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.

Caution: Federal law 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, and precautions.

This Operator's Manual describes how SedLine information is displayed when used with Root®, including display details as well as accessing and changing user-configurable settings. For additional information related to Root, refer to the Operator's Manual for Root.

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About this Manual

This manual contains setup and operational instructions for the SedLine® Sedation Monitor. Review it thoroughly before attempting to set up and operate the SedLine® Sedation Monitor. Keep it in a convenient location for easy reference during operation and maintenance.

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

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 instrument or damage to other property. The following is an example of a caution:

Caution: This is an example of a caution statement.

A *note* is given when additional general information is applicable. The following is an example of a note:

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 displays electrode status, EEG waveforms, Density Spectral Array (DSA), and Patient State Index (PSI).

The operator controls the unit using menus and dedicated buttons to select various display options. The system consists of 4 major components: Root, SedLine Module, SedLine Patient Cable, and SedLine Sensors.

Indications for Use

The SedLine® Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It 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.

Contraindications

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

Warnings and Cautions

Warning: A complete reading of this manual by personnel in contact with SedLine prior to use is essential for safety. Improper setup, operation, maintenance, or parts replacement could result in injury to personnel and damage to SedLine components.

Caution: SedLine is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

Caution: Always use SedLine precisely in accordance with the directions in this manual, including site selection, sensor placement, and subject behavior during testing. Failure to follow all of the directions in this manual could lead to inaccurate measurements**.**

Safety Information

Warning: Do not start or operate the SedLine Module unless the setup was verified to be correct.

Warning: Always use the SedLine Module and SedLine Sensor in conjunction with Root. Do not use parts from other systems. Injury to personnel or equipment damage could occur.

Warning: Do not use the SedLine Module if it appears or is suspected to be damaged.

Warning: Do not adjust, repair, open, disassemble, or modify the SedLine Module. Injury to personnel or equipment damage could occur. Return the SedLine Module for servicing.

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

Warning: Explosion hazard: Do not use the SedLine Module in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

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: Electrical Shock Hazard: To protect against injury, 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.

Caution: An operator may only perform maintenance procedures specifically described in the manual. Otherwise, return the SedLine Module for servicing.

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

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

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: 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 SedLine Module.

Caution: Close proximity to high frequency interference may cause display artifacts. As a mitigation, consider changing Root location or plug Root into a different outlet if potential artifacts are displayed.

Caution: Continuous 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:

- In patients receiving nitrous oxide or ketamine. These agents may result in increased EEG activity power at higher frequencies, in the band > 12 Hz, and this may present an EMG-like pattern.
- 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.

Compliance Information

Warning: 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.

Caution: For FCC compliance information, refer to the Operator's Manual for Root.

General Information

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: Patient State Index (PSI) information shall be used in conjunction with other indicators of patient state in the delivery of anesthetics.

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.

Warning: 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: Impedance monitoring can interfere with other monitoring devices, in particular evoked potential monitors.

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

Chapter 1: Technology Overview

Theory of Operation

The Patient State Index (PSI) 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. 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, displayed in numeric form, and presented in a color-coded trend graphic for monitoring the effect of certain anesthetics on the state of the brain.

Chapter 2: System Descriptions

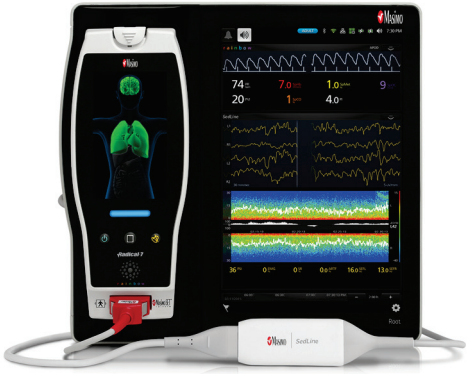
The SedLine system is comprised of four (4) components:

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

Root

SedLine is displayed on Root for the user. This information includes electrode status, EEG waveforms, PSI, DSA, electromyograph (EMG), artifacts (ARTF), suppression ratio (SR), and spectral edge frequency (SEFL for left side and SEFR for right side). The following image illustrates these features being displayed on Root.

The following image illustrates these features being displayed on Root along with information from the Radical-7 Pulse CO-Oximeter.



SedLine Module

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

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. Confirm that you have all system components:
   - Root
   - SedLine Module
   - SedLine Patient Cable
   - SedLine Sensor
2. Confirm that Root holds adequate battery power.
3. Confirm that you have alcohol swabs for sensor application.

Connecting the Module to the Patient Cable

The image below shows various SedLine system components connected.

