

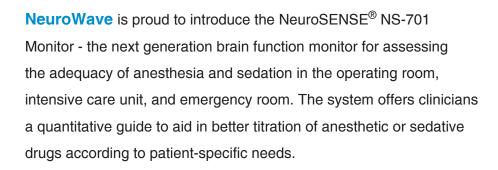
Introducing: NeuroSENSE® Monitor

With WAV_{CNS} Bilateral Indices



Our Mission

Develop, manufacture, and market patient monitoring products using advanced signal processing of brain waves for Neurology, Critical Care, Anesthesia and Emergency Medicine clinical applications, to improve patient outcome and quality of life.



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, without delay.

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

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



Improved patient outcomes

Known Benefits of Brain Function Monitoring

- ➤ Accurate patient-specific drug administration allows for adequate anesthesia/sedation and may lead to the following benefits:
 - Improved outcomes patients can:
 - Wake up faster and more predictably
 - Recover faster and be eligible for earlier discharge
 - Have decreased post-surgical nausea and vomiting
 - Reduced likelihood of excessive depth of anesthesia or under-sedation
 - Reduced drug consumption and associated costs
- ➤ Clinical quality EEG provides the user with continuous information about the patient's brain function to guide clinical decisions at the bedside





NeuroSENSE® Product Highlights ~





The NeuroSENSE Model
NS-701 quantifies cortical
activity. 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
brain activity.

- ► Patented delay-free tracking of patient state via low-noise WAV_{CNS} bilateral indices [1]
 - WAV_{CNS} (Wavelet Anesthetic Value for Central Nervous System)
 indices react instantaneously to changes in patient state
 - Automatic trending facilitates immediate response without increasing the index noise
- ► True bilateral monitoring with great inter-hemispheric reproducibility [2]
 - Increased reliability due to redundancy Pronounced asymmetry between indices due to underlying pathologies or artifacts can be easily observed

- Superior discrimination between consciousness and unconsciousness [3]
 - Accurately determines patient state to support clinical decision
- ► Linear response to increasing EEG suppression [4]
 - More accurate quantification of deeper anesthetic states
- ► Compliant with the guidelines of International Federation of Clinical Neurophysiology (IFCN) and American Clinical Neurophysiology Society (ACNS)
 - High-resolution clinical EEG tracings suitable for interpretation by EEG clinicians
- ► Easy-to-use review capability for both EEG tracings and processed data trends
 - Accessible during both live case monitoring and archived case review
 - 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

The NeuroSENSE® is an easy-touse complement to the standard of care during anesthesia or sedation and may be used as an aid in monitoring the effects of anesthetics on the brain. The software is intuitive; including a simple, eloquent user interface with touchscreen capability. The customer can easily and quickly install software updates supplied by the manufacturer. In addition, the EasyPrepTM disposable electrodes require only minor patient preparation, and are affordably priced.

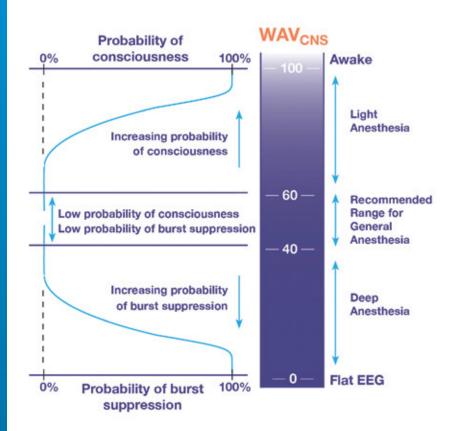
EasyPrepTM Electrode Kit Specifications:

- 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
- Ordering information:
 - Part Number: 000-5107-PRD
 - Description: EasyPrep[™]
 Electrode Kit (EK-701)
 - Quantity: boxes of 25





The recommended WAV_{CNS} range for general anesthesia is between 40 and 60 as 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 burst suppression [5]. 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].



▶ Published and biologically understandable WAV_{CNS} algorithm [1]

 WAV_{CNS} is based on the gamma-band of the normalized EEG signal, linked to conscious processing and awareness

► NeuroSENSE® Selected References

- IEEE Transactions on Biomedical Engineering, 2006; 53(4): 617-632
- Proceedings of the 2010 Annual Meeting of the American Society of Anesthesiologists, 2010; A1363
- 3. Anesthesiology, 2006; 105:A1030
- Proceedings of the 2010 Annual Meeting of the American Society of Anesthesiologists, 2010; A1348
- Proceedings of the 2010 Annual Meeting of the American Society of Anesthesiologists, 2010; A1347

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
- Bandwidth: 0.125 300 Hz
- Noise: < 2 μVpp (0.125 100 Hz)
- Sampling Frequency: 900 S/s per channel
- CMRR: > 110 dB @ 60 Hz
- Continuous measurement of electrode-skin contacts

- Display Specifications:
 - Weight: 7 lb 12 oz
 - Size: 11.5" × 9.75" × 3.0"
 - Resolution: 1024 × 768
 - 10.4" resistive touch screen
 - Simple pole mount
- Touch screen interface
- Protected against water ingress (IPX3)
- Archived Data:
 - EEG Signals: 256 S/s, 16 bits
 - Processed Variables: 1 S/s
 - File Format: EDF+
- Device Connectivity:
 - eXacto® Anesthesia Record System, Mexys S.A.







For more information, visit www.neurowavesystems.com



NeuroSENSE® is compliant with the following standards/regulations for medical devices: UL60601-1, CAN/CSA 601.1, IEC 60601-1, IEC 60601-2-26, IEC 60601-1-2, IEC 60601-1-4, CE Mark

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