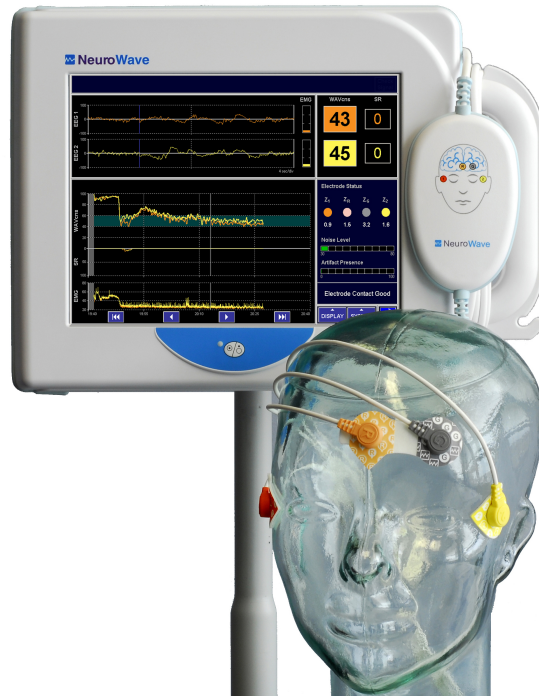


NeuroSENSE[®] Monitoring System

Model: NS-901

- USER MANUAL -



Rx only

Federal (USA) law restricts this device to sale by or on the order of a physician.



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Introduction and Contact

This manual is intended for medical personnel, researchers, and biomedical engineering personnel to provide guidance on the proper installation, operation, and cleaning of the NeuroSENSE Monitoring System, Model NS-901. Keep this manual in a convenient location in the vicinity of the NeuroSENSE System NS-901.

This manual does not intend, nor can it be relied upon, to provide for every event that can happen during installation, operation, or maintenance of the NeuroSENSE System NS-901. If additional questions arise, please direct them to:

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08021, Barcelona, España

CE 2797

NOTE: ANY SERIOUS INCIDENT THAT HAS OCCURRED IN RELATION TO THE DEVICE SHOULD BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND/OR PATIENT IS ESTABLISHED. STATE IN WHICH THE USER AND/OR PATIENT IS ESTABLISHED.

Indications for Use

The NeuroSENSE® Monitoring System, Model NS-901, is intended for monitoring the brain state of adult and pediatric patients (18 years of age and older) in the operating room and other clinical settings by acquiring electroencephalographic (EEG) signals.

The WAV_{CNS} Index, a quantifier of EEG activity calculated and displayed by the NeuroSENSE NS-901 Monitor, may be used as an aid in monitoring the hypnotic effect of anesthetics. The anesthetics include inhaled anesthetics and propofol in combination with opioids. The NeuroSENSE Monitor is intended to be used under the direction and interpretation of a qualified medical professional.



Validation of the WAV_{CNS} algorithm was performed in a randomized-controlled clinical trial in 75 surgical patients (age: 18 to 71 years, male/female: 18/57). Anesthesia was induced with propofol/remifentanyl and maintained with desflurane and supplemental doses of fentanyl as needed. The study confirmed that the WAV_{CNS} index distinguishes consciousness from unconsciousness during induction of anesthesia and emergence from anesthesia, and that it also correlates with randomized changes in inhaled anesthetic entidal concentration during maintenance of anesthesia.



The displayed EEG signals are not affected by the artifact detection and/or removal algorithms. The EEG waveforms are displayed as acquired after the user-selected display filters are applied. A user can choose to apply any or none of the following: high-pass filter (to remove very low frequencies and DC bias), low-pass filter (to remove high frequencies) and/or notch filter (to remove 50/60 Hz interference).



THE NEUROSENSE IS INTENDED FOR USE AS AN ADJUNCT TO CLINICAL JUDGEMENT AND TRAINING. IT SHOULD NEVER BE USED AS A SOLE BASIS FOR CLINICAL ASSESSMENT OF THE PATIENT'S STATE OR GUIDING ANESTHETIC MANAGEMENT. THE NEUROSENSE READINGS SHOULD ALWAYS BE INTERPRETED USING CLINICAL JUDGEMENT, WITHIN THE CONTEXT OF THE CLINICAL SITUATION AND IN CONJUNCTION WITH OTHER CLINICAL SIGNS.

LIKE WITH ANY MONITORED PARAMETER, ERRONEOUS WAV_{CNS} VALUES MAY OCCUR DUE TO CERTAIN ARTIFACTS AND CONDITIONS (E.G., EXCESSIVE EYE OR FACIAL MUSCLE ACTIVITY; HEAD AND BODY MOVEMENTS; MOVEMENT OR DAMAGE OF PATIENT CABLE, ELECTRODES OR ELECTRODE LEADS; STRONG OR UNUSUAL ELECTROMAGNETIC INTERFERENCE; BAD (HIGH-IMPEDANCE) SKIN CONTACT (E.G., DUE TO PROFUSE SWEATING OR TEARING); USE OF NON-RECOMMENDED OR EXPIRED ELECTRODES AND INCORRECT ELECTRODE PLACEMENT OR CONNECTION).

WAV_{CNS} VALUES SHOULD BE INTERPRETED CAUTIOUSLY WITH CERTAIN ANESTHETIC COMBINATIONS, E.G., USE OF EITHER KETAMINE OR NITROUS OXIDE WITH NARCOTICS TO PRODUCE UNCONSCIOUSNESS. THE NEUROSENSE READINGS SHOULD ALSO BE INTERPRETED WITH CAUTION IN PATIENTS WITH KNOWN NEUROLOGICAL PATHOLOGY OR SEIZURE ACTIVITY, OR THOSE TAKING PSYCHOACTIVE MEDICATIONS. OTHER CONTRAINDICATIONS INCLUDE SKIN CONDITIONS AND PHYSIOGNOMY THAT PRECLUDE APPLICATION OF ELECTRODES ON THE PATIENT'S FOREHEAD.

General Description of the NeuroSENSE Monitoring System

The NeuroSENSE Monitoring System, Model NS-901, is a medical device for brain function monitoring in the operating room and other clinical settings. The NeuroSENSE system acquires and processes brain waves or electroencephalogram (EEG) signals obtained from noninvasive electrodes placed on a patient's forehead. The EEG is collected from 2 frontal, bilateral EEG channels so to monitor independently both brain hemispheres. The raw EEG signals and processed EEG variables are continuously displayed by the system for interpretation by a clinician and for use as a supplement to the anesthesia standard of care. The proprietary processed variable, WAV_{CNS} (Wavelet-based Anesthetic Value for Central Nervous System), quantifies the patient's brain activity as affected by anesthetic drugs.

