Operator's Manual

SedLine® Sedation Monitor

Masimo

Not for Sale in the USA - For Export Only

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. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

Note: Cleared Use Only: The device and related accessories are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

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***

Contents

About This Manual

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

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

WARNING: This is an example of a warning statement.

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

CAUTION: This is an example of a caution statement.

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

Note: This is an example of a note.

Product Description, Indications, and Contraindications

Product Description

SedLine® Sedation Monitor is a patient-connected, 4-channel processed electroencephalograph (EEG) monitor designed specifically for intraoperative or intensive care use. It 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.

Intended 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

None.

Note: Refer to the appropriate sensor directions for use for the applicable contraindication.

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

WARNING: The Patient State Index (PSi) is indicated for adults and has not undergone a full evaluation on pediatrics.

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: Cables and sensors are provided with X-Cal® technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of patient monitoring time.

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 next generation PSi V2000:

- Alfentanil
- Desflurane

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

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

Note: Lateral electrodes on the RD sensors (adult and pediatric) are adjustable.

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 SedLine is based upon the principle that brain activity results in electrical activity that can create detectable potential difference at the skin surface of the forehead that increase with increased brain activity and decrease with reduced brain activity.

The Patient State Index (PSi) utilizes this relationship to establish characteristics of the EEG that can be quantified to establish multivariate combinations of quantitative electroencephalogram (QEEG) variables that are sensitive to the brain activity under changing levels 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: Description

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

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

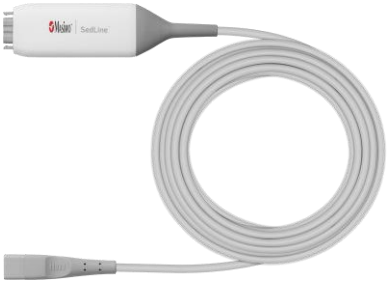
Root

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

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

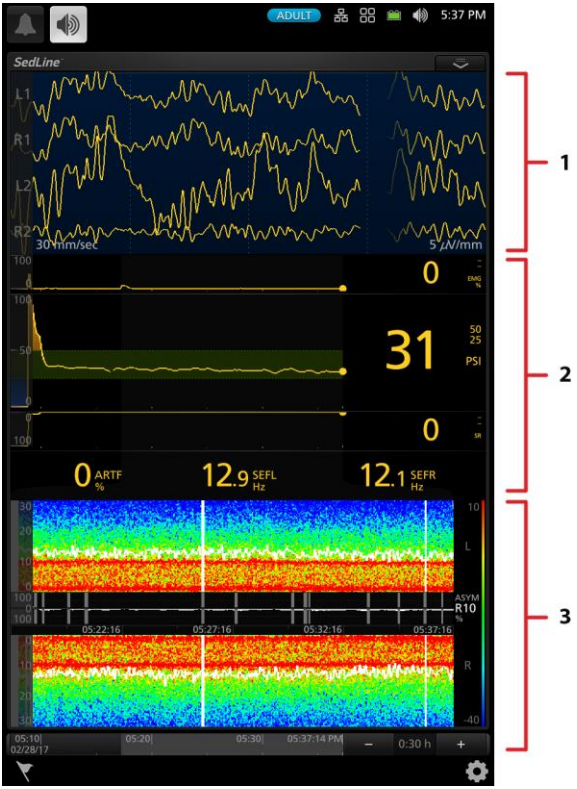
For directions on how to connect the SedLine Sensor, see the Directions for Use (DFU) for SedLine Sensors.

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.



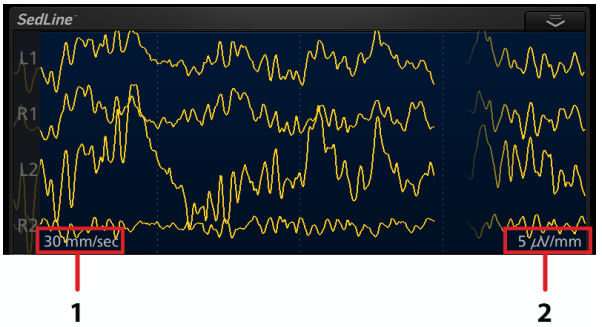
1	EEG Display. See ***EEG Display*** on page 24.
2	Parameters Display. See ***Parameters Display*** on page 26.
3	DSA Display. See ***DSA (Density Spectral Array) Display*** on page 28.

