

Operator's Manual

SedLine[®] Sedation Monitor



For Sale in the USA

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 (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.

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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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

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About This Manual

This manual explains how to set up and use 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 displays electrode status, EEG waveforms, Density Spectral Array (DSA), and Patient State Index (PSi), EMG Index, Suppression Ratio (SR) and Artifact (ARTF).

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 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.

Safety Information, Warnings and Cautions

CAUTION: SedLine is to be operated by, or under the supervision of, qualified personnel only. Read the manual, accessories, directions for use, all precautionary information, and specifications before use. Refer to the Operator's Manual for Root 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 Root. 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: 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 Root, or plugging Root 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:

- 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.

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.

CAUTION: Replace the cable or sensor when a replace sensor or low SIQ message is consistently displayed while monitoring consecutive patients after completing the low SIQ troubleshooting steps listed in the troubleshooting section.

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 section 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.

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 section in the Operator's Manual for Root.

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

NOTE: For EMC compliance information, refer to the Operator's Manual for Root.

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, 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:

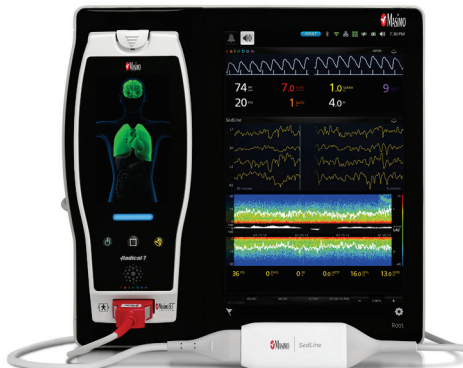
- Root
- SedLine Module
- SedLine Patient Cable
- SedLine Sensor(s)

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

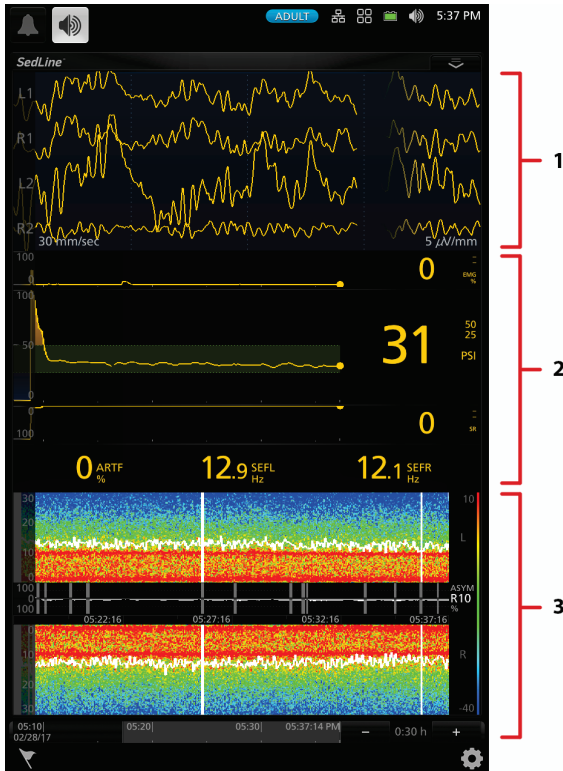
For directions on how to connect the SedLine Sensor, see the Directions for Use (DFU) for SedLine Sensors.

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.



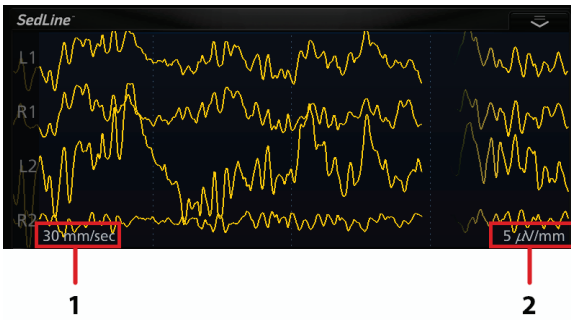
1	EEG Display. See EEG Display on page 24.
2	Parameters Display. See Parameters Display on page 26.
3	DSA Display. See DSA (Density Spectral Array) Display on page 27.