The user interacts with the system via a touch screen interface (e.g., to change the display or system settings or to access and review archived data).

Theory of Operation

The brain is the target organ of anesthetic drugs, while the EEG is a noninvasive measurement of brain cortical activity. Most general anesthetics produce dose-dependent suppression of neuronal activity within the CNS, and consequently alter cortical activity and induce unconsciousness in a dose-dependent manner¹. The NeuroSENSE system calculates a number of processed EEG variables to quantify the levels of a patient's brain activity based on continuous, non-invasive EEG measurements.

Using a wavelet-based decomposition of the EEG signal and a statistical function for information extraction, the NeuroSENSE System NS-901 calculates a proprietary quantitative descriptor of the central nervous system, referred to as WAV_{CNS} (see **White Paper**, downloadable from NeuroWave's website, for published articles and references on WAV_{CNS}). Wavelet analysis is a powerful signal processing technique for non-stationary signals such as EEG. The unique and proprietary application of this technique allows the NeuroSENSE system to track without delay the changes in the patient's brain status. This is done by continuously calculating and displaying the WAV_{CNS} and other processed EEG variables, based on 1-second epochs from a single-channel EEG signal.

Independent processed EEG variables including WAV_{CNS} indices are calculated and displayed for 2 frontal, bilateral EEG channels, one per brain hemisphere. The NeuroSENSE readings may be used as an aid in monitoring the hypnotic effect of anesthetics on the brain of adult patients, and are to be interpreted by a qualified medical professional.

For improved reliability, the NeuroSENSE employs algorithms for automatic detection and removal of physiological and environmental artifacts that commonly contaminate EEG signals. Also, the NS-901 system has built-in circuitry for detection and minimization of interference due to electro-surgical units. The system also performs self-tests, automatic calibration of the amplifiers and continuous check of the electrode-skin contacts to ensure proper operation and optimal signal quality.

Processed Variables

The NeuroSENSE Monitoring System, Model NS-901, calculates and displays the following processed

1. With increasing blood-drug concentration, the EEG signal evolves from a low-amplitude, large-bandwidth, noise-like signal, to a higher amplitude signal with slower waves. If a large amount of anesthetic is given, the cortical activity completely disappears, resulting in an isoelectric or flat signal.

variables for each of the 2 frontal, bilateral EEG channels:

- The current WAV_{CNS} value
- The WAV_{CNS} trend
- Suppression Ratio (SR) and its corresponding sub-trend (user selectable)
- Electromyogram (EMG) and its corresponding sub-trend (user selectable)
- A number of spectral variables and plots:
 - Density Spectral Array (DSA)
 - Median Edge Frequency (MEF)
 - Spectral Edge Frequency (SEF)
 - Spectral Powers in EEG frequency bands (α , β_1 , β_2 , δ , θ and γ)

The processed variables are described in detail in Chapter 5.

In addition, the following are displayed by the system:

- Two EEG waveforms in real time and at all times
- System alarms and notifications including User-selectable alarms, and related messages
- Signal Quality indicators

WAV_{CNS} Guidelines

The WAV_{CNS} (Wavelet-based Anesthetic Value for Central Nervous System) Index is a proprietary EEG index calculated by the NeuroSENSE Monitor. This processed EEG variable may be used as an aid in monitoring the hypnotic effect of anesthetic agents on adult patients. It is a number ranging from 0 to 100, where values near 100 indicate a fully awake state, while values near 0 represent a fully suppressed EEG with no substantial activity (flat EEG). An appropriate range for the WAV_{CNS} index during general anesthesia has been established to be between 40 and 60. The WAV_{CNS} values within this range correspond to a low probability of a patient being either conscious or exhibiting significant burst suppression² indicative of deep anesthesia.

The WAV_{CNS} Index is calculated and displayed independently and simultaneously for 2 frontal, bilateral EEG channels corresponding to each brain hemisphere. In the absence of unilateral brain pathology and with good signal quality, the level of agreement between the WAV_{CNS} Indices for the left and right cerebral hemispheres is typically within ± 8 units with a negligible bias.



PRONOUNCED INTER-HEMISPHERIC ASYMMETRY MAY OCCUR DUE TO CERTAIN ENVIRONMENTAL, PHYSIOLOGICAL OR PATHOLOGICAL FACTORS (E.G., PRESENCE OF ARTIFACTS, STRONG ELECTROMAGNETIC INTERFERENCE, BILATERAL DIFFERENCE IN FACIAL MUSCLE ACTIVITY, BILATERAL DIFFERENCE IN THE AMOUNT OF FULLY SUPPRESSED EEG ACTIVITY, UNILATERAL BRAIN PATHOLOGY, ETC.).

IN SITUATIONS WHERE THE TWO BILATERAL WAV_{CNS} INDICES EXHIBIT A LARGE DIFFERENCE INDICATING DIFFERENT DEPTHS OF ANESTHESIA, CLINICAL ASSESSMENT OF THE PATIENT'S STATE AND ANESTHETIC MANAGEMENT SHOULD STRICTLY BE BASED ON CLINICAL JUDGEMENT AND TRAINING, WITHIN THE CONTEXT OF THE CLINICAL SITUATION AND IN CONJUNCTION WITH OTHER CLINICAL SIGNS.

2. Burst suppression is defined as periods of flat EEG separated by periods of fast and large amplitude activity. The NeuroSENSE Monitoring System calculates the Suppression Ratio (SR) to help in assessing deep anesthesia. The SR value represents the amount of time with suppressed EEG epochs within the last minute. SR is displayed as a number within a range of 0-100%. For the purpose of establishing the WAV_{CNS} guidelines, significant burst suppression was considered to correspond to SR values greater than 40%.

