

Next Generation SedLine[®] Brain Function Monitoring

More Complete Data, Now with an Enhanced Patient State Index (PSi)



Next Generation SedLine helps clinicians monitor the state of the brain under anesthesia with:

- > An enhanced signal processing engine, which improves performance of the Patient State Index (PSi)
- > Four simultaneous channels of frontal electroencephalogram (EEG) waveforms, enabling bilateral data acquisition and processing of EEG signals
- > A Multitaper Density Spectral Array (DSA), which may enhance visibility of EEG features



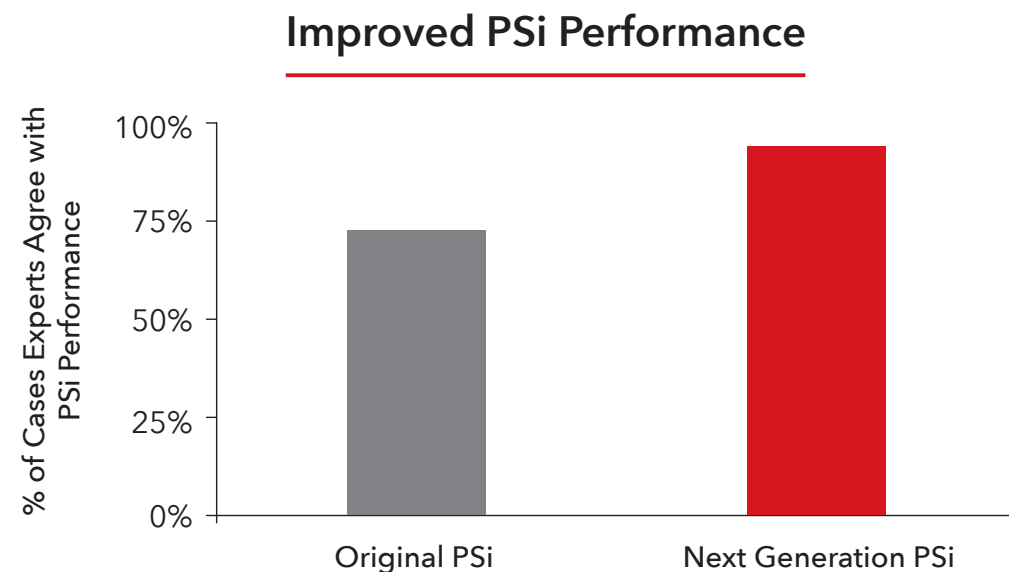
Improved Patient State Index (PSi)

Next Generation SedLine features an enhanced signal processing engine which provides an enhanced Patient State Index (PSi), a processed EEG parameter related to the effect of anesthetic agents.

Expert Scoring of Next Generation SedLine¹

EEG experts scored the improvement in PSi performance between the original SedLine PSi and Next Generation SedLine PSi.

Experts found a **25% average improvement** in Next Generation PSi performance.