EEG Display

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*
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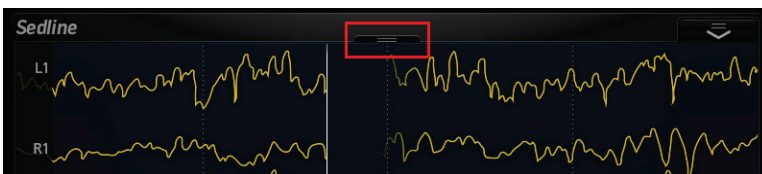
* Touch to adjust the max and min values.

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 adjust the max and min values directly.

Note: When Synchronized Waveforms on Root are Enabled (On) under Access Control, the EEG Chart Speed cannot be changed. Refer to the Operator's Manual for Root.

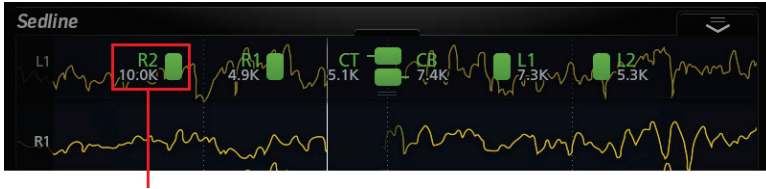
Electrode Status

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.



Note: The feature can be enabled or disabled through **Additional Settings** on page 40.

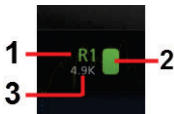
The Electrode Status display provides electrode connectivity status of the sensor. There are six (6) icons on the Electrode Status display that correspond to the six sensor electrodes, as shown in the following illustration. For example, the Electrode Status display icon labeled as R2 corresponds to 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/CB (Left/Right/Center) represents the corresponding sensor electrodes. In the example above, 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** on page 45.

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		Electrode impedance is extremely high or disconnection of sensor electrodes.
Dark Gray with Cyan X		Gel-bridging detected on the affected electrodes.

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

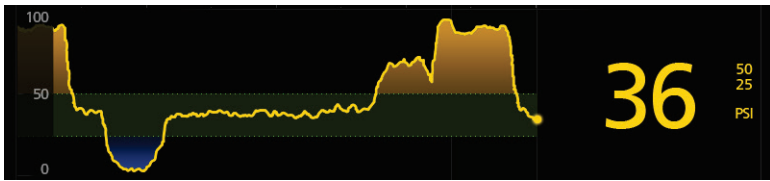
Parameters Display

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.

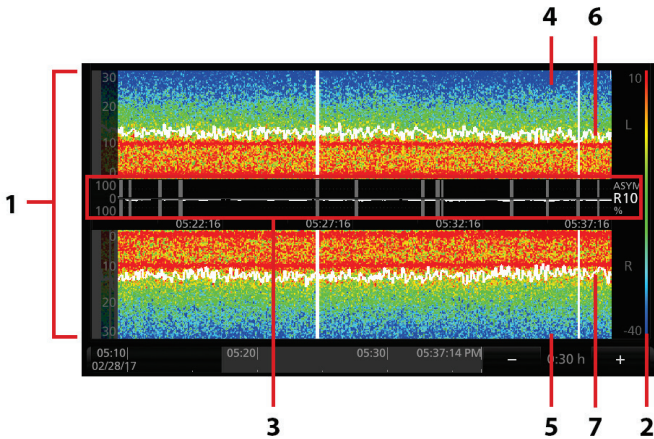
Trend

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.

DSA (Density Spectral Array) Display

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



1	Frequency Range (Hz)*	5	Right Side Spectrogram**
---	-----------------------	---	--------------------------

2	Power Spectrum Range (dB)*	6	SEFL
3	Asymmetry Graph	7	SEFR
4	Left Side Spectrogram**	-	--

* Touch to adjust the max and min values.

** Touch to adjust the 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 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 differential 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 differential EEG activity (R1 and R2).

On the spectrogram:

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

The vertical axes for both spectrograms display the frequency range, 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.

The DSA is available in 2 formats for interpretation; normal contrast (Hanning) or high contrast (Multitaper) (SedLine firmware V2010 or higher).

High Contrast Enhance (Multitaper) DSA

A High Contrast Enhance (Multitaper) Density Spectral Analysis (DSA) is an option with SedLine (requires firmware 2010 or higher).