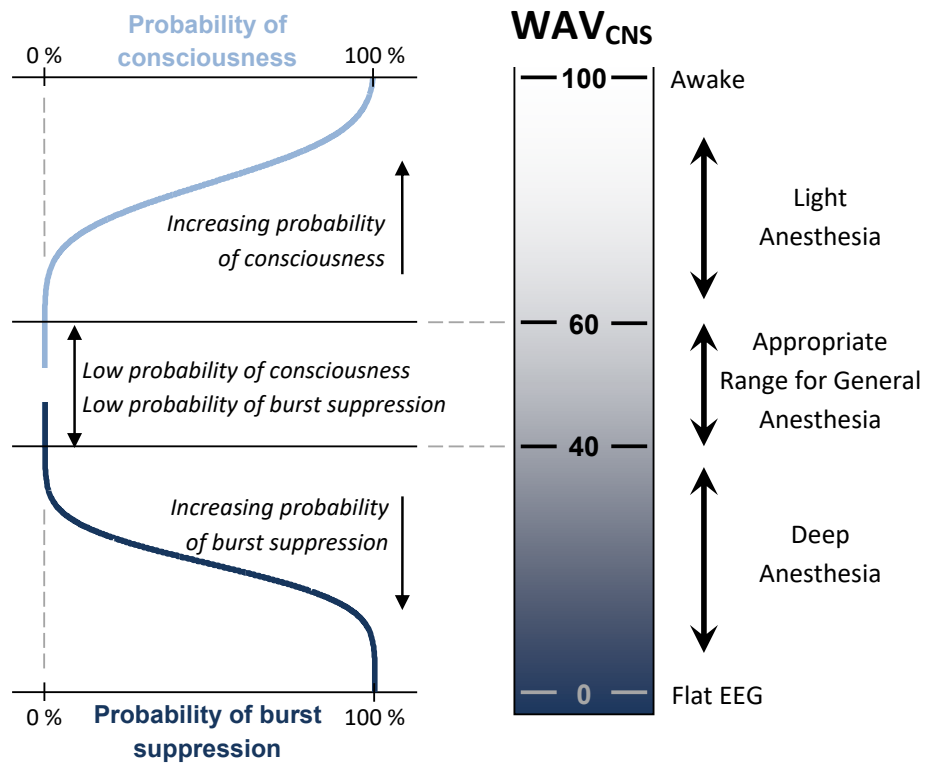


Figure 1: WAV_{CNS} Scale. An appropriate WAV_{CNS} range for general anesthesia is between 40 and 60 since within this range there is a very low probability of a patient being either awake or in deep anesthetic state as characterized by the presence of significant burst suppression (SR > 40%).

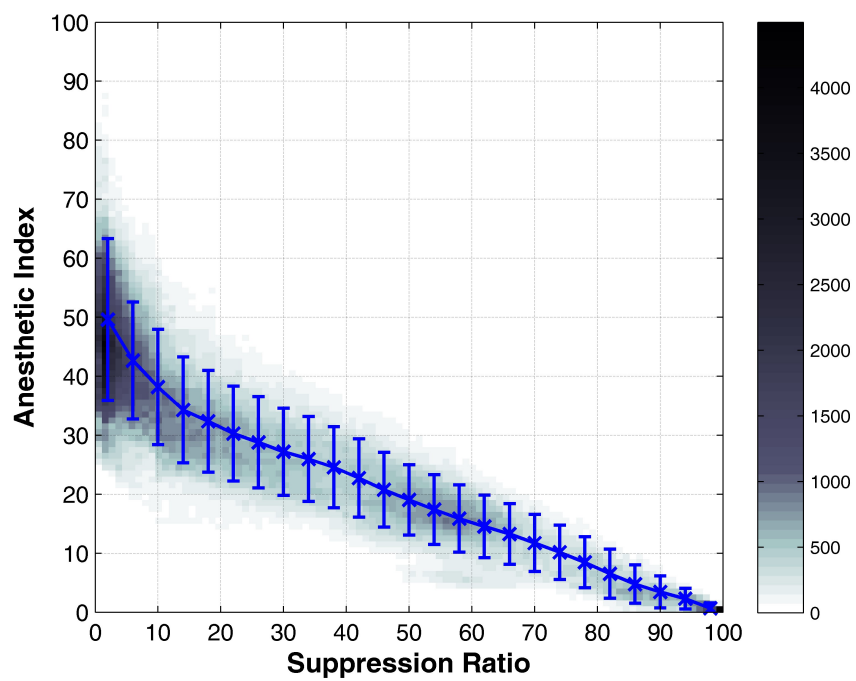


Figure 2: Relationship (density plot and mean \pm std) between WAV_{CNS} anesthetic index and suppression ratio (SR). Deep anesthetic states are characterized by the presence of significant burst suppression.

System Overview

Figures 3 and 4 depict the NeuroSENSE System NS-901 and its components that are briefly described below:

Display Module

The Display Module DM-901 serves as an integrated computing platform and display unit. It also serves as the user interface, with touch-screen interaction.

EEG Module (with integrated Patient Cable and Data Cable)

The EEG Module EM-901 collects the EEG signals through the patient cable connected to the electrodes placed on the patient's forehead. The acquired signals are digitized and then sent via the data cable to the Display Module, for signal processing and display of raw EEG signals and processed EEG variables.

EasyPrep™ Electrode Kit (sold separately)

The EasyPrep Electrode Kit (EK-901) contains the disposable electrodes and skin preparation materials. The packaging in the electrode kit guides the user on how to prepare the patient's skin and where to place the electrodes.

Smart Pack Rechargeable Battery (optional)

The Smart Pack SP-901 is a rechargeable Lithium Ion battery pack that allows for the NeuroSENSE system to operate on a backup battery in case the mains power becomes unavailable. Maximum of 2 battery packs SP-901 can be installed in the Display Module DM-901. Each new, fully charged SP-901 pack allows for approximately 2 hours of operation on battery power. The Display Module DM-901 also includes an internal charger for charging the installed batteries. Each SP-901 pack requires up to 3 hours to be fully charged when the mains power is connected. The Smart Pack SP-901 is an optional accessory and can be purchased separately.

NeuroWave also offers an optional rolling support accessory RS-901, which has been tested for easy and secure mounting of the NeuroSENSE system.