To connect the module to the patient cable

1. Identify the module connector end.

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

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

Connecting the Module to Root

To connect the module to Root

1. Identify the Masimo Open Connect (MOC-9 ™) end of the module.

2. Insert the MOC-9 end of the module securely into a MOC-9 port on Root.

Connecting the SedLine Sensor to the Patient

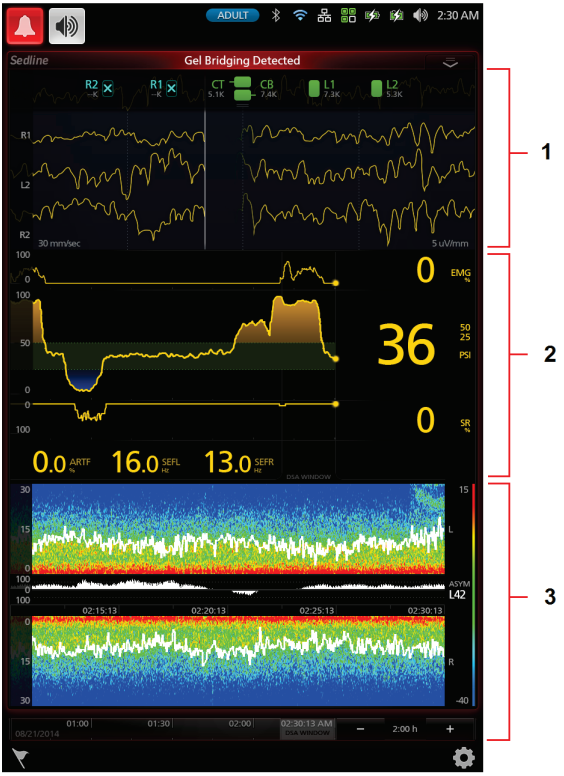
For directions on how to connect the SedLine Sensor, see the Directions for Use (DFU) for SedLine Sensors.

Chapter 4: Operation

The following sections describe how SedLine information is displayed when used with Root, including display details and accessing and changing user-configurable settings. For additional information, see Operator's Manual for Root.

The SedLine Window

When SedLine is connected to Root, parameters and measurements display in a window. SedLine parameters can display as numeric values and graphical representations of the information acquired through the SedLine Sensor.



1	EEG Display
2	Parameters Display
3	DSA Display

EEG Display

Electrode Status

This feature in the SedLine window is used to monitor electrode impedance. To reveal the Electrode Status Display, swipe down on the tab shown below.

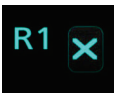
The Electrode Status display provides electrode connectivity status of the sensor. There are six (6) icons on the Electrode Status display that correspond to the six sensor electrodes, as shown in the following illustration. For example, the Electrode Status display icon labeled as R2 corresponds to the R2 electrode of the sensor.

Each icon label corresponds with electrode label on SedLine Sensor

Each individual electrode status is composed of three components:

1. L/R/C (Left/Right/Center) represents the corresponding sensor electrodes. Here, the R1 electrode label corresponds to the R1 electrode of the sensor.
2. The color rectangle adjacent to the electrode label represents the electrode impedance status. Refer to the icon color chart in this section for details on different colors and statuses.
3. The numeric value under the electrode label represents the level of electrode impedance.

Each electrode icon can change colors to indicate the impedance status of the corresponding electrode. The following table describes the icon color and its meaning. For troubleshooting details, see **Chapter 8: Troubleshooting**.

Icon Color	Example	Description
Green		Electrode impedance is in good range and acceptable.
Yellow		Electrode impedance is marginal but acceptable.
Red		Electrode impedance is out of acceptable range.
Blue		Unreliable connection or disconnection of sensor electrodes.
Light Gray		Impedance values are unavailable due to sensor, patient cable, or module not adequately detected.
Dark Gray with Cyan X		Gel-bridging detected on the electrode.
Dark Gray		Electrode monitoring disabled. All electrodes will be dark gray.

The range for electrode impedance values is 0.0 to 65.0 kilo-ohms (K). The display of electrode impedance values can be turned on or off by the user.

EEG Waveforms

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

The display is configured to contain four (4) data input sources. These input sources are acquired from electrodes on the sensor: L1, R1, L2, and R2. After input data is acquired, the data displays as trends.

1 EEG Chart Speed **2** EEG Amplitude

The vertical axis displays the electrode source. The data values are conveyed by horizontal gold trend lines which scroll from left to right across the display. The horizontal axis represents time. The trend amplitude and speed are configurable by the user. Pressing the **chart speed** on the bottom left corner or the **amplitude** in the bottom right corner leads the user to the SedLine Additional Settings menu.

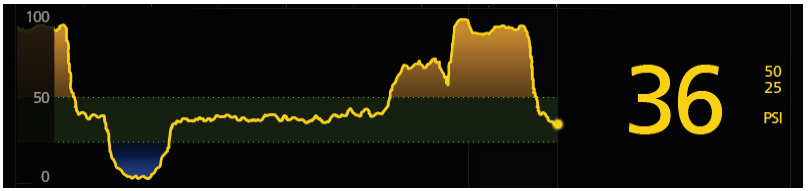
Parameters Display

Each parameter display consists of a trend line and a numeric value.

- The gray region on the trend line represents the 20-minute window that is shown on the DSA display.
- The user can swipe on any trend line to see historical information on all trend lines.
- The user can pinch in and out on any trend line to expand and contract the time frame shown on all trend lines.

PSI (Patient State Index)

The Patient State Index (PSI) is related to the effect of certain anesthetic agents on a patient.



Numeric Value

PSI is represented by a numeric value that ranges from 0 to 100. When a PSI numeric value is not available, the value displays dashes (--). The PSI value displays in conjunction with two smaller numeric values, the high alarm limit and low alarm limit. A brief explanation of PSI is available by pressing the **Numeric Value** and then the **About** icon in the menu that appears.