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*

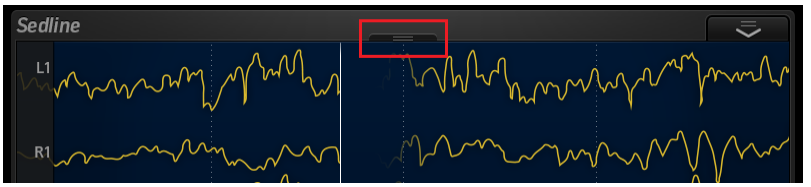
* Touch to adjust the max and min values.

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 though Additional Settings Menu.

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.

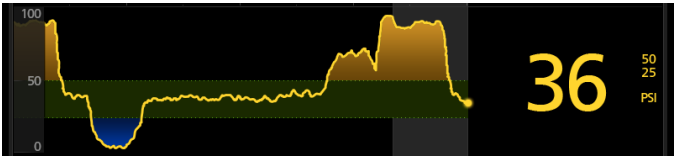
Parameters Display

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.

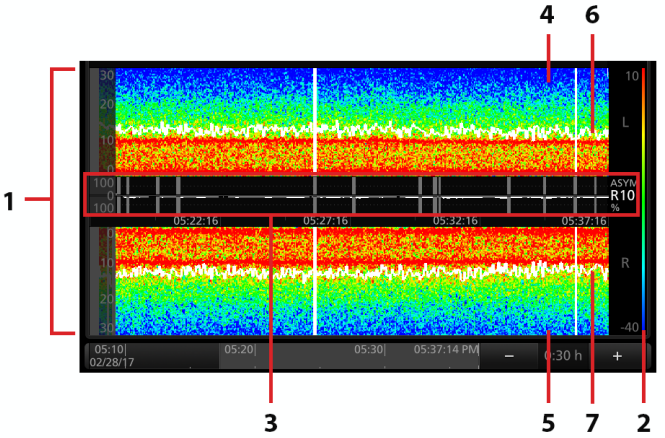
Trend

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).

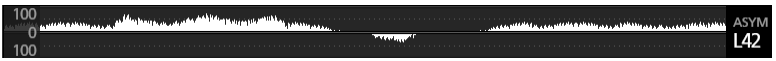
Note: With Root software version v1.8.1.4 or higher, the default setting is Multitaper.

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

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

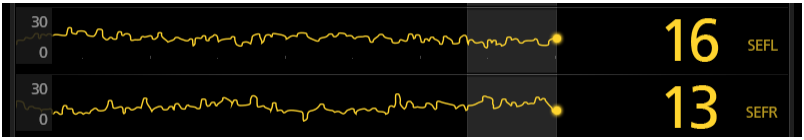
ARTF is represented by a numeric value that ranges from 0 to 100%. When an ARTF numeric value is not available, the value displays dashes (--). A brief explanation of ARTF is available by pressing the **Numeric Value** and then the **About** icon in the menu that appears.

