes

To clean the patient cable

- Moisten a lint-free towel with a mild soapy solution or mild disinfectant. Do not use abrasive cleaners
- Wipe down surfaces of the patient cable with the lint-free towel
- Dry completely after cleaning

General Maintenance for Module

Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with hospital, as well as local and governmental regulations.

The following is a checklist for the general maintenance of SedLine:

- Visually inspect equipment for functional or structural damage, including poor seals, cracks, damaged springs, etc.
- Visually inspect cables, connectors, and connector pins for signs of damage or wear.
- Visually inspect product identification labels to ensure they are clear and legible.
- Visually inspect for evidence of fluid ingress.

Service Instructions

The SedLine system has no customer serviceable parts. Attempting to service SedLine will void the warranty. Safety tests and internal adjustments should be done by qualified personnel only.

See Sales & End-User License Agreement on page 30.

See Contacting Masimo on page 30.

Repair Policy

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the instrument repaired.

Please clean contaminated and/or dirty equipment before returning, following the cleaning procedure. See ***Cleaning Procedures*** on page 29. Make sure the equipment is fully dry before packing.

To return SedLine for service, See ***Return Procedure*** on page 30.

Return Procedure

Please clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. Contact your authorized distributor to request an RMA number. Package the equipment securely – in the original shipping container if possible – and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the equipment. Please include the RMA number in the letter.
- Warranty information – a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the instrument is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating that SedLine has been decontaminated for bloodborne pathogens.
- Return the SedLine Module to the shipping address provided by the authorized distributor.

Contacting Masimo

To contact Masimo, refer to the following:

USA, Canada, and Asia Pacific:	Europe:	All Other Locations:
Masimo Corporation 52 Discovery Irvine, California 92618 Tel:+1 949 297 7000 Fax:+1 949 297 7001	Masimo International Sàrl Puits-Godet 10 2000 Neuchatel-Switzerland Tel:+41 32 720 1111 Fax: +41 32 724 1448	Contact your local Masimo Representative

Sales & End-User License Agreement

This document is a legal agreement between you (“purchaser”) and Masimo Corporation (“Masimo”) for the purchase of this Product (“Product”) and a license in the included or embedded Software (“Software”)

except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: each new Product and the Software media as delivered are free from defects in workmanship or materials. Masimo's sole obligation under this warranty is to replace any product that it deems to be covered under warranty with a replacement SedLine.

Exclusions

The warranty does not extend to, and Masimo is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the Product or Software without Masimo's written authorization; b) supplies, instruments or electrical work external to the Product or not manufactured by Masimo; c) disassembly or reassembly of the Product by anyone other than an authorized Masimo agent; d) use of the Product with Sensors or other accessories other than those manufactured and distributed by Masimo; e) use of the Product and Software in ways or in environments for which they are not labeled; and f) neglect, misuse, improper operation, accident, fire, water, vandalism, weather, war, or any act of God. This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product. This warranty does not extend to any Product that has been reprocessed, reconditioned or recycled.

This warranty also does not apply to any Products provided to Purchaser for testing or demonstration purposes, any temporary Products Modules or any Products for which Seller does not otherwise receive a usage or purchase fee; all such Products are provided AS-IS without warranty.

This warranty, together with any other express written warranty that may be issued by Masimo is the sole and exclusive warranty as to the Product and Software. This warranty is expressly in lieu of any oral or implied warranties, including without limitation any implied warranty of merchantability or fitness for a particular purpose. Masimo shall not be liable for any incidental, special or consequential loss, damage or expense directly or indirectly arising from the use or loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product and Software (under contract, warranty, tort, strict liability or other claim) exceed the amount paid by purchaser for the Products giving rise to such claim. The limitations in this section shall not be deemed to preclude any liability that cannot legally be disclaimed by contract.

End-User License

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