Trend

PSI trend conveys the PSI numeric values over a period of time. The vertical axis range is 0 to 100 and is configurable by the user. The horizontal axis represents time; the period is configurable by the user.

- Green conveys that the PSI reading is within threshold limits.
- Yellow conveys that the PSI reading is above the threshold limits.
- Blue conveys that the PSI reading is below the threshold limits.

EMG (Electromyography)

Electromyography (EMG) is a measure of detected muscle activity, such as jaw clenching.

Numeric Value

EMG is represented by a numeric value that ranges from 0 to 100%. When an EMG numeric value is not available, the value displays dashes (--). A brief explanation of EMG is available by pressing the **Numeric Value** and then the **About** icon in the menu that appears.

Trend

EMG trend conveys the EMG numeric values over a period of time. The vertical axis range is 0 to 100% and it is configurable by the user. The horizontal axis represents time which is configurable by the user.

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.

Numeric Value

SR is represented by a numeric value that ranges from 0 to 100%. When an SR numeric value is not available, the value displays dashes (--). A brief explanation of SR is available by pressing the **Numeric Value** and then the **About** icon in the menu that appears.

Trend

SR trend conveys the SR numeric values over a period of time. The vertical axis range is 100% to 0 and it is configurable by the user. The horizontal axis represents time which is configurable by the user.

ARTF (Artifact)

Artifact (ARTF) is a measure of how much physiological (non-brain related) and environmental noise the system detects.

Numeric Value

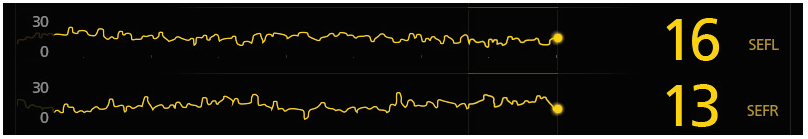
ARTF is represented by a numeric value that ranges from 0 to 100%. When an ARTF numeric value is not available, the value displays dashes (--). A brief explanation of ARTF is available by pressing the **Numeric Value** and then the **About** icon in the menu that appears.

Trend

ARTF trend conveys the ARTF numeric values over a period of time. The vertical axis range is 0 to 100% and it is configurable by the user. The horizontal axis represents time, the period of which is configurable by the user.

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.



Numeric Value

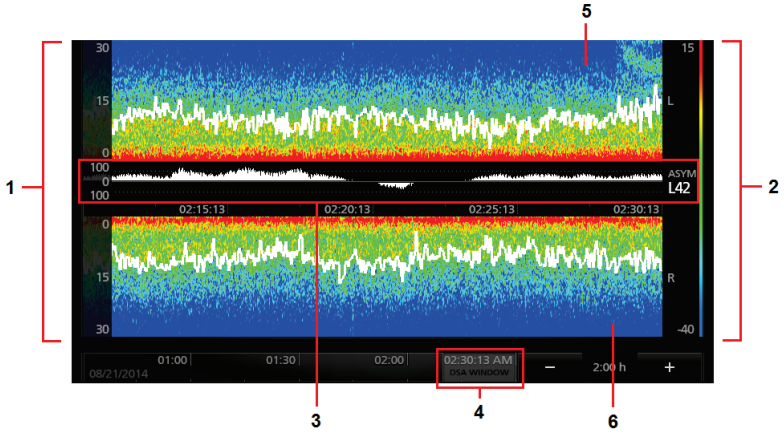
SEFL and SEFR are represented by numeric values that range from 0 to 30 Hz. When SEFL and SEFR numeric values are not available, the values display dashes (--). A brief explanation of SEF is available by pressing the **Numeric Value** of either SEFL or SEFR and then the **About** icon in the menu that appears.

Trend

SEFL and SEFR trends convey the SEFL and SEFR numeric values over a period of time. The vertical axis range is 0 to 30 Hz and it is configurable by the user. The horizontal axis represents time which is configurable by the user.

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 a specific frequency range.



1	Frequency Range (Hz)*	**4**	DSA Window Indicator
2	Power Spectrum (db)*	**5**	Left Side Spectrogram**
3	Asymmetry Graph	**6**	Right Side Spectrogram**

*touch to adjust max and min values

**touch to adjust spectral edge frequency line thickness

The spectrograms update from the right to left and corresponds to the PSI numeric value every 1.2 seconds. While the DSA displays only 20 minutes of information, it can be scrolled backwards to view up to 2 hours of trend information. The DSA Window Indicator represents the 20-minute time frame of the currently displayed DSA on the general timeline at the bottom of the screen.

The spectrogram labeled "L" on the right side represents the activity of the EEG from the left frontal scalp region, and the "L" waveforms in the EEG Display correspond to this bipolar EEG activity (L1 and L2). Conversely, the spectrogram labeled "R" on the right side represents the activity of the EEG from the right frontal scalp region, and the "R" waveforms the EEG Display correspond to this bipolar EEG activity (R1 and R2).

On the spectrogram:

- Artifact is displayed as vertical white lines.
- Periods of EEG suppression is displayed as vertical thick black lines with blue tick mark at 0 Hz position.
- Periods of no data are displayed in total black.
- Left and right 95% spectral edges are displayed as white trend lines.

