

presenting: **NeuroSENSE[®] Monitor**
With Bilateral WAV_{CNS} Indices

Because monitoring
the brain matters



Our Mission

**Research, develop,
manufacture and market
innovative monitoring
& drug delivery medical
devices using
advanced neuro-
physiological signal
processing & control
system engineering
for Anesthesia, Critical Care
and Military Medicine,
to improve patient safety,
outcomes and quality of life.**

NeuroWave is proud to present the NeuroSENSE® NS-901 Monitor - a new generation brain function monitor for assessing the adequacy of anesthesia and sedation in the operating room and other clinical settings. The system offers clinicians a quantitative guide to aid them in monitoring the effects of anesthetic or sedative drugs for facilitating anesthetic management tailored to the surgery and patient's specific needs.

Powered by leading-edge technologies in signal acquisition and processing of non-invasive electroencephalogram (EEG) signals, the NeuroSENSE provides accurate responses to changes in patient state – immediately, and without delay.

The NeuroSENSE is a unique bilateral brain function monitor for the anesthesia specialty that simultaneously provides independent indices of brain activity for each hemisphere.

This offers clinicians greater insight to assist them in detecting brain function asymmetry (due to, for example, unilateral pathology) and in making decisions for safer and improved patient care.

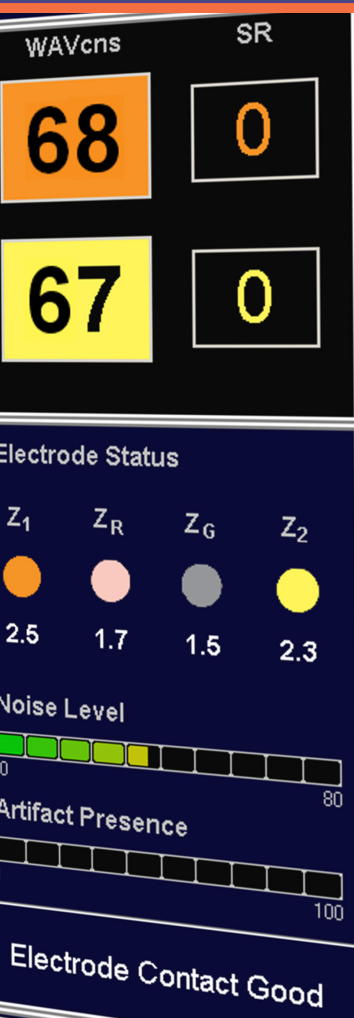


Brain Function Monitoring **Applications**

- ▶ Patient-specific drug administration to facilitate delivery of adequate anesthesia/sedation.
- ▶ Multiple practice advisories have recommended the use of brain function monitoring “as an option during any type of general anaesthesia in patients at risk of adverse outcomes, including those at higher risk of unintended awareness and of excessively deep anaesthesia” [9], in patients receiving Total Intravenous Anesthesia (TIVA) [9, 10, 11], and in general to avoid deep anaesthesia [12].
- ▶ Depth of anesthesia monitoring may be a useful tool to help clinicians prevent the complications of too little or too much anesthesia [13].



NeuroSENSE[®] Product Highlights



The NeuroSENSE NS-901 is a new generation brain function monitor. It acquires and displays two frontal EEG signals, and calculates a number of processed EEG parameters including the bilateral WAV_{CNS} indices — wavelet-based quantifiers of patient's brain activity.

- ▶ **Patented delay-free tracking of patient state via low-noise WAV_{CNS} bilateral indices [1]**
 - WAV_{CNS} (Wavelet-based Anesthetic Value for Central Nervous System) indices react instantaneously to changes in patient's state
 - Automatic trending provides immediate response without increasing the index noise
 - Published algorithm - the WAV_{CNS} is based on the gamma-band of the normalized EEG signal, linked to conscious processing and awareness
- ▶ **True bilateral monitoring with high inter-hemispheric reproducibility [2]**
 - Pronounced asymmetry between indices due to underlying pathologies or artifacts can be easily observed [3]

► **Superior discrimination between consciousness and unconsciousness [4]**

- Accurately determines patient's state to support clinical decision

► **Linear response to increasing EEG suppression [5]**

- More accurate quantification of deeper anesthetic states

► **Predictable response to changes in the EEG signal [6]**

- Ideally suited for used as feedback in closed-loop
Total IntraVenous Anesthesia (TIVA) [7]

► **Easy-to-use review capability for both EEG tracings and processed data trends**

- Accessible during both live case monitoring and archived case review
- Case review includes Density Spectral Array
- Intuitive touch-screen interface for case browsing

► **Comprehensive case archive**

- Includes raw EEG signals, processed EEG parameters, automated annotations, markers and signal quality indicators
- All data transferrable to USB drive in EDF+ format

► **Robust hardware and software with excellent signal quality**

- Advanced automated artifact detection and removal
- Electro-surgical interference detection and filtering
- Cardiac defibrillation-proof
- Continuous measurement of electrode-skin contacts and lead-off detection

The NeuroSENSE® is an easy-to-use complement to the standard of care during anesthesia or sedation and may be used to monitor the hypnotic effect of anesthetics on the brain [4]. The software is intuitive; including a simple, eloquent user interface with touchscreen capability. The user can easily and quickly install software updates supplied by the manufacturer. In addition, the EasyPrep™ bilateral disposable electrodes require only minor patient preparation, and are affordably priced.