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

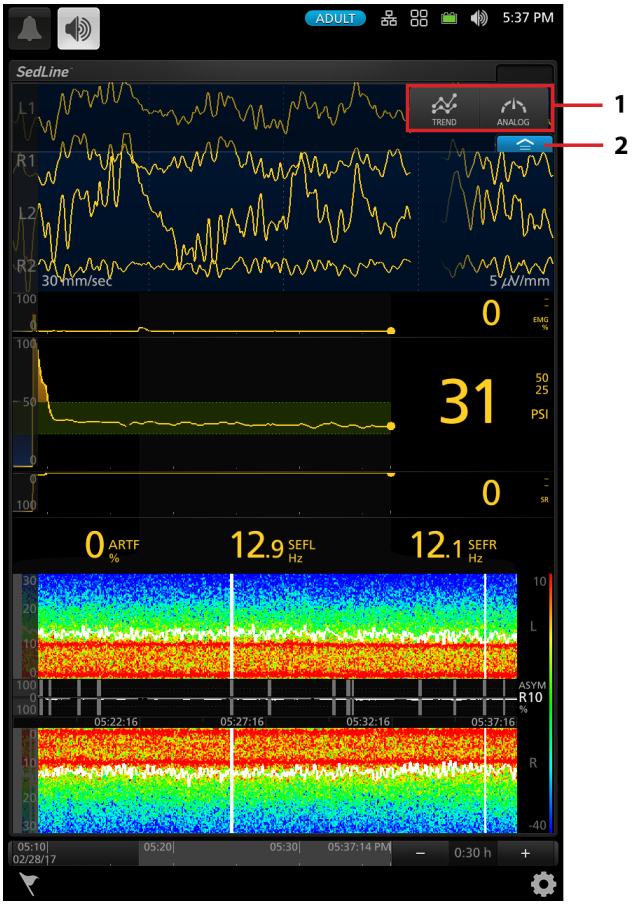
SEFL and SEFR are represented by numeric values that range from 0-30Hz. When SEFL and SEFR numeric values are not available, the values display dashes (--). A brief explanation of SEF is available by pressing the **Numeric Value** of either SEFL or SEFR and then the **About** icon in the menu that appears.

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.



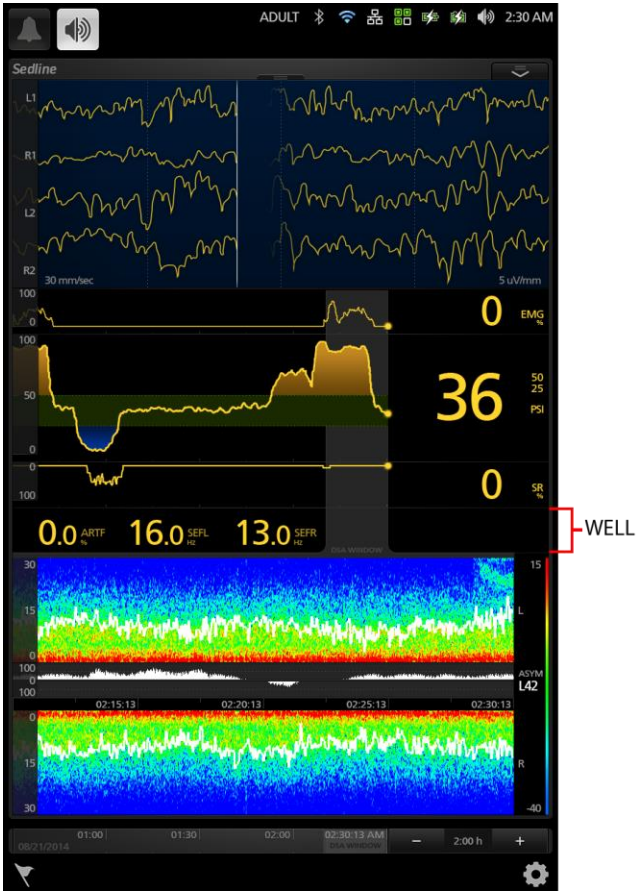
1	View Options: Trend, Analog	2	Action Menu

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

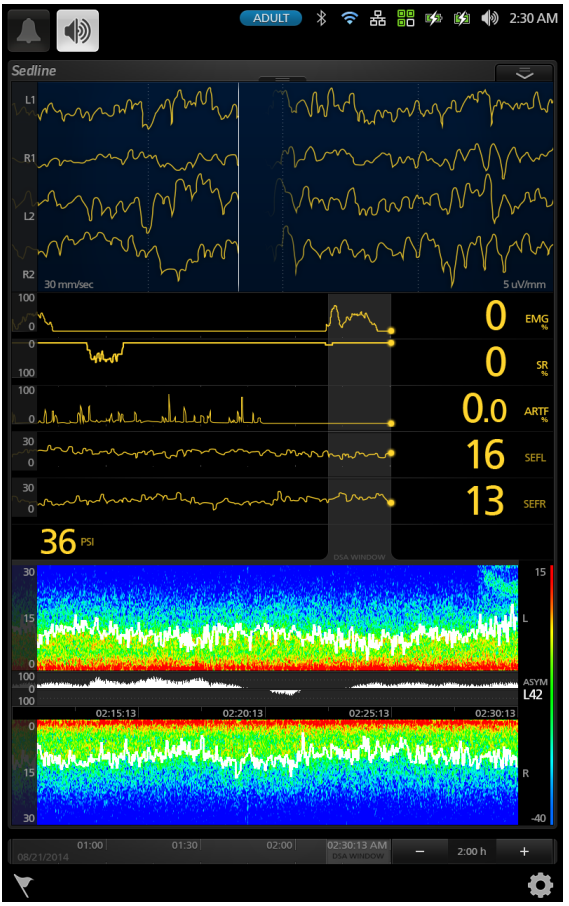
Each parameter can be minimized to display only its Numeric Value and Parameter Label. To minimize a parameter's Trend Display, press and hold its Numeric Value until it dims, then drag-and-drop it into the Well.