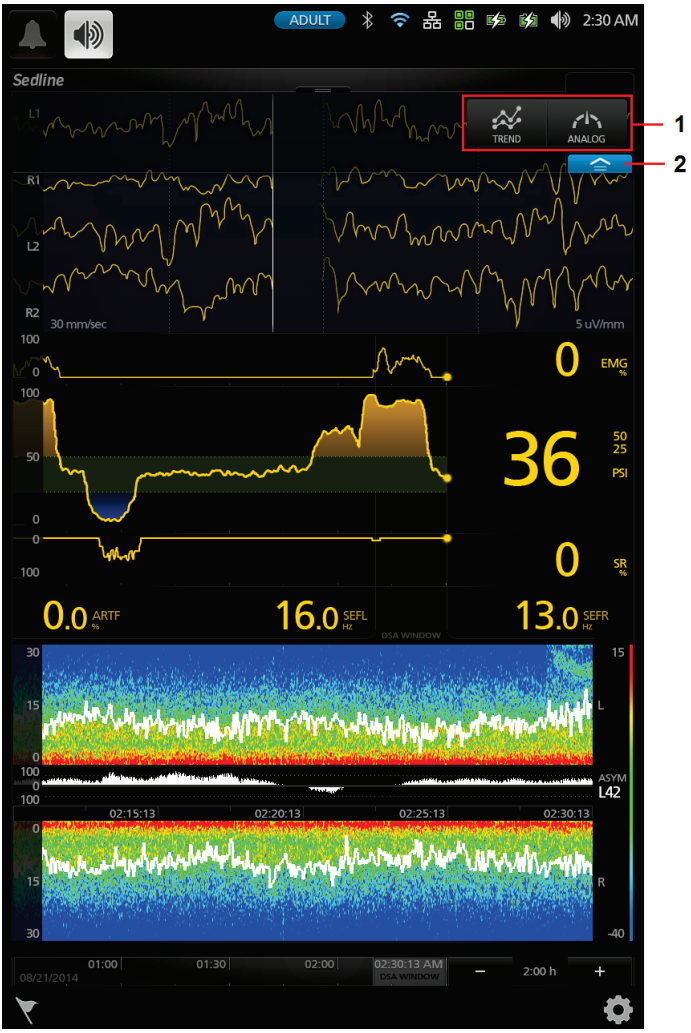
The vertical axes for both spectrograms display the frequency range displayed on the spectrogram, while the vertical color bar on the right represents the power of the EEG as measured in decibels. The horizontal axis shows the timestamps of the DSA information.

Asymmetry Graph

The Asymmetry Graph visualizes and quantifies the difference in the brain activity between the left and the right sides with an asymmetry measurement, ASYM, displayed to the right of the graph. An ASYM value of zero implies that the left and right hemispheres have the same level of activity. An ASYM value preceded by an "L" implies that the left hemisphere has more activity relative to the right hemisphere. Conversely, an ASYM value preceded by an "R" implies more activity on the right hemisphere relative to the left hemisphere. Higher values indicate greater difference in EEG activity between the two hemispheres.

View Options

When SedLine is the only MOC-9 technology connected to Root, the SedLine window will display in full as shown in the following image. To change the view in the SedLine window, toggle between the **Trend** and **Analog** tabs.



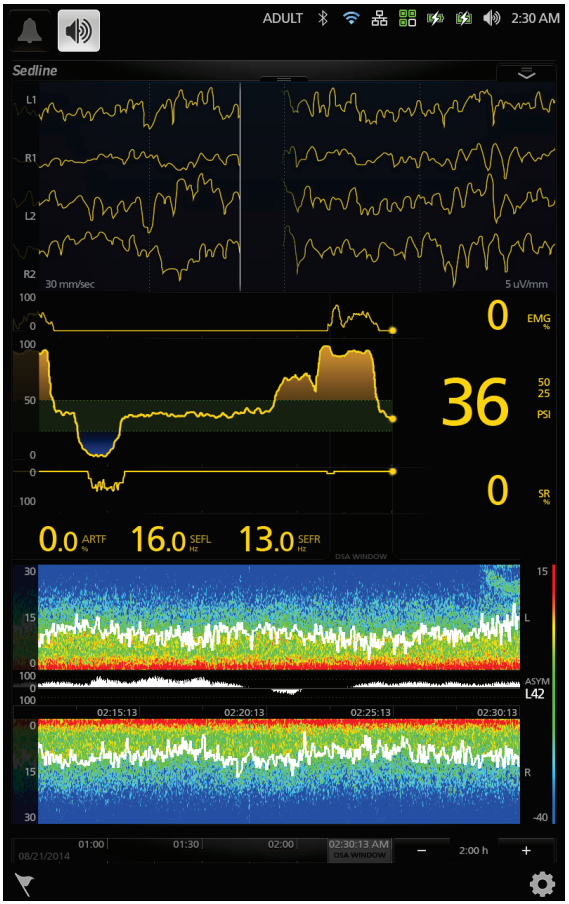
1	View Options: Trend, Analog
2	Drop-Down Menu

The Parameters Display can be customized by expanding and minimizing the parameters and measurements in both Trend View and Analog View.