Note: With Root software version v1.8.1.4 or higher, the default setting is Multitaper.

To access the Multitaper version of SedLine:

1. Access the SedLine option from the main menu.
2. Select parameter settings.
3. Select Density Spectral Array (DSA).
4. Select Additional Settings.
5. Select Multitaper from the available options.

The Multitaper DSA will start to form once this option is confirmed by selecting OK.

Asymmetry Graph



The Asymmetry Graph 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.

EMG (Electromyography)

Electromyography (EMG) is a measure of activity in forehead and nearby muscles detecting activities such as grimacing or 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

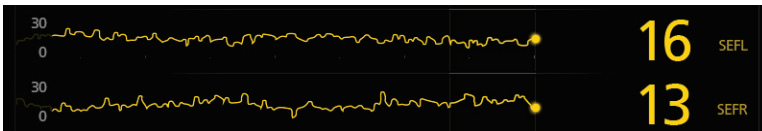
ARTF is represented by a numeric value that ranges from 0 to 100%. When an ARTF numeric value is not available, the value displays dashes (--). A brief explanation of ARTF is available by pressing the **Numeric Value** and then the **About** icon in the menu that appears.

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

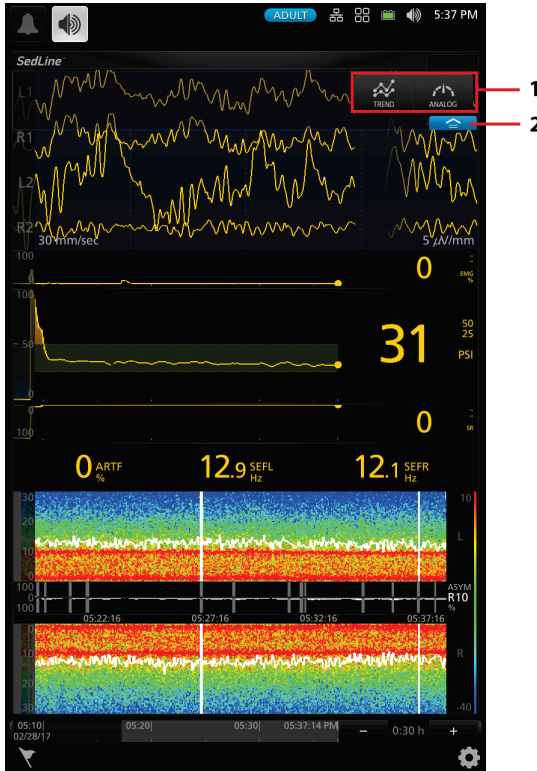
SEFL and SEFR are represented by numeric values that range from 0-30Hz. When SEFL and SEFR numeric values are not available, the values display dashes (--). A brief explanation of SEF is available by pressing the **Numeric Value** of either SEFL or SEFR and then the **About** icon in the menu that appears.

Trend

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

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.



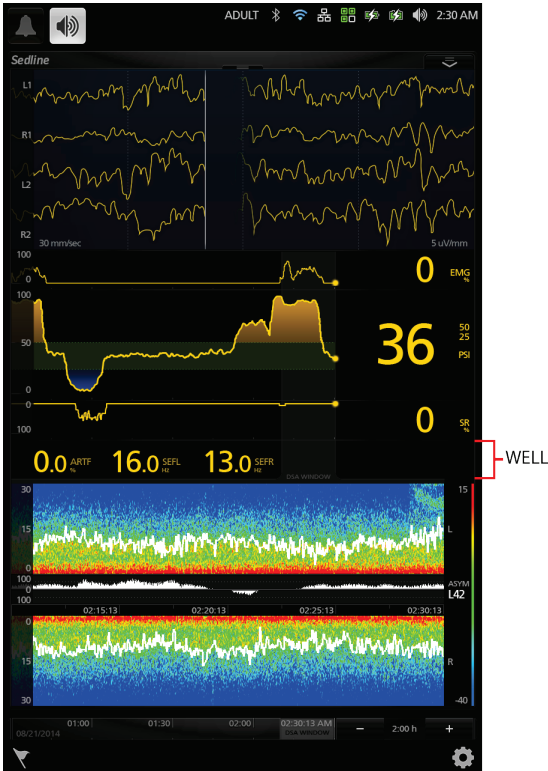
1	View Options: Trend, Analog	2	Action Menu
---	-----------------------------	---	-------------

