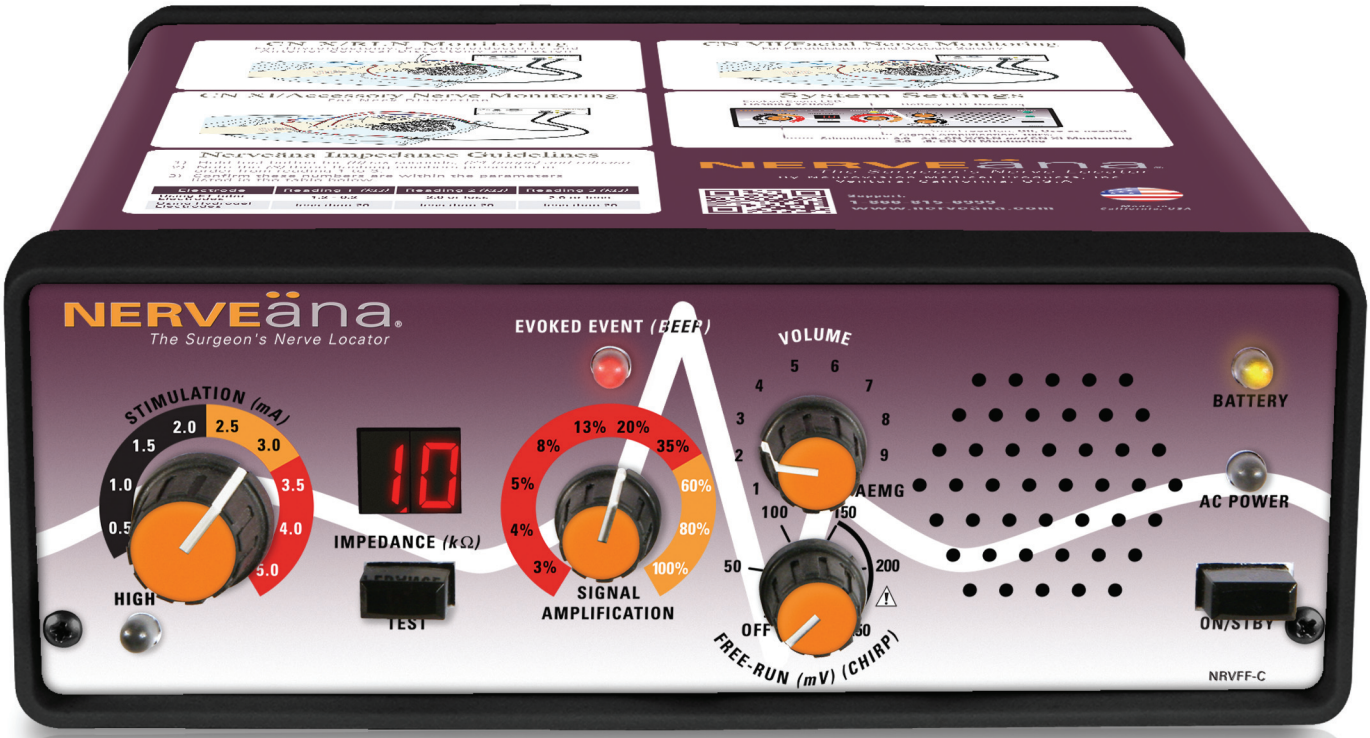
NERVEäna®

The Surgeon's Nerve Locator



User Manual

Model: **NV005.C**

Warning Indications

Warning indications used in this manual and on the Nerveäna® equipment.

BS EN ISO 15223-1
Symbols used with medical device labels

Symbol	Symbol Title
	Manufacturer
EC REP	Authorized representative in the European Community
	Use-by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
STERILE	Sterile
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
	Do not resterilize
	Do not use if package is damaged
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Temperature limit
	Humidity limitation

For a complete guide of ISO standards & symbols visit: **iso.org/obp**

BS EN ISO 15223-1 *cont.*
Symbols used with medical device labels

Symbol	Symbol Title
	Do not re-use
	Consult instructions for use
	Caution

IEC 60601-1
Symbols for Medical electrical equipment

Symbol	Symbol Title
	CLASS II equipment
	TYPE BF APPLIED PART
	General warning sign
	Warning: dangerous voltage
	Refer to instruction manual/booklet **icon may also appear in black, meaning does not change*
	WEEE Directive Mark: do not dispose, collect separately IS EN 50419:2006
IP31	IP Classification: Protected against solid foreign objects of ≥ 2,5 mm. Protection against vertically falling water drops.