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.

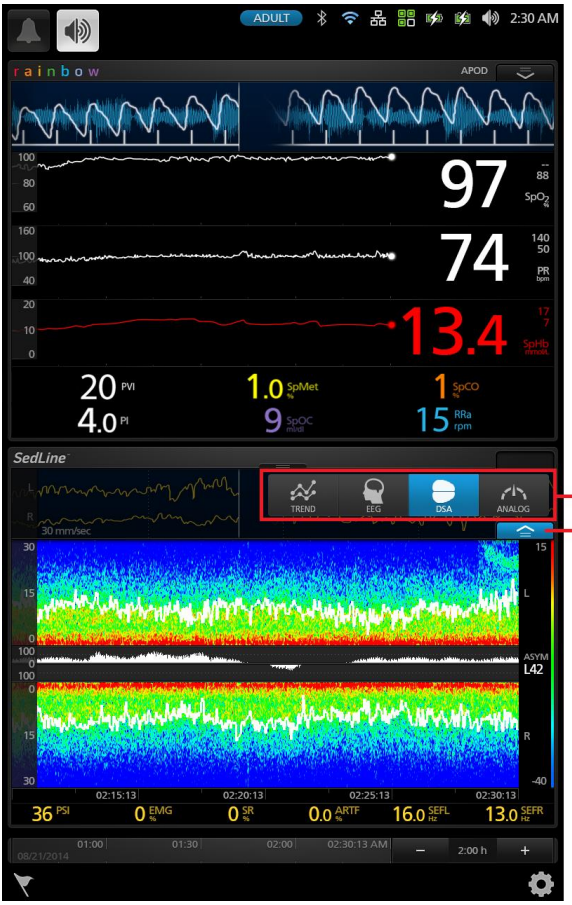
In the following example, the first image is a default view, and its Parameters Display shows EMG, PSi and SR with ARTF, SEFL and SEFR in the Well.



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.

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
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

* High and Low PSi alarm limits are defaulted to 50 and 25 to align with expected range of PSi values when patients are sedated.

** 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

*Defaults were set to provide resolution to low power EEG differences expected during sedation. Increasing the dB limits will lower the resolution to low power EEG differences and while increasing the resolution to higher power EEG differences.

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:

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

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

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

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 µV/mm	1, 2, 3, 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
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.

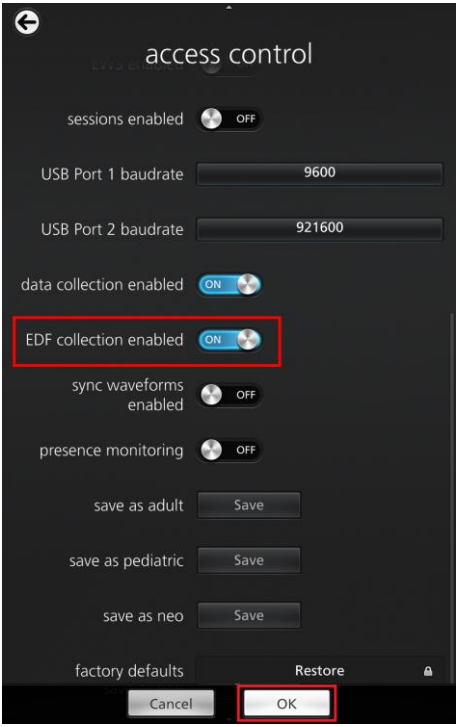
** Available on SedLine with software V2333 or higher.