EasyPrep™ Electrode Kit Specifications:

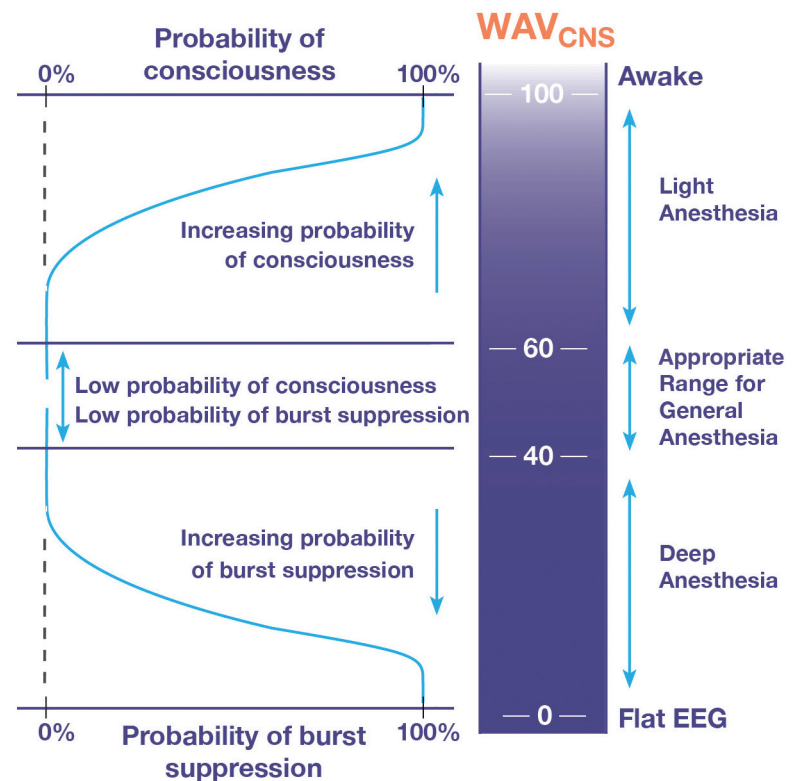
- Contains 4 pre-gelled adhesive Ag-AgCl electrodes and a skin prep pad
- Single patient use
- Maximum usage time: 24 hours
- Shaped and color-coded for fast and easy placement
- Latex Content: Does not contain natural rubber latex
- Ordering information:
 - Part Number: 000-7106-PRD
 - Description: EasyPrep™ Electrode Kit (EK-901)
 - Quantity: box of 50

Quality of Care



An adequate WAV_{CNS} range for general anesthesia is between 40 and 60. Within this range there is a very low probability of a patient being either awake or in a deep anesthetic state, as characterized by the presence of significant burst suppression [8].

In the absence of unilateral brain pathology and with good signal quality, the level of agreement between the WAV_{CNS} bilateral indices for the left and right cerebral hemispheres is typically within ± 8 units with a negligible bias [2].