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

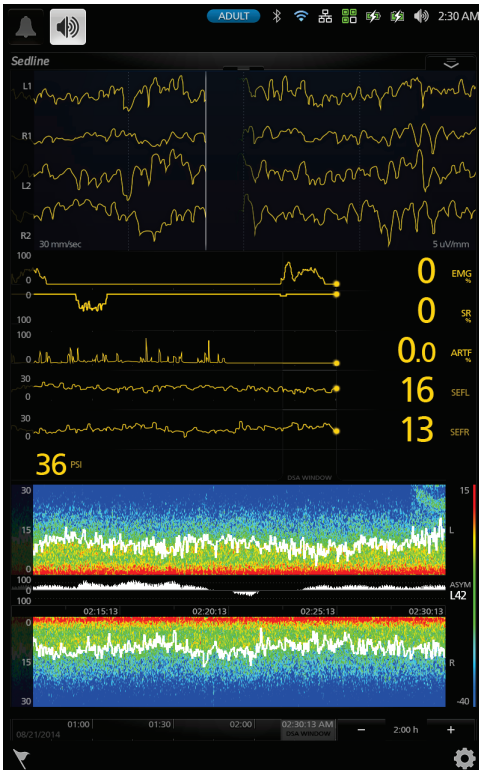
Each parameter can be minimized to display only its Numeric Value and Parameter Label. To minimize a parameter's Trend Display, press and hold its Numeric Value until it dims, then drag-and-drop it into the Well.

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.

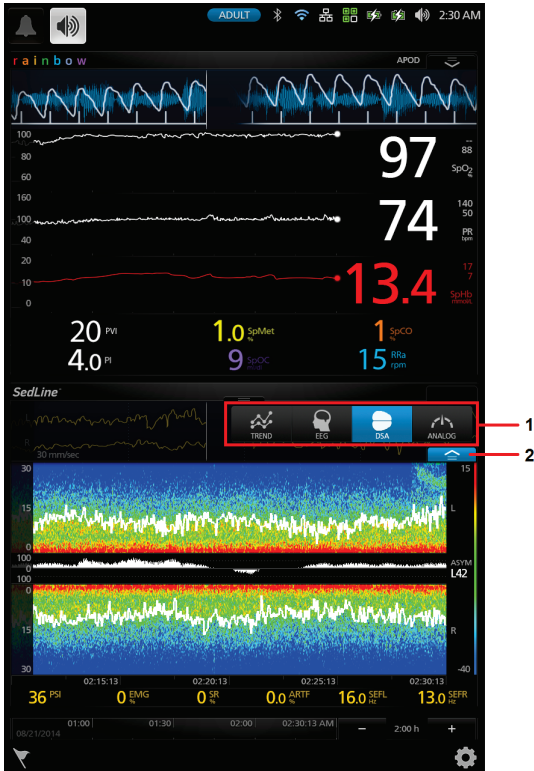
In the following example, the first image is a default view, and its Parameters Display shows EMG, PSi and SR with ARTF, SEFL and SEFR in the Well.



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	Action Menu
---	---------------------------------------	---	-------------

To select a viewing option, press the action 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	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	50	5 to 99 in steps of 1, or Off
Low Limit	Lower limit that triggers an alarm	Low/Medium*	25	Off, or 1 to 95 in steps of 1
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 1 to 10 in steps of 1
Low Caution Range	Value above Low Limit to trigger caution light	NA	Off	Off, or 1 to 10 in steps of 1

Options	Description	Alarm Priority	Factory Default	Selectable Settings
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30 sec, 1, 2, or 5 min
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

* SedLine has the ability to control alarm priority based on the clinical use case. When Audible Alarms are set to Off, the alarm priority is Low. When Audible Alarms are set to On, the alarm priority is Medium.