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 150 EDF files, with each file containing up to 60 minutes of data when the EEG chart speed is set to 15 mm/s, up to 30 minutes of data when set to 30mm/s and up to 85 minutes of data when set to 8mm/s. When recording exceeds maximum number of files, the oldest file will be erased as the newest session starts recording.

Specific EDF data sessions can be downloaded to USB storage by specifying the recording date. To specify a recording date, name the EDF download folder on the storage device with the format "edf_YYYYMMDD". For example, to download data for SedLine cases recorded on August 1, 2019, the folder should be named "edf_20190801"

Note: This edf recording is accurate for Root software version V 2.0.9.6 and higher.

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.

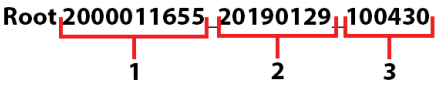
Note: Ensure that all information has been transferred before unplugging the USB stick as this may cause corruption of the .edf files.

Import .edf Files

To import the data from the USB stick onto a computer

1. Access the USB drive’s base directory from the computer
2. Open the “edf” folder
3. Select the desired session file
4. Open the .edf files with an EDF viewing program, such as EDF Viewer or Polyman.

Note: Files are labeled with the serial number of the Root device, the date and the time in the 24 hour clock with seconds



1. Serial Number of Root device
2. Date (Year, Month, Date)
3. Time (24 hour with seconds)

Note: EEG samples are collected at the following rate with the downloaded edf file:If the EEG chart speed is set at 30mm/sec: the download is 178.154 samples/second; if the EEG chart speed is set at 15 mm/sec: the download is 89.077 samples/second; 8mm/sec the download is 63.015 samples/second.

Chapter 5: Alarms and Messages

Messages and Indications

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

Message	Possible Cause	Next Steps
SedLine is Disconnected	Indicates that the SedLine module is not connected.	Reconnect the module.
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.	• Confirm the sensor is properly inserted into the patient cable connector. • The sensor may be defective and may need to be replaced. • The patient cable may be defective and may need to be replaced. • The module may be defective and may need to be replaced.
Replace Sensor	• Sensor has used all its available patient monitoring time. • Sensor is non-functional. • Defective sensor.	• Confirm the sensor is properly inserted into the patient cable connector. • Replace the sensor if it has been used for more than 24 hours of patient monitoring. • Confirm the expiration date of the sensor has not passed.
Incompatible Sensor	Indicates the sensor type cannot be used in conjunction with SedLine.	• Confirm the sensor is properly inserted into the patient cable connector. • Re-apply sensor. See *Directions for Use* for Sensor. • Confirm the expiration date of the sensor has not passed. • The sensor may need to be replaced.
Sensor Off Patient	Indicates the electrodes of the sensor are not connected to the patient's forehead.	• Confirm the CB and CT are properly connected. • Confirm the sensor is properly inserted into the patient cable connector. • The sensor may be defective and may need to be replaced. • The patient cable may be defective and may need to be replaced. • The module may be defective and may need to be replaced.
High Impedance	Indicates the impedance values of the sensor electrodes are too high.	• Confirm all electrodes of the sensor are properly connected. • The sensor may need to be replaced.

Message	Possible Cause	Next Steps
Gel Bridging Detected	Indicates that the active (L1, R1) and ground (CB) electrodes may have gel between them.	• Clean any gel that has leaked outside of the electrodes on the patient's forehead. • Confirm that all electrodes of the sensor are properly connected. • The sensor may need to be replaced.

Alarms and Indications

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

Alarm Text	Indication	Next Steps
PSi High > ##	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.
PSi Low < ##	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 6: 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.

Troubleshooting SedLine

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.
Incompatible Sensor	Re-apply sensor. See *Directions for Use* for Sensor.
High Impedance	1. Confirm all electrodes of the sensor are properly connected. 2. The sensor may need to be replaced.