Other Marks used by Neurovision Medical Products

Symbol	Symbol Title
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
CE	European Conformity mark
	Not made with natural rubber latex

IEC 60601-1 Warnings

The Nerveäna® device has been evaluated to standard IEC 60601-1:2005 + A1 Ed 3.1 . Do not connect equipment not evaluated for compatibility with the Nerveäna® system, or not evaluated for compliance with IEC 60601-1:2005 + A1 Ed 3.1. Only sterile Nerveana accessories are suitable for use within the patient environment. When unit is in operation, no contact with non medical equipment should be made. Avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth. Only standard PCs should be connected to the Nerveana USB port. If any component outside the system is connected to the Nerveana, the responsible organization must evaluate the final medical electrical system to clause 16 of IEC 60601-1 including measurement of the leakage current. Use care to avoid over-rotating knobs beyond the stop to avoid breakage.

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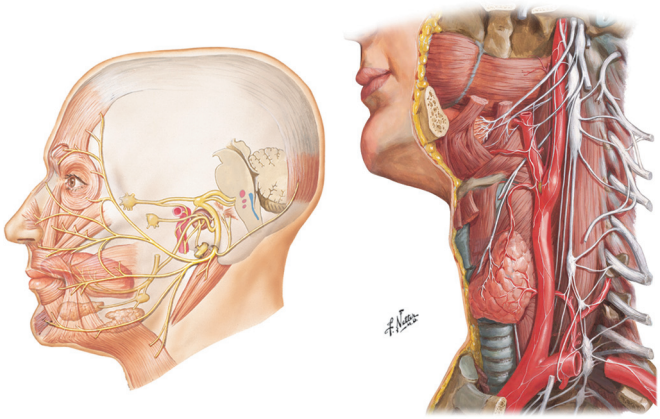
Chapter 1 Nerveäna® Setup Instructions



for

Thyroidectomy, Parathyroidectomy and Anterior Cervical Discectomy and Fusion
CN X/RLN Monitoring

Parotidectomy and Otologic Surgery
CN VII/Facial Nerve Monitoring

Neck Dissection
CN XI/Accessory Nerve Monitoring

STEP 1

Nerveäna® Setup

Charge the Nerveäna® for 12 hours before use. Confirm that a sterilized Scorpion instrument is available. Begin setup by placing the Nerveäna® battery powered device on a stand within 6 ft. of the patient's head. Connect cable assemblies labeled EMG and STIM to the ports at the back of the machine. Secure the labeled ends of the cables to the head of the OR table using the metal clips attached to the cables.

TADPOLE® Hydrogel Electrode

Applying the Tadpole® surface electrode

Locate the Tadpole® hydrogel electrode pouch. Apply the electrode to the patient's forehead. Before applying Tadpole® electrodes, utilize the 10-2-10 method. Stretch the skin and make 10 scuffs using the abrasive pad found in the electrode package. Next, wipe the area 2 times using an alcohol wipe. Wait 10 seconds to allow the area to dry. Place electrodes firmly and cover with tape.

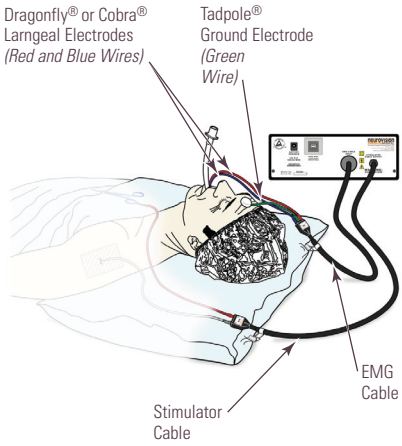
STEP 2

Choose from one of the following surgical setups:

Use in Thyroidectomy, Parathyroidectomy and Anterior Cervical Discectomy and Fusion

Setup for CN X/RLN Monitoring

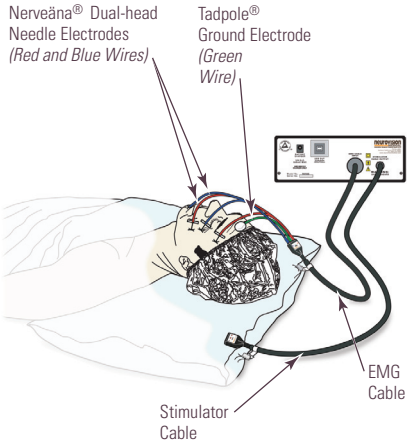
- Locate the Dragonfly® or Cobra® laryngeal electrode peel pouch and the electrode instructions for use.
- If using a Dragonfly® electrode, ask the Anesthesiologist or surgeon to apply the electrode to the ET tube then intubate the patient.
- Connect the blue and red electrode wires to the color coded ports on the EMG cable assembly.
- Plug the green Tadpole® hydrogel electrode lead wire into the color coded port on the EMG cable assembly and proceed to step #3.