Trends

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

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 30/40 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
Y-Axis Max	Upper limit of power spectrum	15 dB	-40 to 40 dB in 5 dB increments
Y-Axis Min	Lower limit of power spectrum	-40 dB	-60 to -20 dB in 5 dB increments

Additional Settings

Options	Description	Factory Default	Selectable Settings
SEF Line Thickness	Thickness of spectral edge trend lines in both spectrograms	3	1, 2, or 3
Max Frequency	Upper limit of frequency displayed for spectral edge trend lines on both spectrograms	30 Hz	30 Hz or 40 Hz
DSA Type*	Type of DSA selectable, based on user preference	multitaper	hanning or multitaper

* The default setting is *multitaper (High Contrast Enhance)* with Root software version v1.8.1.4 or higher.

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 grimacing or 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% in 5% increments
Y-Axis Min	Lowest EMG value that can be displayed	0%	0% to 95% in 5% increments

Additional Settings*

Options	Description	Factory Default	Selectable Settings
EMG Sensitivity	Sets the sensitivity level for EMG detection.	Standard	Standard or Maximum

* Available on SedLine with software V232x or higher.

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.

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium	10	2 to 99 in steps of 1, or Off
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 1 to 10 in steps of 1
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30 sec, 1, 2, or 5 min

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SR value that can be displayed	100%	5% to 100% in 5% increments
Y-Axis Min	Lowest SR value that can be displayed	0%	0% to 95% in 5 % 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% in 5% increments
Y-Axis Min	Lowest ARTF value that can be displayed	0%	0% to 95% in 5 % 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 0-30/40 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. SEF values display the predominant EEG frequency and corresponding changes.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SEFL or SEFR value that can be displayed	30 Hz	5 Hz to 30 Hz in 5 Hz increments
Y-Axis Min	Lowest SEFL or SEFR value that can be displayed	0 Hz	0 Hz to 25 Hz in 5 Hz increments

Additional Settings

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

Use the *Additional Settings* screen to configure the following:

Options	Description	Factory Default	Selectable Settings
EEG Amplitude	Amplitude of the EEG waveforms	5 μ V/mm	1, 2, 3, 5, 10, 25, 50, or 100 μ V/mm
EEG Chart Speed*	Charting speed of the EEG waveforms	30 mm/sec	15 or 30 mm/sec
EEG Display Filter	Filters the 50Hz and 60Hz line frequency present in the AC power supply	On	On or Off
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	Displays impedance values on the Electrode Status display	On	On or Off
DSA Artifacts**	Enable or disable the artifact indicator (vertical white lines) on the DSA	On	On or Off

* When Synchronized Waveforms on Root are Enabled (On) under Access Control, the EEG Chart Speed cannot be changed. Refer to the Operator's Manual for Root.

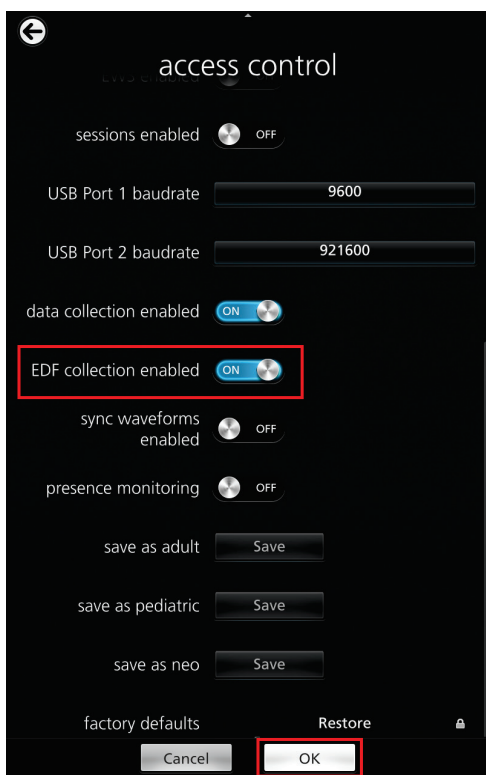
** Available on SedLine with software V232x or higher.

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

Alarms and Indications

SedLine has a Patient State Index (PSi) audible and visual alarm.

Alarm Text	Indication	Action
<i>PSi High</i> > ##	Indicates the PSi is greater than the high alarm limit value configuration setting.	If you wish to change the audible alarm limit: 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.
<i>PSi Low</i> < ##	Indicates the PSi is less than the low alarm limit value configuration setting.	If you wish to change the audible alarm limit: 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.