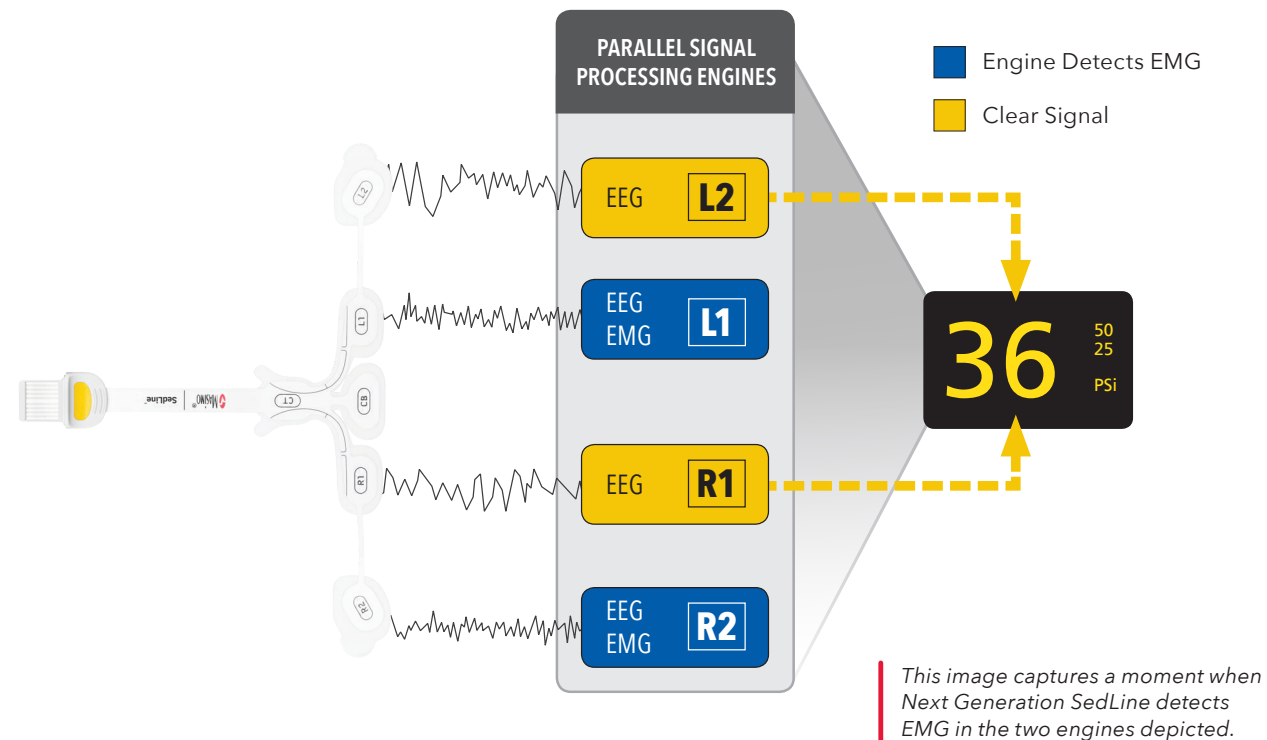
To evaluate the performance of Original PSi and Next Generation PSi, independent EEG experts reviewed validation cases with both Original PSi and Next Generation PSi (blinded to the version), along with additional clinical information (MOAAS scores, EEG waveforms, drug doses, and vital signs). Compared to the expert-assessed anesthetic depth, an error was defined as a case when expert assessment of PSi was 'Low' or 'High' and success was defined as a case when the expert assessment of PSi was 'Good'.



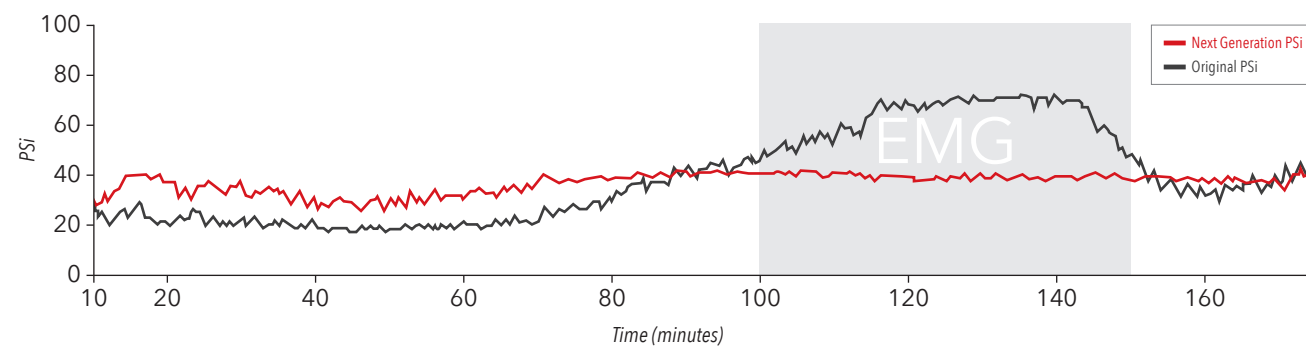
Next Generation SedLine Brain Function Monitoring helps clinicians monitor the state of the brain under anesthesia with bilateral data acquisition and processing of four leads of electroencephalogram (EEG) signals.

Parallel Signal Processing Engines

Next Generation SedLine utilizes Masimo's Parallel Signal Processing Engines to extract a clearer EEG signal for computing PSi.