Message	Action
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.
PSi Value is "--"	1. Check that a pediatric sensor is not being used. 2. Confirm all electrodes of the sensor are properly connected. 3. The sensor may need to be replaced.
Low SIQ message displayed (Low signal quality)	Re-apply sensor. See *Directions for Use* for Sensor.

Troubleshooting PSi

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

Observation	Potential Cause	Next Steps
No PSi reading in the absence of an EEG waveform	The SedLine sensor, patient cable or module may not be connected, may be defective, or may have passed its expiration date.	See Directions for Use (DFU) for the Sensor and ensure that adequate impedance has been achieved.
No PSi reading in the presence of an EEG signal	Insufficient data available or artifact is above 50%.	Follow the troubleshooting steps to correct artifact. See ***Troubleshooting in the Presence of Artifact*** on page 47.

Troubleshooting Unexpected Changes in PSi

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

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

Troubleshooting in the Presence of Artifact

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

Symptom	Potential Cause	Next Steps
Interference during Electrocautery	The SedLine Module may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.	1. Check that the electrosurgical generator and cables are physically separated from the Root monitor and the SedLine module and sensors. 2. Verify that the patient is not in contact with potentially grounded metal objects, such as bed rails, patient positioning devices, etc. 3. Ensure reliable grounding and avoid using power strips. Verify that the electrosurgical generator and Root monitor are plugged directly into the same wall outlets. 4. Verify that the path of electrosurgical current, from the cutting side to the return pad, is directed away from the SedLine electrodes. This should be ensured through appropriate placement of the return pad and electrodes. **Note:** If the recommended steps do not appear to resolve the artifact, it is advisable to read the PSi when electrocautery is temporarily not in use.
Electromagnetic Interference	Sources of electromagnetic interferences may cause inaccurate PSi readings.	1. Ensure that devices with electrical motors, such as patient beds with pneumatic positioners, blood warmers, and heating blankets (such as Bair Hugger™), are positioned away from the SedLine module and sensor. 2. Ensure that cables are not positioned across the patient body and that surplus cable length is not coiled around limbs or metal objects.
Electromyography (EMG) Interference	• Confirm that the elevation in the EMG parameter corresponds to the change in the PSi. • The elevation in EMG may be associated with patient movement and/or surgical stress.	1. Take action to reduce surgical stress, which could decrease EMG interference. 2. Check for patient movement and wait until patient movement has stopped for more representative PSi estimation. 3. Verify if the patient is being moved by the OR team. Wait until patient adjustment/ manipulation is complete for more representative PSi estimation.

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.
Blue 	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 	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.

Chapter 7: 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)

Compliance

EMC Compliance
See Operator's Manual for Root.

Safety Compliance
UL 60601-1
CAN/CSA C22.2 No. 601.1
IEC 60601-1, 2nd Edition
EN 60601-1, 2nd Edition
IEC 60601-2-26, 2nd Edition
ANSI/AAMI ES60601-1
CAN/CSA C22.2 No. 60601-1
IEC 60601-1, 3rd Edition
IEC 60601-2-26, 3rd Edition

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

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	European Union Conformity Mark		ETL Intertek certification See ***Declarations on Page 1*** for certifications
IPX1	Protected against vertically falling water drops.		Separate collection for electrical and electronic equipment (WEEE)
	Defibrillation-proof. Type BF applied part	**Rx ONLY**	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician
EC REP	Authorized representative in the European community		Biohazardous Waste
	Not made with natural rubber latex		Caution
	Manufacturer	SN	Serial number
	Date of manufacture YYYY-MM-DD	REF	Catalog number (model number)
	Storage temperature range	####	Masimo reference number
	Keep dry		Storage humidity limitation
	Atmospheric pressure limitation		Fragile, handle with care
<	Less than		Do not use if package is damaged
>	Greater 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

Symbol	Description	Symbol	Description
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Chapter 8: Service and Maintenance

Cleaning Procedures

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

See ***Safety Information, Warnings and Cautions*** on page 9.

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

To clean the module

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

To clean the patient cable

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

General Maintenance for Module

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

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

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

Service Instructions

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 56.

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.

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