Chapter 8: Troubleshooting

Troubleshooting SedLine

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
<i>SedLine is Disconnected</i>	Reconnect the module.
<i>No Sensor Connected</i>	<ol style="list-style-type: none">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.
<i>Replace Sensor</i>	<ol style="list-style-type: none">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.
<i>Incompatible Sensor</i>	<ol style="list-style-type: none">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.
<i>Sensor Off Patient</i>	<ol style="list-style-type: none">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.
<i>Incompatible Sensor</i>	Re-apply sensor. See <i>Directions for Use</i> for Sensor.
<i>High Impedance</i>	<ol style="list-style-type: none">1. Confirm all electrodes of the sensor are properly connected.2. The sensor may need to be replaced.

Message	Action
<i>Gel Bridging Detected</i>	<ol style="list-style-type: none"> 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.
<i>Low SIQ message displayed (Low signal quality)</i>	Re-apply sensor. See <i>Directions for Use for Sensor</i> .




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 noisy or 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.
Yellow 	Minor electrode adjustment may be required.
Red 	Gently push/wiggle affected electrodes until all are yellow and/or green.

Icon Color	Action
Blue 	<ol style="list-style-type: none"> 1. Ensure that the sensor connection with the patient cable is secure. 2. Gently push/wiggle electrodes until all are yellow and/or green. 3. The Sensor may need to be replaced.
Dark Gray with Cyan X 	<ol style="list-style-type: none"> 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.

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.	<ol style="list-style-type: none"> 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. <p>Note: For details on applying the sensor, see the Directions for Use (DFU) for the sensor.</p>

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.	<ol style="list-style-type: none"> 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 SedLine Module to other devices can cause high frequency interference.	<ol style="list-style-type: none"> 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

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)
Humidity	15% to 95%, non-condensing
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)

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		
	Old PSi V1031 Success rate	New PSi V2000 Success rate
Overall	73%	90%
GABA with NMDA	72%	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
UL 60601-1
CAN/CSA C22.2 No. 601.1
IEC 60601-1, 2 nd Edition
EN 60601-1, 2 nd Edition
IEC 60601-2-26, 2 nd Edition
ANSI/AAMI ES60601-1
CAN/CSA C22.2 No. 60601-1
IEC 60601-1, 3 rd Edition
IEC 60601-2-26, 3 rd Edition

























EMC Compliance













EMC Compliance
See Operator's Manual for Root.

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
	Mark of conformity to European medical device directive 93/42/EEC		ETL Intertek certification See <i>Declarations on Page 1</i> 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)
	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		Federal Communications Commission (FCC) Licensing
	Non-ionizing electromagnetic radiation	FCC ID:	Identifies unit has been registered as a radio device
	Warning, electricity	IC Model:	Industry Canada Identification

Symbol	Description	Symbol	Description
	Electrostatic		Biohazardous Waste
	No parameter alarms		Not for continuous monitoring (No alarm for SpO ₂)
	Caution		Product contains no PVC (polyvinyl chloride) material
	Manufacturer		Not made with natural rubber latex
	Date of manufacture YYYY-MM-DD		Catalog number (model number)
	Storage temperature range		Masimo reference number
	Keep dry		Serial number
	Storage humidity limitation		Fragile, handle with care
	Atmospheric pressure limitation		Do not use if package is damaged
	Nurse Call Interface		Equipotential Ground Terminal
	AC current		SatShare Interface
	Fuse		Wireless Symbol level

Symbol	Description	Symbol	Description
	Stand-By		Wireless features can be used in member states with the restriction of indoor use in France -Class 2 wireless device
 RS-232	RS-232 Interface		Iris Connection
	Analog Out Interface		Ethernet
	Greater than		USB port
	Less than		China Restriction of Hazardous Substances
---	---		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eIFU is not available in all countries.		

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 **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:
 - 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.
- Visually inspect for evidence of fluid ingress.

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 **Sales & End-User License Agreement** on page 57.

See **Contacting Masimo** on page 57.

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 **Cleaning Procedures** on page 55. Make sure the equipment is fully dry before packing.

To return SedLine for service, please follow the **Return Procedure** on page 56.

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 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

Contacting Masimo

Masimo Corporation
52 Discovery
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.

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

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