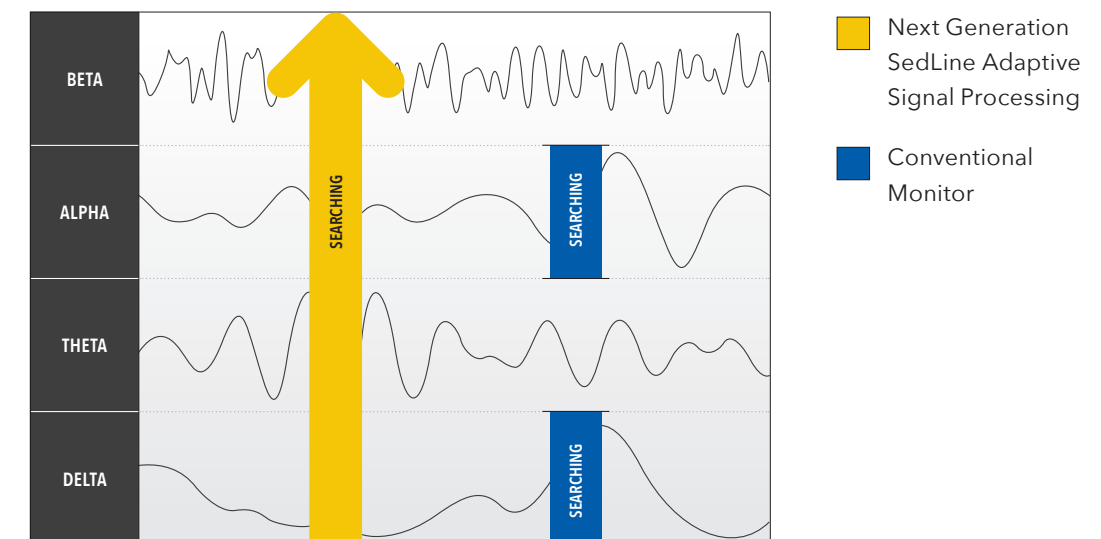
The case below demonstrates Next Generation SedLine's improvement to PSi.¹



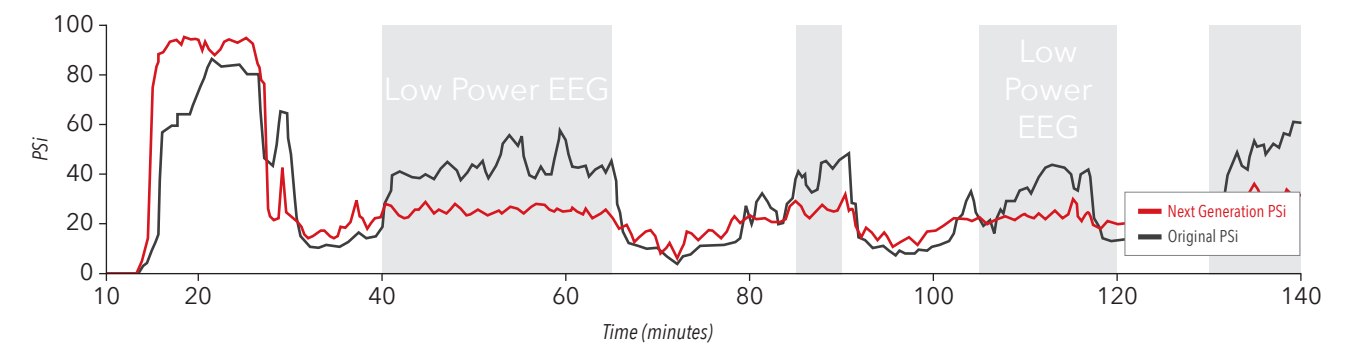
EMG is a common confounding factor that can interfere with EEG signals used in brain function monitoring.²

Adaptive Signal Processing with Band-Independent Features

When computing PSi, Next Generation SedLine uses adaptive signal processing with band-independent features to search for EEG features across many frequency bands.