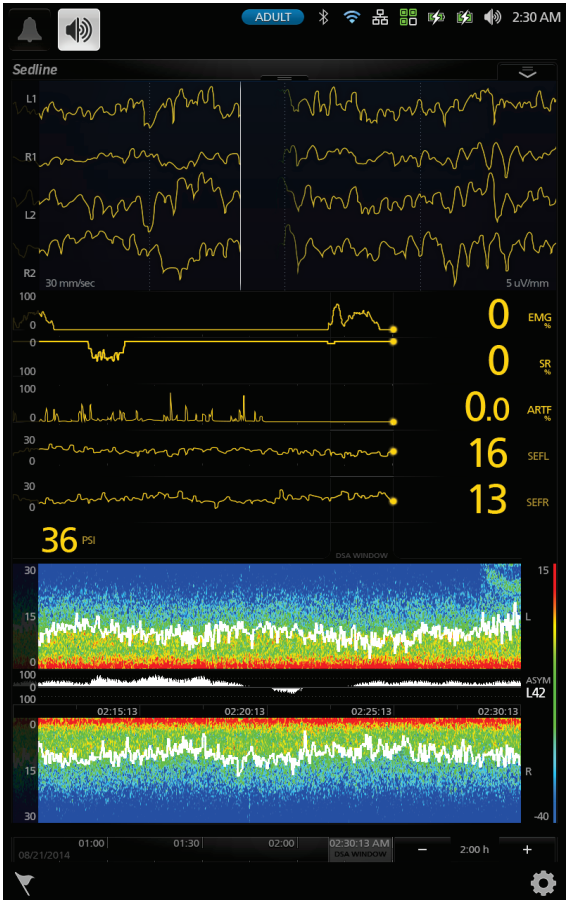
Each parameter can be minimized to display only its Numeric Value and Parameter Label. To minimize a parameter's Trend Display, press and hold its Numeric Value until it dims, then drag-and-drop it into the Well.

Each parameter in the Well can also be expanded. To expand a parameter, press and hold its Numeric Value until it dims, then drag-and-drop it into the Trend Display area.

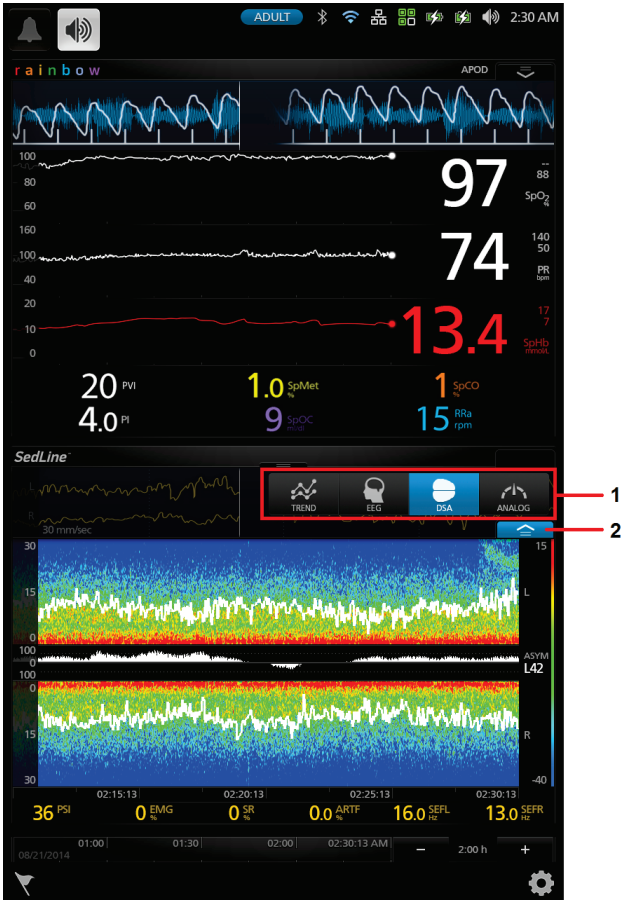
In the following example, the first image is a default view, and its Parameters Display shows EMG, PSI and SR with ARTF, SEFL and SEFR in the Well.



The second image shows the customized view after ARTF, SEFL and SEFR are expanded and PSI is minimized.



When multiple MOC-9 technologies are connected, the user will have the option to select one of several pre-configured layouts for optimal viewing. Shown in the following illustration is the SedLine window at 37.5% of the display.



1	View Options: Trend, EEG, DSA, Analog
2	Drop-Down Menu

To select a viewing option, press the drop-down menu icon and press **Trend**, **EEG**, **DSA**, or **Analog** icons.

Chapter 5: Menu Options

Parameter Settings

Parameter configuration settings provide the user access to seven parameters: PSI, DSA, SEFL, SEFR, EMG, SR, and ARTF.

To access a specific parameter's configuration settings

- Press the parameter desired directly from the SedLine window.

To access all parameter configuration settings

1. Press the Main Menu icon at the bottom right corner of the screen to access menu options.

2. From the Main Menu, press the SedLine icon.
3. Press the Parameter Settings icon.
4. Press the parameter that you want to configure.

All changes to configuration settings must be accepted by pressing **OK** when prompted. To decline changes made, press **Cancel**.

PSI

About

An informational read-only screen with definition of PSI:

The Patient State Index (PSI) is related to the effect of certain anesthetic agents on a patient.