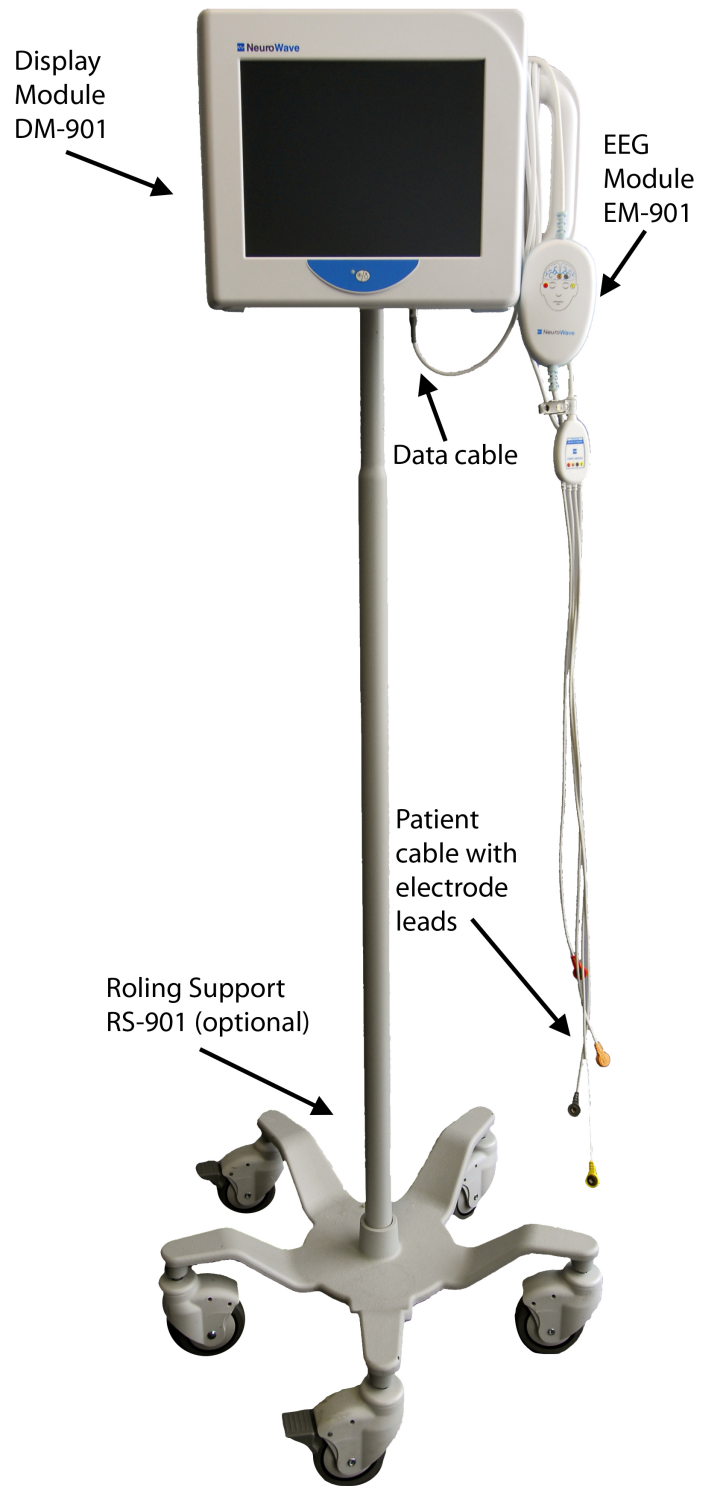


Figure 3: NeuroSENSE System NS-901 Components.

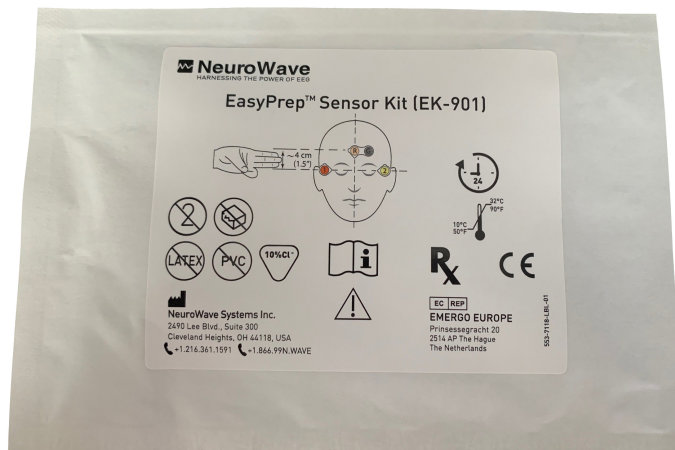


Figure 4: EasyPrep Electrode Kit (EK-901).

To purchase EasyPrep EK-901 electrode kits, contact NeuroWave or your local distributor and order Part Number 000-7106-PRD (Quantity: pack of 50).





To purchase the NeuroSENSE SP-901 Smart Pack rechargeable batteries, contact NeuroWave or your local distributor and order Part Number P/N 000-7109-PRD. The installation and use instructions are provided within this document.

To purchase the NeuroSENSE RS-901 rolling support, contact NeuroWave or your local distributor and order Part Number 000-7107-PRD. The assembly and mounting instructions are provided in a separate RS-901 Assembly Instructions document.

Chapter 1

Safety Precautions

Read this section thoroughly before operating the NeuroSENSE Monitoring System NS-901. In addition, do not use this device unless it has been installed, operated and maintained, as instructed by this user manual. The following symbols and terms will be used throughout this manual:

Symbol	Name	Definition
	WARNING	<p>A warning advises against actions that could result in injury to the operator, patient or others.</p> <p>WARNINGS WILL ALWAYS BE WRITTEN IN ALL CAPS AND BOLD.</p>
	<i>ELECTRICAL SHOCK HAZARD</i>	<p>An electrical shock hazard warning specifically warns the operator of actions that could potentially result in electrical shock and subsequent injury to the operator, patient or others.</p> <p><i>ELECTRICAL SHOCK HAZARDS WILL BE WRITTEN IN ITALIC-BOLD AND ALL CAPS.</i></p>
	CAUTION	<p>A caution advises against actions that could lead to damage or malfunction of the NeuroSENSE System NS-901, although an injury to the operator, patient or others is unlikely.</p> <p>CAUTIONS WILL ALWAYS BE WRITTEN IN ALL CAPS.</p>
	<i>Note</i>	<p>A note provides supplemental information that may clarify a procedure or allow a user to adapt device settings for their personal needs.</p> <p><i>Notes will always be written in italic.</i></p>