The case below demonstrates Next Generation SedLine's improvement to PSi.¹

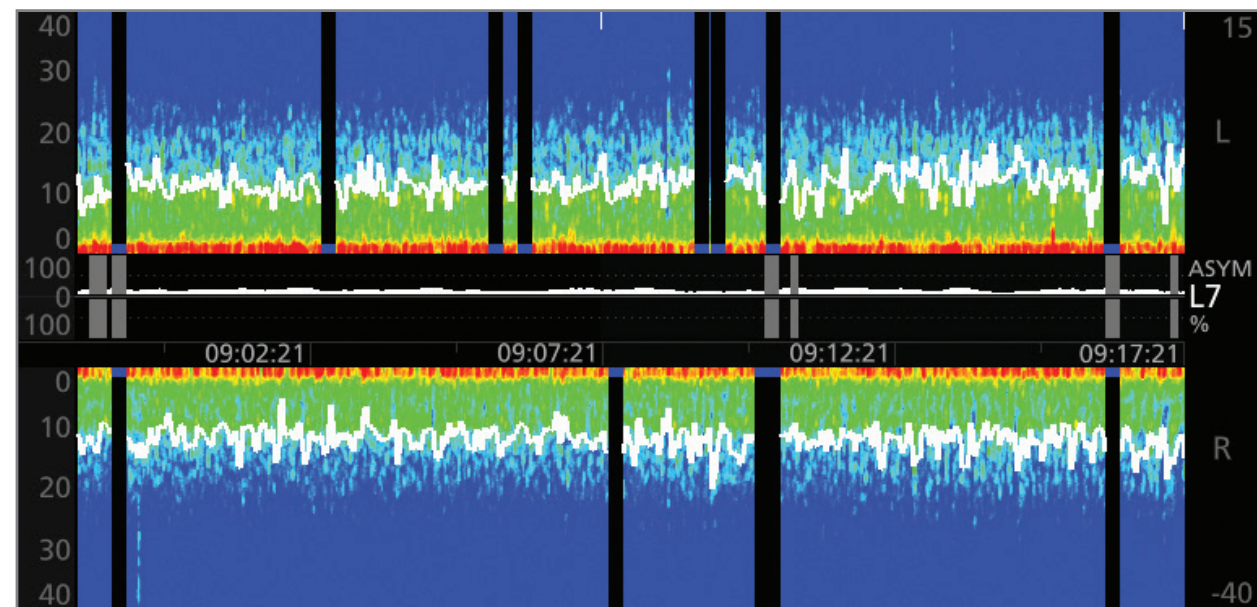


Power across all frequency bands decreases with age.³

Multitaper Density Spectral Array (DSA)

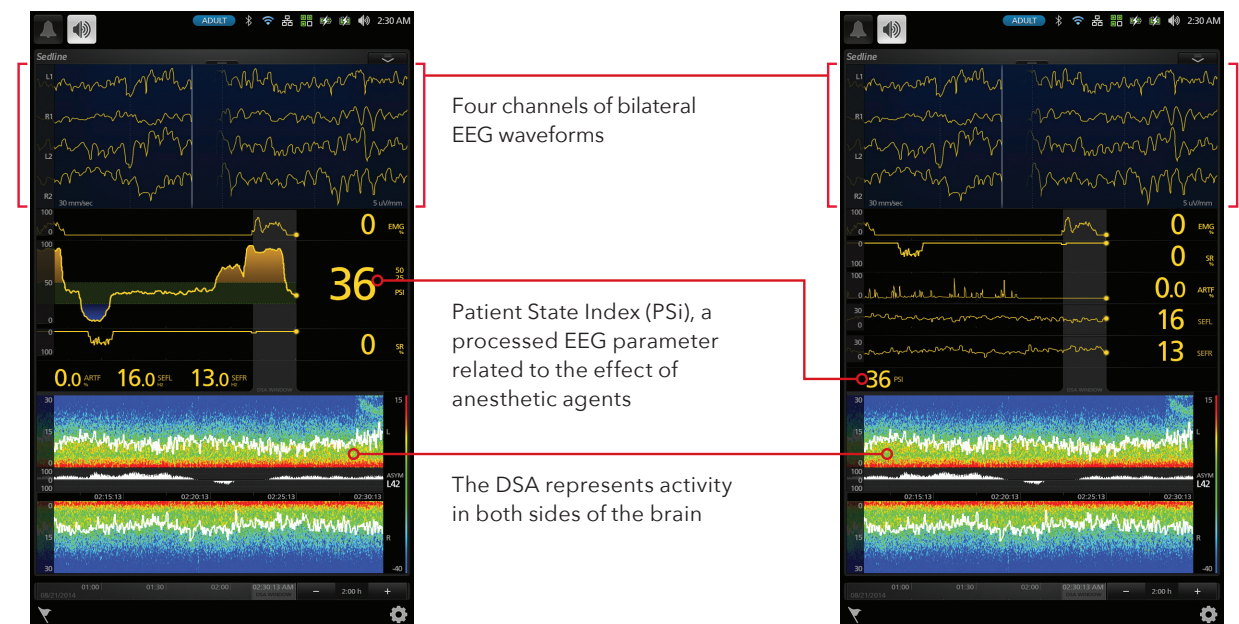
Next Generation SedLine offers clinicians the flexibility of choosing to display either an enhanced Multitaper Density Spectral Array (DSA) or a standard Hanning DSA. The DSA contains left and right spectrograms representing the power of the EEG on both sides of the brain.