Alarms

Options	Description	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	50	Off, 5 to 99
Low Limit	Lower limit that triggers an alarm	25	Off, 1 to 95
High Caution Range	Value below High Limit to trigger caution light	Off	0 to 10
Low Caution Range	Value above Low Limit to trigger caution light	Off	0 to 10
Silence Duration	Length of time that the audible alarm remains silenced	2 min	30 sec, 1, 2, or 5 min
Audible Alarms	Disables audible alarm	On	On or Off

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest PSI value that can be displayed	100	5 to 100
Y-Axis Min	Lowest PSI value that can be displayed	0	0 to 95
Threshold Max	Upper limit of target PSI range (green band on PSI Trend display)	50	5 to 100
Threshold Min	Lower limit of target PSI range (green band on PSI Trend display)	25	0 to 95

DSA

About DSA

An informational read-only screen with definition of DSA:

The Density Spectral Array (DSA) is a color representation of the power of the EEG between 0 and 30 Hz showing activity in the right and left areas of the brain using spectral edge frequency as the indices. The DSA represents the last 20 minutes of R and L frontal-prefrontal EEG activity tracked by the 95% Spectral Edge Frequency.

Trends

Options	Description	Factory Default	Selectable Settings
Upper	Upper limit of power spectrum	-10 db	-40 to 40 db (5 db increments)
Lower	Lower limit of power spectrum	-40 db	-60 to -20 db (5 db increments)

Additional Settings

Options	Description	Factory Default	Selectable Settings
SEF Line Thickness	Thickness of spectral edge trend lines in both spectrograms	2	1, 2, 3
Max Frequency	Upper limit of frequency displayed for spectral edge trend lines on both spectrograms	30 Hz	30 or 40 Hz

About ASYM

An informational read-only screen with definition of ASYM:

The asymmetry graph shows the degree of asymmetry in between the left and right hemispheres of the brain over time. The asymmetry parameter (ASYM) to the right of the graph indicates the percentage of EEG power present in the left or right hemisphere with respect to total EEG power present.

EMG

About

An informational read-only screen with definition of EMG:

EMG (electromyography) is a measure of detected muscle activity, such as jaw clenching. The EMG value varies from 0% to 100%.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest EMG value that can be displayed	100%	5% to 100% (5% increments)
Y-Axis Min	Lowest EMG value that can be displayed	0	0 to 95% (5 db increments)

SR

About

An informational read-only screen with definition of SR:

Suppression Ratio (SR) is a measure of how much the electrical activity of the frontal and pre-frontal cortex of the brain is suppressed.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SR value that can be displayed	100%	5% to 100% (5% increments)
Y-Axis Min	Lowest SR value that can be displayed	0	0 to 95% (5 db increments)

ARTF

About

An informational read-only screen with definition of ARTF:

Artifact (ARTF) is a measure of how much physiological (non-brain related) and environmental noise the system detects.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest ARTF value that can be displayed	100%	5% to 100% (5% increments)
Y-Axis Min	Lowest ARTF value that can be displayed	0	0 to 95% (5 db increments)

SEFL and SEFR

About

An informational read-only screen with definition of SEF:

The Spectral Edge Frequency (SEF) identifies the frequency below which 95% of the total power of the patient's EEG is located. SEF is a common EEG power signal processed parameter represented on the DSA display's 0-30 Hz scale. 95% SEF power is displayed as a white horizontal line and as a value for both left and right frontal-prefrontal hemispheres of the brain. EF values display the predominant EEG frequency and corresponding changes.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SEF value that can be displayed	30 Hz	5 Hz to 30 Hz (5% increments)
Y-Axis Min	Lowest SEF value that can be displayed	0	0 to 25 Hz (5 db increments)

Additional Settings

SedLine Additional Settings provide the user access to EEG and DSA settings as well as SedLine Sensor information.

To access the Additional Settings screen

1. From the Main Menu, press the SedLine icon.
2. Press the Additional Settings icon.

All changes to configuration settings must be accepted by pressing **OK** when prompted. To decline changes made, press **Cancel**.

Options	Description	Factory Default	Selectable Settings
EEG Amplitude	Amplitude of the EEG waveforms	5 μV/mm	1, 2, 3, 4, 5, 10, 25, 50, or 100 μV/mm
EEG Chart Speed	Charting speed of the EEG waveforms	30 mm/sec	15 or 30 mm/sec
DSA Placement	Location of DSA display (DSA above or below PSI)	EEG/PSI/DSA	EEG/PSI/DSA or EEG/DSA/PSI
Monitor Impedance	Deactivate the Electrode Status display	On	On or Off
Display Impedance	Hide impedance values on the Electrode Status display	On	On or Off

Chapter 6: EEG Download

The four (4) channels of EEG data can be downloaded as .edf files (European Data Format) onto a USB stick.

Enable EEG Data Collection

Activate EEG waveform storage session by enabling **Data Collection** in the **Access Control** menu (see image below), and then press the **OK** button on the screen. (See Operator's Manual for Root for further instructions on accessing the **Access Control** menu). Root will then record any EEG waveforms displayed into sessions. Terminate the recording session by disabling **Data Collection** in the **Access Control** menu.

Root will record up to 12 continuous hours of EEG waveforms per session. When recording exceeds 12 sessions, the oldest session will be erased as the newest session starts recording.