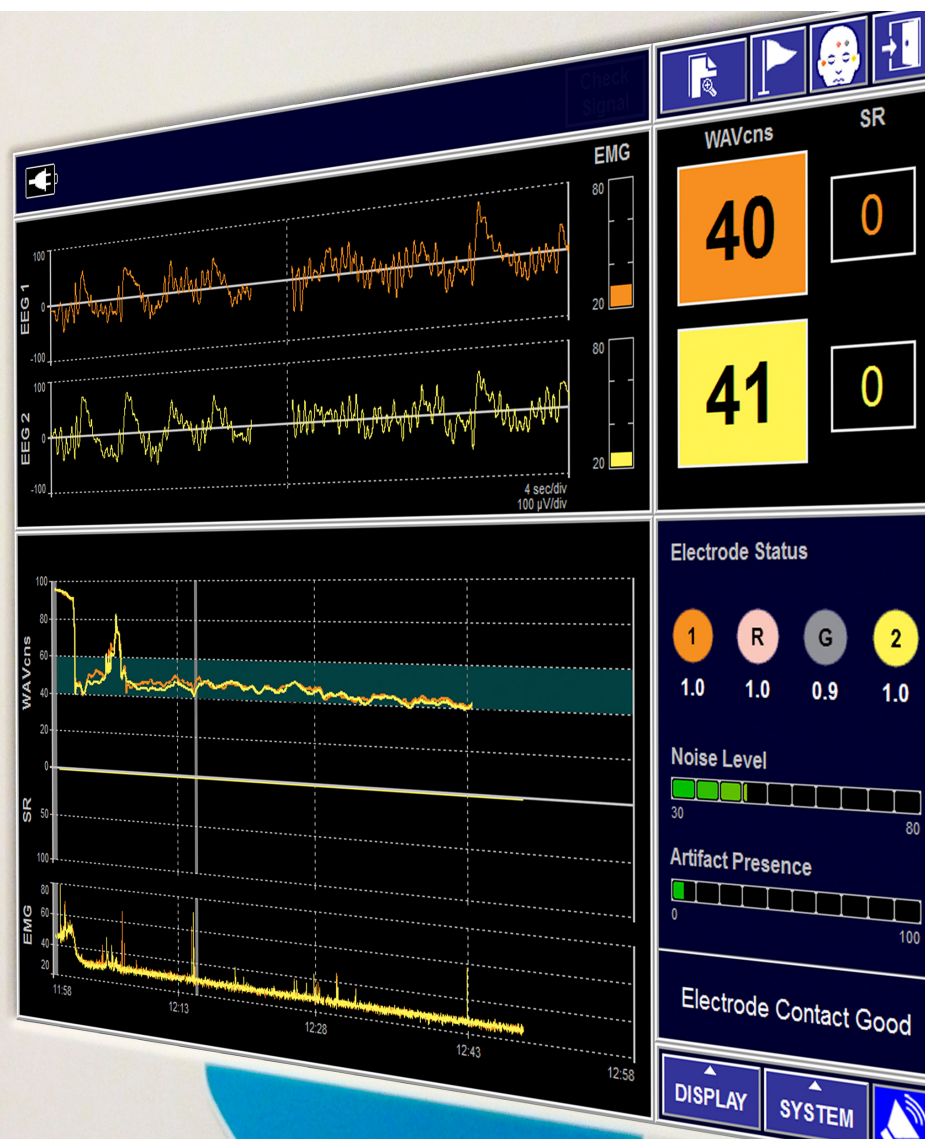


► References

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2. Proceedings of the 2010 Annual Meeting of the American Society of Anesthesiologists, 2010; A1363
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6. J. Clinical Monitoring and Computing, 2011; 25(1): 81-87.
7. Anesthesia & Analgesia, 2018; 127(4): 883-894.
8. Proceedings of the 2010 Annual Meeting of the American Society of Anesthesiologists, 2010; A1347.
9. National Institute for Health and Care Excellence (NICE). Diagnostics guidance 6, 2012.
10. Anaesthesia, 2016; 71(4): 470-471.
11. Brazilian J. Anesthesiology, 2015; 65(6): 427-436.
12. European J. Anaesthesiology, 2017; 34(4): 192-214.
13. Anesthesia Patient Safety Foundation (APSF) Newsletter, Oct 2019; 34(2):43-45.

NeuroSENSE[®] Technical Specifications

- 2 EEG channels (4 electrodes) for bilateral monitoring
- Processed Variables (per hemisphere):
 - WAV_{CNS} index (Wavelet-based Anesthetic Value for Central Nervous System)
 - Electromyographic (EMG) power (70-110 Hz)
 - Suppression ratio (SR)
 - Electrode-skin contact impedances
 - Signal quality indicators
 - Density spectral array, Spectral powers, MEF, SEF
- Noise: < 2 μ Vpp (0.125 - 100 Hz)
- Sampling Frequency: 896 S/s per channel
- Bandwidth: 0.125 - 200 Hz
- CMRR: > 110 (90) dB @ 60 Hz in isolation (direct) mode
- Continuous Electrode Impedance Check: @ 165 Hz
- Display Module Specifications:
 - Weight: 7.5 lb
 - Size: 11.5" x 9.75" x 3.0"
 - 10.4" resistive touch screen
 - Simple VESA 75 mount
- Ingress Protection:
 - EEG Module: IPX4
 - Display Module: IPX3, all surfaces IPX4 except the bottom
- Battery life: up to 2 hours (optionally up to 4 hours)
- Archived Data (EDF+ Format):
 - EEG Signals: 256 S/s, 16 bits
 - Processed Variables: 1 S/s
- Device Connectivity:
 - via Capsule Connectivity Management





For more information, visit www.neurowavesystems.com

NeuroSENSE® is compliant with the following standards/regulations for medical devices:

IEC 60601-1, IEC 80601-2-26, IEC 60601-1-2, C € 2797

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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.