1.1 WARNINGS

- 1.1.1 THE NEUROSENSE IS INTENDED FOR USE AS AN ADJUNCT TO CLINICAL JUDGEMENT AND TRAINING. IT SHOULD NEVER BE USED AS A SOLE BASIS FOR CLINICAL ASSESSMENT OF THE PATIENT'S STATE OR GUIDING ANESTHETIC MANAGEMENT. THE NEUROSENSE READINGS SHOULD ALWAYS BE INTERPRETED USING CLINICAL JUDGEMENT, WITHIN THE CONTEXT OF THE CLINICAL SITUATION AND IN CONJUNCTION WITH OTHER CLINICAL SIGNS.
- 1.1.2 LIKE WITH ANY MONITORED PARAMETER, ERRONEOUS WAV_{CNS} VALUES MAY OCCUR DUE TO CERTAIN ARTIFACTS AND CONDITIONS (E.G., EXCESSIVE EYE OR FACIAL MUSCLE ACTIVITY; HEAD AND BODY MOVEMENTS; MOVEMENT OR DAMAGE OF PATIENT CABLE, ELECTRODES OR ELECTRODE LEADS; STRONG OR UNUSUAL ELECTROMAGNETIC INTERFERENCE; BAD (HIGH-IMPEDANCE) SKIN CONTACT (E.G., DUE TO PROFUSE SWEATING OR TEARING); USE OF NON-RECOMMENDED OR EXPIRED ELECTRODES AND INCORRECT ELECTRODE PLACEMENT OR CONNECTION).
- 1.1.3 WAV_{CNS} VALUES SHOULD BE INTERPRETED CAUTIOUSLY WITH CERTAIN ANESTHETIC COMBINATIONS, E.G., USE OF EITHER KETAMINE OR NITROUS OXIDE WITH NARCOTICS TO PRODUCE UNCONSCIOUSNESS. THE NEUROSENSE READINGS SHOULD ALSO BE INTERPRETED WITH CAUTION IN PATIENTS WITH KNOWN NEUROLOGICAL PATHOLOGY OR SEIZURE ACTIVITY, OR THOSE TAKING PSYCHOACTIVE MEDICATIONS. OTHER CONTRAINDICATIONS INCLUDE SKIN CONDITIONS AND PHYSIOGNOMY THAT PRECLUDE APPLICATION OF ELECTRODES ON THE PATIENT'S FOREHEAD. DO NOT PLACE THE ELECTRODES ON THE PATIENT'S FOREHEAD IF THEY CANNOT BE SAFELY AND CORRECTLY PLACED.
- 1.1.4 PRONOUNCED INTER-HEMISPHERIC ASYMMETRY MAY OCCUR DUE TO CERTAIN ENVIRONMENTAL, PHYSIOLOGICAL OR PATHOLOGICAL FACTORS (E.G., PRESENCE OF ARTIFACTS, STRONG ELECTROMAGNETIC INTERFERENCE, BILATERAL DIFFERENCE IN FACIAL MUSCLE ACTIVITY, BILATERAL DIFFERENCE IN THE AMOUNT OF FULLY SUPPRESSED EEG ACTIVITY, UNILATERAL BRAIN PATHOLOGY, ETC.).
- 1.1.5 IN SITUATIONS WHERE THE TWO BILATERAL WAV_{CNS} INDICES EXHIBIT A LARGE DIFFERENCE INDICATING DIFFERENT DEPTHS OF ANESTHESIA, CLINICAL ASSESSMENT OF THE PATIENT'S STATE AND ANESTHETIC MANAGEMENT SHOULD STRICTLY BE BASED ON CLINICAL JUDGEMENT, WITHIN THE CONTEXT OF THE CLINICAL SITUATION AND IN CONJUNCTION WITH OTHER CLINICAL SIGNS.
- 1.1.6 THE NEUROSENSE SYSTEM SHOULD ALWAYS BE USED ACCORDING TO THE INSTRUCTIONS SET FORTH IN THIS MANUAL. DO NOT OPERATE THE NS-901 DEVICE BEFORE READING AND UNDERSTANDING THIS MANUAL. DO NOT OPERATE THE DEVICE UNLESS IT HAS BEEN PROPERLY INSTALLED AS INSTRUCTED IN THIS MANUAL. IMPROPER USAGE MAY LEAD TO PERSONAL INJURY OR DEVICE DAMAGE.
- 1.1.7 THIS USER MANUAL SHOULD BE KEPT IN CLOSE PROXIMITY TO THE NEUROSENSE SYSTEM AT ALL TIMES.
- 1.1.8 PLACE THIS EQUIPMENT ON A RELIABLE SURFACE DURING INSTALLATION. DROPPING IT OR LETTING IT FALL COULD CAUSE DAMAGE.
- 1.1.9 THE NEUROSENSE SHOULD BE CHECKED BY QUALIFIED TECHNICAL PERSONNEL IF EXPOSED TO A SEVERE MECHANICAL OR THERMAL SHOCK, WHICH MAY IMPACT NORMAL OPERATION AND/OR SAFETY INCLUDING WATER INGRESS

PROTECTION RATING. IN CASE OF VISIBLE DAMAGE OR LOSS OF NORMAL OPERATION, CONTACT NEUROWAVE FOR SERVICING.

- 1.1.10 ENSURE THAT BOTH THE DISPLAY MODULE AND THE EEG MODULE ARE MOUNTED SECURELY. GENERAL PRECAUTIONS SHOULD BE TAKEN WHEN POSITIONING THE NEUROSENSE TO AVOID PERSONAL INJURY. IF YOU USE A THIRD PARTY MOUNTING OPTION, MAKE SURE THAT IT HAS AN ADEQUATE LOAD CAPACITY TO SUPPORT THE WEIGHT OF THE NEUROSENSE COMPONENTS. IN ADDITION, IN CASE OF I.V. POLE MOUNTING, ENSURE THAT THE I.V. POLE HAS A WIDE ENOUGH BASE TO PREVENT TIPPING.
- 1.1.11 DO NOT SUBSTITUTE THE SUPPLIED HARDWARE FOR THE BRACKET MOUNTING AND MAKE SURE TO INSTALL PROVIDED WASHERS. OTHERWISE, THE RESILIENCE OF THE SYSTEM TO ELECTROSTATIC DISCHARGE MAY BE COMPROMISED.
- 1.1.12 DO NOT PULL ON THE CABLES OF THE NEUROSENSE AS THIS MAY RESULT IN THE NEUROSENSE TIPPING OVER.
- 1.1.13 CARE SHOULD BE TAKEN WHEN USING THE DEVICE IN POSITIONS WITH LIMITED ACCESS TO LEADS AND ELECTRODES, SUCH AS IN PRONE OR LATERAL DECUBITUS POSITIONS, SINCE THIS MAY LEAD TO PRESSURE TRAUMA ON EYES AND FACE. WHENEVER LEADS OR ELECTRODES ARE BEING OBSCURED, ENSURE THEY ARE ROUTED AWAY FROM THE EYES AND THE PATIENT'S HEAD/FOREHEAD IS SECURED IN SUCH A WAY TO AVOID EXCESSIVE PRESSURE BEING APPLIED TO EYES OR FACE BY THE LEADS OR ELECTRODES.
ALSO, POSITION ALL THE CABLES INCLUDING THE POWER CORD AND PATIENT AND DATA CABLES SO THAT PEOPLE CANNOT STEP ON THEM. DO NOT PLACE ANYTHING OVER THE CABLES. POSITION THE CABLES, INCLUDING THE ELECTRODE LEADS, SUCH TO PREVENT PATIENT STRANGULATION, OTHER BODILY INJURY AND/OR DAMAGE TO THE CABLES CAUSED BY MOVEMENT OR POSITIONING OF OTHER MEDICAL EQUIPMENT.
- 1.1.14 DO NOT COVER THE OPENINGS ON THE DISPLAY MODULE BECAUSE THESE OPENINGS ARE FOR AIR CONVECTION. THIS COULD LEAD TO OVERHEATING OF THE MODULE AND CAUSE DAMAGE.
- 1.1.15 DO NOT TAMPER WITH, DROP OR CAUSE MECHANICAL IMPACT TO THE SMART PACK RECHARGEABLE BATTERY (SP-901).
- 1.1.16 THE SMART PACK RECHARGEABLE BATTERY (SP-901) MUST BE TESTED PERIODICALLY (AT LEAST ANNUALLY) TO VERIFY THAT THE NEUROSENSE MONITORING SYSTEM WILL CONTINUE TO OPERATE ON BATTERY POWER. REFER TO SECTIONS 9.2.2 AND 9.2.4 FOR BATTERY TESTS AND BATTERY CARE INSTRUCTIONS. FOR REPLACEMENT, THE SP-901 BATTERY PACK MUST BE REMOVED BY A QUALIFIED SERVICE TECHNICIAN WHILE THE DEVICE IS NOT IN USE, SEE REPLACEMENT INSTRUCTIONS IN SECTION 3.3.2.
- 1.1.17 THE WORN-OUT SMART PACK BATTERY (SP-901) MUST BE DISPOSED OF OR RECYCLED ACCORDING TO LOCAL LAWS AND REGULATIONS.
- 1.1.18 TO CHARGE THE SMART PACK RECHARGEABLE BATTERY (SP-901), DO NOT USE ANY OTHER CHARGER THAN THE ONE INTEGRATED WITHIN THE DISPLAY MODULE DM-901. THE USE OF NON GENUINE CHARGERS CAN RESULT IN FIRE HAZARD AND CAUSE PERSONAL INJURY. TO CHARGE THE SMART PACK RECHARGEABLE BATTERY (SP-901), SIMPLY CONNECT THE NEUROSENSE SYSTEM TO THE MAINS FOR AT LEAST 3 HOURS PER BATTERY PACK INSTALLED (MAXIMUM OF 2). THE SP-901 BATTERY PACK(S) SHOULD BE REPLACED IF NOT CHARGED AFTER LONG EXPOSURE TO THE CHARGER. REPLACEMENT SHOULD BE DONE BY A QUALIFIED SERVICE TECHNICIAN WHILE THE DEVICE IS NOT IN USE, SEE REPLACEMENT INSTRUCTIONS IN 3.3.2.
- 1.1.19 THE SMART PACK RECHARGEABLE BATTERY (SP-901) SHOULD NOT BE CHARGED AT TEMPERATURES EXCEEDING 45°C (113°F) OR BELOW 10°C (50°F). THE NEUROSENSE SYSTEM SHOULD NOT BE OPERATING ON BATTERY POWER AT TEMPERATURES EXCEEDING 65°C (149°F) OR BELOW 0°C (32°F).