When using a Multitaper DSA, EEG data are transformed into the frequency domain, which may provide a better display of EEG features.



Next Generation SedLine on Root®

The Next Generation SedLine module easily plugs into the Root patient monitoring platform via Masimo Open Connect® (MOC-9®) ports. Root's customizable, easily-interpretable display offers multiple views of brain monitoring information expanding visibility in the operating room and intensive care unit.



A More Complete Picture of the Brain

Next Generation SedLine can be used simultaneously with O3® Regional Oximetry on the Root platform for a more complete picture of the brain.

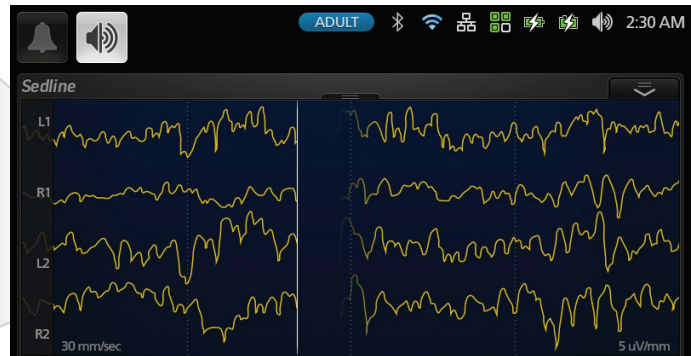
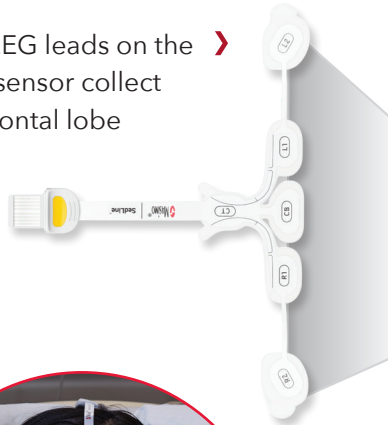


RD SedLine™ EEG Sensor

- > Soft foam pads for comfortable application on a patient's forehead
- > Adhesive anchors ensure secure sensor placement for optimal signal quality
- > Pre-filled gel electrodes help streamline sensor application workflows
- > Durable, heat-laminated flex cables allow flexible placement and repositioning



Four active EEG leads on the RD SedLine sensor collect data in the frontal lobe



- < Application graphics for O3 regional oximetry sensor placement simplify simultaneous application of both monitoring technologies

SedLine Specifications

PHYSICAL CHARACTERISTICS	ENVIRONMENTAL
Module Physical Dimensions Width 1.3 in (3.3 cm) Length 4.0 in (10.2 cm) Thickness 0.8 in (2.0 cm)	Module Operating Conditions Operating Temperature 41-104°F (5-40°C) Operational Humidity 15-95%, non-condensing Module Storage Conditions Storage Temperature -40-158°F (-40-70°C) Storage Humidity 15-95%, non-condensing Exposure to Pressure 500-1060 mbar

Sensor Specifications

Application Site Forehead Active Channels 4 Active Electrodes L1, L2, R1, and R2	Ground Electrode CB Reference Electrode CT Duration of Use Maximum of 24 hours Latex Content Does not contain natural rubber latex
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¹ Retrospective analysis of clinical data on file. ² Lobo, Francisco A., and Stefan Schraag. Limitations of anaesthesia depth monitoring. *Current Opinion in Anesthesiology*. 24, no. 6 (2011): 657-664. ³ Purdon P et al. *Brit J of Anaesth*. 10.1093 46-57.

The RD SedLine EEG Sensor is not licensed for sale in Canada.

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.

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