Download EEG Waveforms

To download the EEG waveforms onto the USB stick:

1. Ensure that there is a folder titled, "edf", in the USB stick that is used to download EEG waveforms from Root. Without this folder, the download cannot activate.
2. Remove all sensors from the patient's application sites and silence any alarms.
3. Plug in the USB stick into one of two USB ports (located on the back of Root), and the EEG information will automatically begin to download.
4. A confirmation message will briefly display at the top of the Root screen when the information transfer is complete.
5. Unplug the USB stick from Root.

Note: The USB stick should have a minimum of 450MB of free storage space in order to download the EEG waveforms from Root.

Note: Ensure that all information has been transferred before unplugging the USB stick as this may cause corruption of the .edf files.

Import .edf Files

To import the data from the USB stick onto a computer

- Access the USB drive's base directory from the computer
- Open the "edf" folder
- Select the desired session folder
- Open the .edf files with an EDF viewing program, such as EDF Viewer or Polyman.

Chapter 7: Alarms and Messages

Messages and Indications

The table below lists the types of messages that can appear on Root when using SedLine.

Error Message	Indication
SedLine is Disconnected	Indicates that the SedLine module is not connected.
No Sensor Connected	Indicates the sensor is not properly connected to the patient cable or the electrodes of the sensor are not connected to the patient's forehead.
Incompatible Sensor	Indicates the sensor type cannot be used in conjunction with SedLine.
Sensor Off Patient	Indicates the electrodes of the sensor are not connected to the patient's forehead.
High Impedance	Indicates the impedance values of the sensor electrodes are too high.
Gel Bridging Detected	Indicates that the active (L1, R1) and ground (CB) electrodes may have gel between them.

Alarms and Indications

SedLine has a Patient State Index audible and visual alarm.

Alarm Text	Indication
PSI High > ##	Indicates the PSI is greater than the high alarm limit value configuration setting.
PSI Low < ##	Indicates the PSI is less than the low alarm limit value configuration setting.

Chapter 8: Troubleshooting

To troubleshoot issues with Root, see the Operator's Manual for Root. To troubleshoot issues with the Masimo sensor, see the Directions for Use (DFU) for the sensor.

If a problem persists, contact an Authorized Masimo Representative.

Message	Action
SedLine is Disconnected	Reconnect the module.
No Sensor Connected	1. Confirm the sensor is properly inserted into the patient cable connector. 2. The sensor may be defective and may need to be replaced. 3. The patient cable may be defective and may need to be replaced. 4. The module may be defective and may need to be replaced.
Replace Sensor	1. Confirm the sensor is properly inserted into the patient cable connector. 2. Replace the sensor if it has been used for more than 24 hours of patient monitoring. 3. Confirm the expiration date of the sensor has not passed.
Incompatible Sensor	1. Confirm the sensor is properly inserted into the patient cable connector. 2. Confirm the expiration date of the sensor has not passed. 3. The sensor may need to be replaced.
Sensor Off Patient	1. Confirm the CB and CT are properly connected. 2. Confirm the sensor is properly inserted into the patient cable connector. 3. The sensor may be defective and may need to be replaced. 4. The patient cable may be defective and may need to be replaced. 5. The module may be defective and may need to be replaced.

Message	Action
Incompatible Sensor	Replace the sensor.
High Impedance	1. Confirm the all electrodes of the sensor are properly connected. 2. The sensor may need to be replaced.
Gel Bridging Detected	1. Clean any gel that has leaked outside of the electrodes on the patient's forehead. 2. Confirm that all electrodes of the sensor are properly connected. 3. The sensor may need to be replaced.

Alarm Text	Action
PSI High > ##	If you wish to delay the audible alarm: press the red alarm bell on the top left of the window. **Note**: If you adjust the alarm limit, the selected value will remain until it is adjusted by the user.
PSI Low < ##	If you wish to delay the audible alarm: press the red alarm bell on the top left of the window. **Note**: If you adjust the alarm limit, the selected value will remain until it is adjusted by the user.

Adjusting Electrodes

The following scenarios may indicate an issue with electrodes or cabling and may be resolved by improving patient-electrode contact:

- If Root displays an electrode status icon in any color other than green.
- If a signal is high in amplitude and appears different from the other channels.

To improve electrode contact

Note: After making any electrode adjustments, wait two (2) to three (3) seconds for SedLine to update. It is important to check the electrodes in the order listed below:

Icon Color	Action
Green	No electrode adjustment necessary.

Icon Color	Action
	
Yellow 	Minor electrode adjustment may be required.
Red 	1. Gently push/wiggle electrodes until all are yellow and/or green. 2. Re-prepping of the application site may be necessary.
Blue 	Confirm that all electrodes, particularly electrodes CT and CB, of the sensor are properly connected.
Light Gray 	1. Replace the patient cable. 2. The module may need to be replaced.
Dark Gray with Cyan X 	1. Clean any gel that has leaked outside of the electrodes on the patient's forehead. 2. Confirm that all sensor electrodes are properly connected. 3. The sensor may need to be replaced.
Dark Gray 	Electrode monitoring is disabled. Turn on electrode monitoring from the additional settings menu.

Trends Not Available

If trends do not appear, this may be due to the one of the following issues:

- Electrode impedance issues
- Artifact issues
- Line power and high frequency artifacts

Electrode Impedance Issues

The EEG window displays waveforms for electrodes only after the module conducts an internal check for impedance issues.