- 1.1.20 THE SMART PACK RECHARGEABLE BATTERY (SP-901) SHOULD NOT BE STORED AT TEMPERATURES EXCEEDING 40°C (104°F) OR BELOW 0°C (32°F). THE (SP-901) SHOULD BE STORED IN A DRY PLACE AND SHOULD NOT BE PLACED IN DIRECT SUNLIGHT OR HEAT. DO NOT EXPOSE THE SP-901 TO HIGH HEAT (E.G., FIRE).
- 1.1.21 DO NOT USE THE NEUROSENSE SYSTEM WHERE CONCENTRATIONS OF FLAMMABLE GASSES MAY OCCUR. THIS EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE. EXPLOSION HAZARD: INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.
- 1.1.22 DO NOT REUSE ELECTRODES. DISCARD AFTER EACH USE.
- 1.1.23 DO NOT PLACE THE EASYPREP ELECTRODES BETWEEN THE SURGICAL SITE AND THE RETURN ELECTRODE OF THE ELECTRO-SURGICAL UNIT. THIS WILL MINIMIZE THE HAZARD OF BURNS IN CASE OF A DEFECT IN THE HIGH-FREQUENCY SURGICAL NEUTRAL ELECTRODE CONNECTION. ALSO, DO NOT PLACE THE EASYPREP ELECTRODES BETWEEN THE ELECTRODES OF ANY ENERGY DELIVERING DEVICE (E.G., BRAIN STIMULATION DEVICES).
- 1.1.24 THE ELECTRODES MUST NOT BE POSITIONED BETWEEN THE DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT.
- 1.1.25 DO NOT CONNECT ANY OTHER EQUIPMENT TO THE NEUROSENSE ELECTRODES. AVOID CONTACT OF THE NEUROSENSE SYSTEM AND ITS COMPONENTS WITH OTHER EQUIPMENT AND OBJECTS DURING OPERATION.
- 1.1.26 USE GENERAL PRECAUTIONS IN ORDER TO AVOID CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. IF THIS HAPPENS, CLEAN THE NEUROSENSE AND ITS COMPONENTS ACCORDING TO THE CLEANING INSTRUCTIONS IN THIS MANUAL. IN THE CASE OF CONTAMINATED ELECTRODES, DISCARD THEM ACCORDING TO YOUR STANDARD PRACTICE FOR BIOHAZARD MATERIALS AND USE NEW ONES.
- 1.1.27 DISCONNECT THIS EQUIPMENT FROM ANY AC OUTLET BEFORE CLEANING. DO NOT USE LIQUID OR SPRAY DETERGENTS. USE A DAMP CLOTH. DO NOT USE AND/OR MIX CLEANING SOLUTIONS THAT MAY RESULT IN HARMFUL GASES AND PERSONAL INJURY.
- 1.1.28 DO NOT AUTOCLAVE THE DISPLAY MODULE OR THE EEG MODULE AND ITS INTEGRATED PATIENT AND DATA CABLES. THIS WILL DAMAGE THE ELECTRONICS AND MAY LEAD TO INJURY TO THE OPERATOR OR PATIENT. THIS WILL ALSO VOID THE WARRANTY.
- 1.1.29 THE NEUROSENSE SYSTEM NS-901 COMPLIES WITH IEC 60601-1-2 REQUIREMENTS FOR ELECTRO-MAGNETIC COMPATIBILITY. IF THIS SYSTEM AFFECTS OR IS AFFECTED BY OTHER EQUIPMENT IN ITS PROXIMITY DUE TO ELECTRO-MAGNETIC INTERFERENCE, TRY THE FOLLOWING:
- INCREASE THE DISTANCE BETWEEN SYSTEMS,
 - RE-ARRANGE SYSTEM CABLING,
 - USE SEPARATE OUTLET CIRCUIT BRANCHES FOR POWERING THE SYSTEMS.
- 1.1.30 THE DEVICE SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE DEVICE SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.
- 1.1.31 NEUROSENSE READINGS SHOULD BE INTERPRETED WITH CAUTION DURING CARDIAC DEFIBRILLATION. A TYPICAL RECOVERY TIME FOLLOWING EXPOSURE TO CARDIAC DEFIBRILLATION VOLTAGE IS 2 SECONDS.
- 1.1.32 NEUROSENSE READINGS SHOULD BE INTERPRETED WITH CAUTION WHEN THE TRAIN-OF-FOUR STIMULATOR IS IN USE.
- 1.1.33 THE NEUROSENSE MONITORING SYSTEM, MODEL NS-901, IS MR UNSAFE. IT MUST NOT BE USED IN AN MRI ENVIRONMENT.

