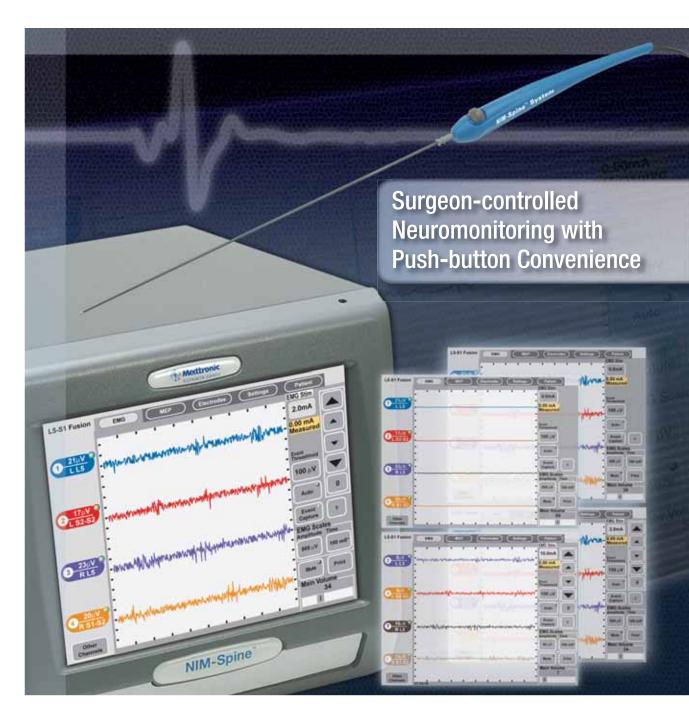


NIM-SPINE[™] System Neural Integrity Monitor





The surgical correction of spinal defects is associated with small, but non-negligible risk to the spinal cord and spinal nerve roots. The benefit of early notification and intervention in those patients who are suffering from unapparent intraoperative neurodeficit has long been understood.

The NIM-SPINE System offers a unique combination of monitoring modalities, along with a full line of recording and stimulation accessories, that allows the surgeon to achieve unrivaled accuracy, surgeon confidence, and trouble-free monitoring. The NIM-SPINE System ushers in a new era of intraoperative neuromonitoring during spinal procedures.

"Motor impairment is among the most feared and devastating outcomes following major surgery (Isley et. al. 2001)."

The NIM-SPINE System is a powerful, multi-modality neural integrity monitor that includes both the technical capabilities demanded by monitoring professionals and the ease of use features necessary to allow the surgeon to directly monitor the patient's nerve root and spinal cord function. The system provides two types of monitoring modalities, electromyographic (EMG) and motor evoked potential (MEP), and intuitive audible and visual real-time feedback to aid in intraoperative decision-making.

"You have the security of knowing you are backed with more than 15 years of clinical experience."

CONFIDENCE-

- Reliable, reproducible results
- Surgeon-controlled monitoring
- · Reassurance of successful procedures
- · Audible and visual feedback upon nerve irritation
- Intraoperative and postoperative printing capabilities

"Sensitivity in identifying potentially misplaced screws...98% with Electrodiagnostic modalities and only 63% with radiography alone (Maguire et. al, 1995)."

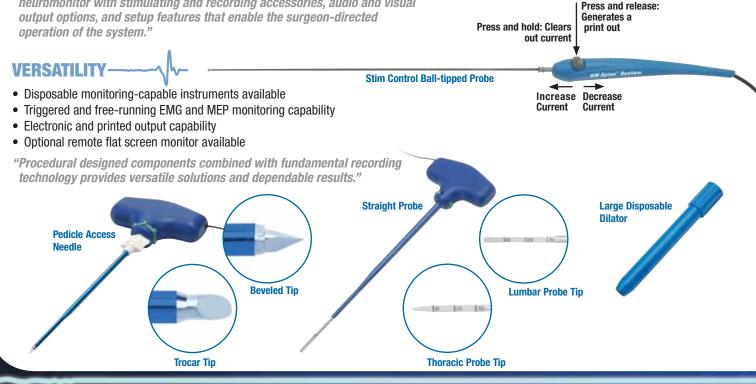
SIMPLICITY

- Quick, user-defined setup
- Intuitive touch screen monitor interface
- Push-button Ball-tipped Probe for stimulating, printing, and current control
- Interactive troubleshooting

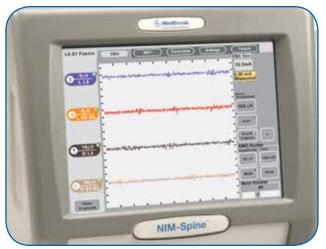
"The NIM-SPINE System combines the precision of a technically advanced neuromonitor with stimulating and recording accessories, audio and visual output options, and setup features that enable the surgeon-directed operation of the system."



The bone screw is easily accessed using the probe.







Touch Screen Monitor Interface



Easy to follow Electrode Placement Guidance



CONTROL SPECIFICATIONS -

Reference Channel

- Helps minimize false positives by comparing active electrodes to a neutral electrode
- Helps assure that true EMG is being registered by detecting false positives

Auto Threshold

- Helps minimize noise in the O.R. while still providing valuable information
- Automatically adjusts the event threshold as the EMG baseline changes to aid in finding the most sensitive setting possible

Amplifier

 Channels 1 through 8 are individually and simultaneously selectable

Impedance Measurement

• Automatic "Check Electrode" feature

Artifact Detection and Rejection

- Synchronized and adjusted muting
- · Automatic detection, muting, and warning

Display/Touch Screen

- Touch screen controls for amplitude, time, display, and capture
- \circ 50, 200, 500 and 2000 μV display modes
- Enable/disable capture mode indicator on touch screen
- 50 ms, 100 ms, or 10 s display modes

EMG Stimulus Characteristics

- EMG Stimulus Type: constant current
- EMG Stimulus Range: 0-30 mA, maximum 120 V compliance
- Monophasic, square pulse waveforms
- Software selectable 1, 4, 7, or 10 Hz
- Stimulus probe is both monopolar (standard) or bipolar

MEP Stimulus Characteristics

- MEP Stimulus Type: constant current
- MEP Stimulus Range: 0-200 mA
- Monophasic, square pulse waveforms
- Software selectable 1 through 8 pulses
- Software selectable 100, 250, or 500 µs pulse width

	M-SP	INE [™] S	VSTEM	
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EMG Threshold Intensity Studies

Reference	"Bad"	"Good"	Method of Determination
Calancie et al. 1994	< 10 mA	≥ 10 mA	Animal model and clinical correlation
Maguire et al. 1995	≤ 6 mA	> 6 mA	Statistically defined as +2 SD above the mean for direct nerve root stimulation
Glassman et al. 1995	≤ 10 mA	> 10 mA > 15 mA	90% Confidence level 98% Confidence level Electrophysiology correlated with computed tomograph
Lenke et al. 1995	≤ 4 mA	> 8 mA	Animal model and clinical correlation
Clements et al. 1996	≤ 11 mA	> 11 mA	Evoked EMG thresholds associated with pedicle wall defect determined by palpation and postoperative radiculopathy

NOTE: Values are not absolute. Patient condition and correlation of other intraoperative data should be considered in the evaluation process.

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