Issue	Action
If 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.

Artifacts Issues

The following information may help resolve artifacts issues.

Issue	Action
Electrode icons on the display are either green or yellow and the ARTF display shows artifacts.	1. Determine if artifact is the problem by referring to the ARTF display. 2. If the problem is artifact, instruct the patient to relax and close his or her eyes. 3. If the problem persists, refer to the **Line Power and High Frequency Artifacts** section.

Line Power and High Frequency Artifacts

The following information may help resolve line power and high frequency artifact issues.

Issue	Action
Proximity of the module to other devices can cause high frequency interference.	1. Confirm that all displayed parameters are within normal limits. 2. Change the location of Root and plug it into another outlet.

Chapter 9: Specifications

Measurement Range

This section contains information about measurement ranges.

Parameter	Range
PSI	0 to 100
EMG	0 to 100%
SR	0 to 100%
ARTF	0 to 100%
DSA (Left and Right)	-60 to 40 dB over frequency range of 0 to 30 Hz
SEFL, SEFR	0 to 30 Hz
Electrode Impedance	0.0 to 65.0 K

Resolution

This section contains information about resolution.

Parameter	Resolution
PSI	1
EMG	1%
SR	1%
ARTF	0.1%
DSA (left and right)	1 Hz
SEFL	1 Hz
SEFR	1 Hz
Electrode Impedance	0.1 K

Environmental

SedLine Module Operating Conditions

Item	Description
Temperature at ambient humidity	5°C to 40°C
Operational Humidity	15% to 95%, non-condensing

SedLine Module Storage and Shipping Conditions

Item	Description
Temperature at ambient humidity	-40°C to 70°C
Storage humidity	15% to 95%, non-condensing
Exposure to pressure	500 to 1060 mbar.

SedLine Module Physical Characteristics

Dimension	Measurement
Width	1.3 in 3.3 cm
Length	4 in 10.2 cm
Thickness	0.8 in 2.0 cm

Regulatory Symbols

The following symbols are on the product hardware or packaging.

Symbols	Definition	Symbols	Definition
	Caution		UL, LLC, certification
	Consult Instructions for Use	FC	Federal Communications Commission (FCC) licensing
	Follow Instructions for Use		Storage Altitude Limitation
	Manufacturer		Storage Temperature Range
	Date of Manufacture		Storage/transport relative humidity range
	Non sterile		Keep Dry
	Defibrillation-Proof. Type BF Applied Part		Fragile/Breakable, Handle with Care
IPX1	IPX1 Protection against liquid drops falling vertically		Do not cut
SN	Serial Number	R_x Only	Federal Law (USA) restricts this device to sale by or on the order of a physician
CE 0123	Mark of Conformity to European Medical Device Directive 93/42/EEC	REF	Catalog number (model number)
	Separate collection for electrical and electronic equipment (WEEE)	EC REP	Authorized Representative in the European Community

Symbols	Definition	Symbols	Definition
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs Note: eIFU is not available for CE mark countries.		

Safety Classifications

1. **Type of Protection against Electric Shock of the Module**

   Class II: Electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions.

2. **Degree of Protection against Electric Shock of the Module**

   An F-type applied part is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated AC supply voltage is applied between the applied part and earth. Root incorporates circuitry, creepage, and clearance distances that provide isolation from the mains in accordance with EN 60601-1. The module also provides patient isolation.

3. **Degree of Protection against effects of Defibrillation**

   SedLine provides protection for the patient and operator during defibrillation when using the SedLine Sensor. The isolation barrier within the module provides this protection.

4. **Degree of Protection against the Ingress of Water**

   Both Root and the module have an ingress of water rating of IPX1 (drip proof).

5. **Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide**

   Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

6. **Mode of Operation of SedLine**

   Continuous: The SedLine may be operated under normal load for a normal period without exceeding the specified limits of temperature.

7. **Classification:**

   Medical electrical equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1/CAN/CSA C22.2 No. 601.1 and IEC 60601-2-26

Safety Compliance

Safety Compliance
UL 60601-1, 1st
CAN/CSA C22.2 No. 601.1
IEC 60601-1, 2nd
EN 60601-1, 2nd
IEC 60601-2-26

EMC Compliance

EMC Compliance
See Operator's Manual for Root.

Chapter 10: 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 the **Warnings and Cautions** section in this manual.

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:
    - Cidex Plus (3.4% glutaraldehyde)
    - 10% bleach solution
    - 70% isopropyl alcohol solution

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.

Service Instructions

SedLine 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 the **Sales & End-User License Agreement** section.

See the **Contacting Masimo** section.

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 described in the **Cleaning Procedures** section. Make sure the equipment is fully dry before packing.

To return SedLine for service, please follow the **Return Procedure** in the next section.

Return Procedure

Please clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for 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 equipment to the following shipping address:

USA, Canada, and Asia Pacific:	Europe:	All Other Locations:
Masimo Corporation 40 Parker Irvine, California 92618 (949) 297-7000 Fax: (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

Contacting Masimo

Masimo Corporation
40 Parker
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

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.

To request a replacement under warranty, Purchaser must contact Masimo for a returned goods authorization. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs shall be the responsibility of Purchaser.

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.

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