- 1.1.34 NEUROSENSE READINGS SHOULD BE INTERPRETED WITH CAUTION DURING THE ELECTRO-CONVULSIVE SHOCK THERAPY (ECT). ALSO, ECT PADS SHOULD NOT COME IN CONTACT WITH THE NEUROSENSE ELECTRODES. IN CASE OF INTERFERENCE, YOU CAN TRY TO RESOLVE IT BY INCREASING THE DISTANCE BETWEEN THE NEUROSENSE ELECTRODES AND ECT PADS.
- 1.1.35 THE ADHESION OF THE ELECTRODES MAY BECOME LOOSE AND THE ELECTRODE-SKIN CONTACT MAY DEGRADE IF PATIENT IS SWEATING OR TEARING PROFUSELY. IN ADDITION, NEUROSENSE READINGS SHOULD BE INTERPRETED WITH CAUTION IF PATIENT IS SWEATING PROFUSELY.
- 1.1.36 THE NEUROSENSE NS-901 SYSTEM SHOULD NOT BE CONNECTED TO A PUBLIC NETWORK.
- 1.1.37 DO NOT CONNECT ANY IEC 60601-1 NON-COMPLIANT DEVICE TO THE NEUROSENSE. ALWAYS TEST THE RESULTING SYSTEM AND ITS CONNECTIONS TO ENSURE COMPLIANCE WITH APPLICABLE SAFETY STANDARDS (E.G., MAKE SURE THE RESULTING SYSTEM'S LEAKAGE CURRENTS COMPLY WITH THE IEC 60601-1 SAFETY LIMITS).
- 1.1.38 CONNECTION OF THE NEUROSENSE TO A NETWORK/DATA COUPLING THAT INCLUDES OTHER EQUIPMENT COULD RESULT IN PREVIOUSLY UNIDENTIFIED RISKS TO PATIENTS, OPERATORS OR THIRD PARTIES.
- THE RESPONSIBLE ORGANIZATION SHOULD IDENTIFY, ANALYZE, EVALUATE AND CONTROL THESE RISKS;
 - SUBSEQUENT CHANGES TO THE NETWORK/DATA COUPLING COULD INTRODUCE NEW RISKS AND REQUIRE ADDITIONAL ANALYSIS; AND
 - CHANGES TO THE NETWORK/DATA COUPLING INCLUDE:
 - CHANGES IN NETWORK/DATA COUPLING CONFIGURATION;
 - DISCONNECTING ITEMS FROM THE NETWORK/DATA COUPLING;
 - UPDATE OF EQUIPMENT CONNECTED TO THE NETWORK/DATA COUPLING; AND
 - UPGRADE OF EQUIPMENT CONNECTED TO THE NETWORK/DATA COUPLING.
- 1.1.39 THE NEUROSENSE SYSTEM SHOULD BE CHECKED BY QUALIFIED TECHNICAL PERSONNEL IF ANY OF THE FOLLOWING SITUATIONS ARISES:
- THE POWER CORD OR PLUG IS DAMAGED,
 - LIQUID HAS PENETRATED INTO THE EQUIPMENT INCLUDING ANY OF ITS COMPONENTS;
 - THE EQUIPMENT HAS BEEN EXPOSED TO MOISTURE;
 - THE EQUIPMENT DOES NOT WORK WELL, OR YOU CANNOT GET IT TO WORK ACCORDING TO THE USER MANUAL;
 - THE EQUIPMENT HAS BEEN DROPPED AND DAMAGED; AND
 - THE EQUIPMENT HAS BEEN EXPOSED TO SEVERE MECHANICAL SHOCK OR HAS OBVIOUS SIGNS OF BREAKAGE.
- 1.1.40 KEEP THIS EQUIPMENT AWAY FROM HUMIDITY THAT EXCEEDS THE LIMITS SPECIFIED IN SECTION 3.1.
- 1.1.41 WHEN USING USER ALARMS, EXERCISE CAUTION WHEN SETTING ALARM LIMITS AND USE MEANINGFUL VALUES. OTHERWISE, THE ALARM SYSTEM CAN BE RENDERED USELESS OR TRIGGER PERSISTENTLY.



1.2 ELECTRICAL SHOCK HAZARDS









- 1.2.1 DO NOT REMOVE THE EEG MODULE OR DISPLAY MODULE COVERS. NEVER OPEN THE EQUIPMENT. INJURY TO THE OPERATOR OR DAMAGE TO THE EQUIPMENT COULD OCCUR. THIS COULD ALSO COMPROMISE IP RATING FOR WATER INGRESS.*
- 1.2.2 DO NOT DISCONNECT THE POWER CORD WITH WET HANDS.*
- 1.2.3 IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE GROUND IS IN DOUBT, THE NEUROSENSE SYSTEM NS-901 SHOULD NOT BE OPERATED.*
- 1.2.4 ENSURE THAT THE VOLTAGE OF THE POWER SOURCE IS CORRECT BEFORE CONNECTING THE DM-901 DISPLAY MODULE TO THE POWER OUTLET.*
- 1.2.5 FOR PROPER GROUNDING, USE A HOSPITAL GRADE, THREE-SLOT GROUNDED OUTLET. DO NOT MODIFY THE THREE PRONGED PLUG SO THAT IT FITS A TWO SLOT OUTLET.*
- 1.2.6 DO NOT EXPOSE THE OPENINGS OF THE DISPLAY MODULE TO LIQUIDS OR SOLID OBJECTS.*
- 1.2.7 DO NOT SUBMERSE IN LIQUID ANY NEUROSENSE SYSTEM COMPONENT INCLUDING THE EEG MODULE AND ITS INTEGRATED PATIENT AND DATA CABLES. AVOID LIQUID INGRESS AS THIS MAY DAMAGE THE EQUIPMENT.*
- 1.2.8 IF LIQUID INGRESS IS SUSPECTED, THE NEUROSENSE SYSTEM AND ITS COMPONENTS SHOULD BE CHECKED BY QUALIFIED TECHNICAL PERSONNEL.*
- 1.2.9 PERIODICALLY (I.E., SEMI-ANNUALLY) CHECK THE LEAKAGE CURRENTS TO ENSURE THAT THEY COMPLY WITH THE LIMITS SET BY APPLICABLE SAFETY STANDARDS (I.E., IEC 60601-1). IN CASE OF AN EVENT SUCH AS SPILLAGE OF BLOOD, SALINE FLUID OR OTHER LIQUID OCCURS, OR AFTER A MAJOR ELECTRICAL POWER SURGE, RE-TEST BEFORE FURTHER USE.*
- 1.2.10 DO NOT ATTEMPT TO OPEN, MODIFY, OR REPAIR THE DISPLAY MODULE, EEG MODULE OR ITS INTEGRATED PATIENT AND DATA CABLES. INJURY TO THE OPERATOR OR DAMAGE TO THE EQUIPMENT COULD OCCUR. THIS COULD ALSO COMPROMISE IP RATING FOR WATER INGRESS. CONTACT NEUROWAVE FOR SERVICING. ALL REPAIRS MUST BE PERFORMED BY QUALIFIED SERVICE PERSONNEL.*
- 1.2.11 TO AVOID THE RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST BE CONNECTED TO A MAINS SUPPLY WITH PROTECTIVE EARTH.*





