





See the SedLine Sedation Monitor Operator's Manual for complete instructions, including warnings, indications for use, intended use, cautions, and notes.





Not intended to replace the Operator's Manual.

SedLine is a patient-connected, 4-channel processed electroencephalograph (EEG) monitor designed specifically for intraoperative or intensive care use. It displays electrode status, EEG waveforms and Density Spectral Array (DSA).

General knowledge of electroencephalograph (EEG) monitoring and an understanding of the features and functions of the SedLine Sedation Monitor are prerequisites for proper use.

Do not operate the SedLine Sedation Monitor without completely reading and understanding these instructions.

Notice

Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

Caution: Federal law restricts this device to sale by or on the order of a physician. For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

For further information contact:

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

www.masimo.com

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EU authorized representative for Masimo Corporation:

EC REP

MDSS GmbH Schiffgraben 41 D-30175 Hannover, Germany

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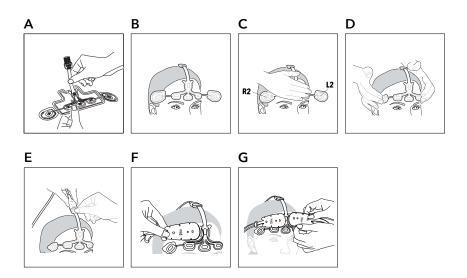
Display Window



- **Electrode Status Display** (See Page 7) Provides sensor electrode connectivity status to indicate whether electrode adjustment is warranted.
- **EEG Display** (See Page 8) Reflects electrical activity of the frontal and prefrontal cortices of the brain.
- 3 Electromyograph (EMG) Measures detected muscle activity, such as grimacing or jaw clenching. This value ranges from 0 to 100%.
- Patient State Index (PSi) (See Page 9) A processed EEG parameter related to the effect of anesthetic agents. This value ranges from 0 to 100.
- Suppression Ratio (SR) Measures how much the electrical activity of the frontal and pre-frontal cortices of the brain is suppressed as a percentage of time. This value ranges from 0 to 100%.
- Artifact (ARTF) Measures how much physiological (not brain-related) and environmental noise the system detects. This value ranges from 0 to 100%.
- Asymmetry Graph Visualizes and quantifies the difference in brain activity between the left and the right sides using an asymmetry measurement.
 - Density Spectral Array (DSA) (See Page 10) Uses color to represent the power levels of EEG between 0 and 30 Hz (Upper limit can be adjusted to 40 Hz).

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Applying the RD SedLine EEG Sensor



To apply the sensor and connect to a module:

- 1. Prepare the forehead skin with alcohol and dry it before applying the sensor.
- 2. Peel the center of the sensor from the tray and discard (A).
- 3. Apply central electrodes onto the forehead. Center CT/CB electrodes on the forehead above the nose (B).
- 4. Press the central electrodes down firmly on to the forehead. Do not press directly on the electrode, otherwise the gel may leak out (C).
- 5. Peel the outer electrodes R2/L2 from the individual trays and apply R2/L2 to the hairless area just above the temple (D).
- 6. Align the yellow indicator on the end of the patient cable to the yellow indicator on the sensor connecter. Push together until the sensor connector fits into the patient cable (E).
- 7. Ensure the SedLine module is connected to the SedLine patient cable and the Root monitor.
- 8. If any of the electrodes is displayed on screen in red, yellow, or blue, push or wiggle the white lining around the electrode until displayed in green. Do not press directly on the electrode as gel may leak out.
- 9. For additional details, see the SedLine Operator's Manual.

Applying with the O3 sensor (when using O3 Regional Oximetry)

Following the application of the RD SedLine EEG sensor, align the rounded section of each O3 sensor with the curved O3 sensor guidelines marked on the T-section of the RD SedLine EEG sensor (F) and position above L1/R1 and L2/R2 (G).

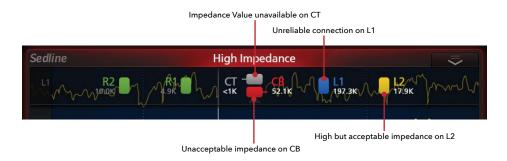
Electrode Status Display

The electrode status display provides the sensor's electrode conductance status.

Display	Description	Action
L1 7.3K	Green - Electrode impedance is within acceptable range.	No electrode adjustment necessary.
L2 17.9K	Yellow - Electrode impedance is marginal but acceptable.	Minor electrode adjustment may be required.
L2 52.1K	Red - Electrode impedance is out of acceptable range.	Gently push/wiggle electrodes until all are yellow and/or green. Re-prepping of electrodes may be necessary.
L1 197.3K	Blue - Unreliable connection or disconnection of Sensor electrodes.	Confirm that all sensor electrodes, particularly electrodes CT and CB, are properly connected.
L1 <1K	Light Gray - Impedance values are unavailable because Sensor, Patient Cable, or Module is not adequately detected.	Replace the Patient Cable. The Module may need to be replaced.
▼ L1K	Dark Gray with a Cyan "X" - Gel-bridging detected on the electrode.	Clean any gel that has leaked outside of the electrodes on the patient's forehead. Confirm that all sensor electrodes are properly connected. The Sensor may need to be replaced.
L2 K	Dark Gray - Electrode monitoring disabled. All electrode icons will be dark gray.	Confirm that the Sensor is plugged into the Patient Cable. Confirm that the Patient Cable is connected to the Module.

Electrode Status Examples

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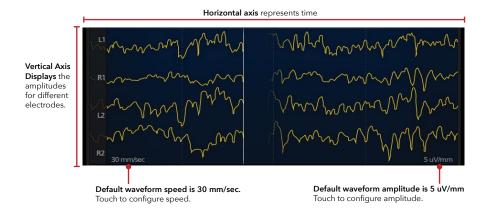




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EEG Display

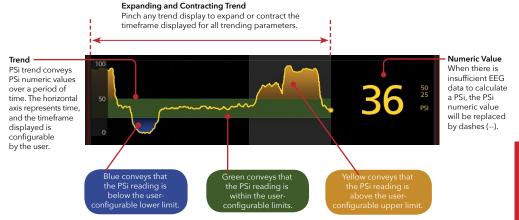
- The EEG waveforms reflect electrical activity of the frontal and pre-frontal cortices of the brain.
- The display is configured to contain 4 data input sources, acquired from the 4 sensor electrodes: L1, R1, L2, and R2.



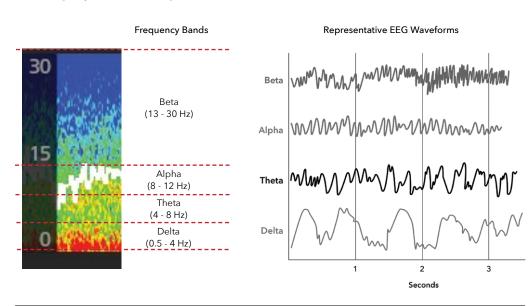
Patient State Index (PSi)

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The PSi is a processed EEG parameter that is related to the effect of anesthetic agents, and takes into consideration, among other factors: (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.



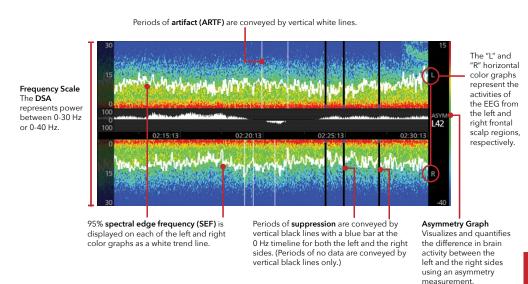
Density Spectral Array (DSA)



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Understanding the DSA

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