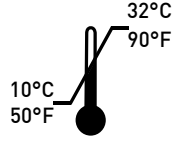
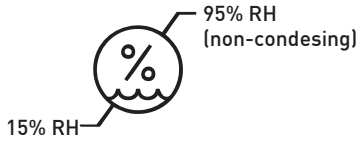
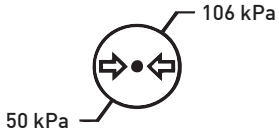















1.3 CAUTIONS









- 1.3.1 AVOID EXPOSING THE NEUROSENSE NS-901 SYSTEM TO SUDDEN TEMPERATURE CHANGES THAT CAN LEAD TO CONDENSATION WITHIN THE DEVICE. ALWAYS ALLOW SUFFICIENT TIME FOR THE CONDENSATION TO EVAPORATE BEFORE PUTTING INTO OPERATION.
- 1.3.2 DO NOT OPEN THE EASYPREP ELECTRODE KIT UNTIL READY FOR USE. THE ELECTRODE GEL COULD DRY OUT, CAUSING HIGH ELECTRODE IMPEDANCE.
- 1.3.3 THE NEUROSENSE SYSTEM NS-901 IS DESIGNED TO OPERATE WITH THE NEUROWAVE'S EASYPREP ELECTRODES. THE USE OF ELECTRODES NOT RECOMMENDED BY NEUROWAVE IS HIGHLY DISCOURAGED AS IT MAY REDUCE THE SIGNAL QUALITY AND INTERFERE WITH THE CALCULATION OF EEG PROCESSED VARIABLES.
- 1.3.4 NEUROWAVE CANNOT GUARANTEE, BE LIABLE FOR, OR BE RESPONSIBLE FOR USE OF THE NEUROSENSE SYSTEM NS-901 WITH ELECTRODES OR ELECTRODE SYSTEMS OTHER THAN THOSE RECOMMENDED BY NEUROWAVE SYSTEMS INC.
- 1.3.5 THIS EQUIPMENT PERFORMS CONTINUOUS IMPEDANCE MEASUREMENT TO THE ELECTRODES IN ORDER TO CHECK THAT THE ELECTRODES ARE IN GOOD CONTACT WITH THE SKIN. THE INJECTED MEASUREMENT SIGNAL AT 165 HZ COULD INTERFERE WITH OTHER MEDICAL EQUIPMENT CONNECTED TO THE PATIENT OR OTHER NEUROMONITORING DEVICES SUCH AS EEG/AUDITORY EVOKED POTENTIALS MONITORS. IF NEED BE, YOU CAN DISABLE THIS MEASUREMENT.
- 1.3.6 THE NEUROSENSE WILL NOT BE ABLE TO ASSESS SIGNAL QUALITY WHEN THE CONTINUOUS IMPEDANCE CHECK IS DISABLED. IN THIS CASE, IT IS RECOMMENDED TO PERIODICALLY PERFORM THE ON-DEMAND ELECTRODE CHECK.
- 1.3.7 UNPLUG THE DM-901 DISPLAY MODULE FROM THE MAIN POWER IF IT WILL NOT BE IN USE FOR A PROLONGED PERIOD OF TIME.
- 1.3.8 DO NOT PLACE THE NEUROSENSE OR ITS CABLES ON ANY MOVING OR VIBRATING SURFACE AS THIS CAN LEAD TO POOR SIGNAL QUALITY. IN CASE OF MECHANICAL VIBRATIONS OF THE NEUROSENSE AND/OR ITS COMPONENTS, BE CAREFUL WHEN INTERPRETING THE READINGS.
- 1.3.9 TO AVOID ACCIDENTAL UNPLUGGING OF THE DATA CABLE, SECURE THE CONNECTION OF THE CABLE TO THE DM-901 BY WRAPPING THE CABLE AROUND THE BRACKET ATTACHED TO THE DM-901, SEE **FIG. 3.5**.
- 1.3.10 WHEN OPERATING WITH A 30 HZ LOW PASS FILTER, THE EEG ACTIVITY ABOVE 30 HZ WILL BE ATTENUATED BEFORE BEING DISPLAYED.
- 1.3.11 USE ONLY MODERATE FORCE WITH ELECTRODE PREP PAD, OTHERWISE SKIN IRRITATION MAY OCCUR.

1.4 Device Symbols Key

Serial Number	S/N
Part Number	P/N
Manufacturer	
European Authorized Representative	
By Prescription Only	
See User Manual / Instructions for Use	
Batch Code	
Use by Date	
Type BF Equipment	
Defibrillator-proof Type BF Equipment	

IPX Water Ingress Protection Rating	IPX
Latex-free Product	
PVC-free Product	
Do Not Reuse	
Maximum 24 Hours of Usage	
Storage Temperature Limits	
Storage Humidity Limits	
Storage Atmospheric Pressure Limits	

Auditory Alarms Paused	
Auditory Alarms Enabled	
Add Marker	
Edit Marker	
Delete Marker	
End Case	
Power Off	
On-Demand Electrode Check	
Take Screenshot	
Exit Menu	
Review Archive or Demo Case	
Play Demo Case	
Live Case Review	

Check Signal (<i>A low-priority signal alarm is on.</i>)	
System Running on Mains Power with Battery Pack(s) Installed	
System Running on Mains Power without Battery Pack(s) Installed	
System Running on Mains Power with Battery Status Unknown (<i>low-priority alarm</i>)	
System Running on Battery Power: Battery Depleted (<i>medium-priority alarm</i>)	
System Running on Battery Power: Battery Charge 0-25%	
System Running on Battery Power: Battery Charge 25-50%	
System Running on Battery Power: Battery Charge 50-75%	
System Running on Battery Power: Battery Charge 75-100%	