For Parotidectomy and Otologic Surgery

Setup for CN VII/Facial Nerve Monitoring

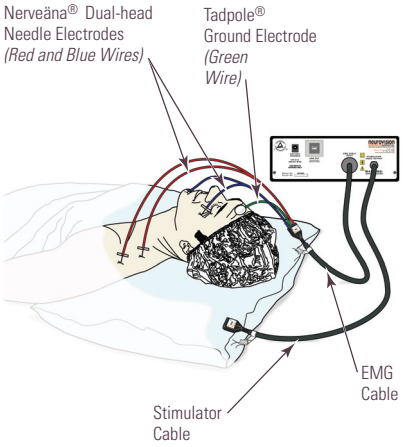
- Locate the packages with the Nerveäna® dual-head needle electrodes *(NPEMG)* or paired hydrogel *(HGELP)*.
- Apply the dual-head needle or hydrogel electrodes with red and blue wires alternating, blue to lower lip and lower eyelid, red to upper lip and forehead. Place the electrodes on the same side as the surgical dissection.
- Drape the electrode lead wires over the face away from dissection and plug the green, red and blue connectors to the color coded ports of the EMG cable assembly and proceed to step #3.



For Neck Dissection

Setup for CN XI/Accessory Nerve Monitoring

- Locate the packages with the Nerveäna® dual-head needle electrodes *(NPEMG)* or paired hydrogel *(HGELP)*.
- Apply the dual-head needle electrodes or hydrogel electrodes with red lead wires to the trapezius area of the shoulder on the same side as the dissection.
- Apply the dual-head needle or hydrogel electrodes with the blue lead wires to the appropriate branches of the facial nerve for additional monitoring coverage.
- Plug the green, red and blue connectors into the color coded ports of the EMG cable assembly and proceed to step #3.



Dragonfly®

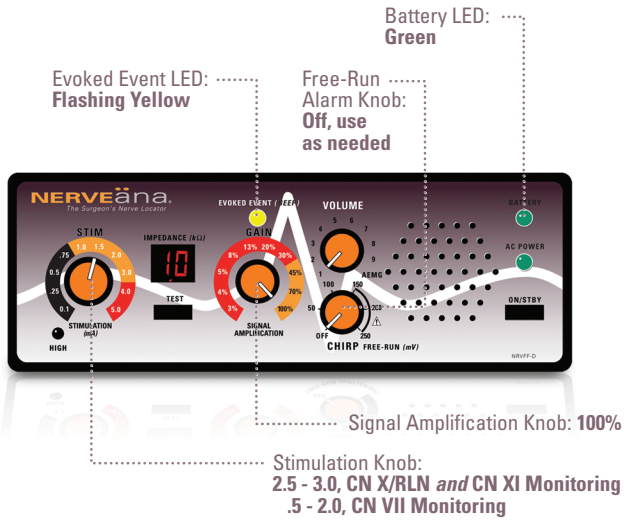
cobra® MONITORING ET TUBE

TADPOLE® Hydrogel Electrode

STEP 3

Nerveäna® System Settings

Press the power button and verify the Nerveäna's settings match those shown below.



Nerveäna® Impedance Guidelines

After the monitor's electrodes have been applied and connected to the EMG cable, it is possible to test their connection from the patient to the machine.

1) Hold test button for six seconds *(24 beeps)* and release.
2) Note the three flashing numbers presented in order *(reading 1 to 3)*.
3) Confirm these numbers are within the parameters listed in the table below.

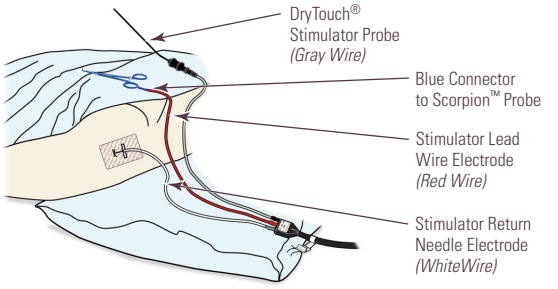
Electrode	Reading 1 *(kΩ)*	Reading 2 *(kΩ)*	Reading 3 *(kΩ)*
Using ET tube Electrodes	0.2 - 1.2	2.0 or less	2.0 or less
Using Needle or Hydrogel Electrodes	less than 10	less than 10	less than 10

STEP 4

NERVEäna
The Surgeon's Nerve Locator

Scorpion™ Stimulator Instrument Setup

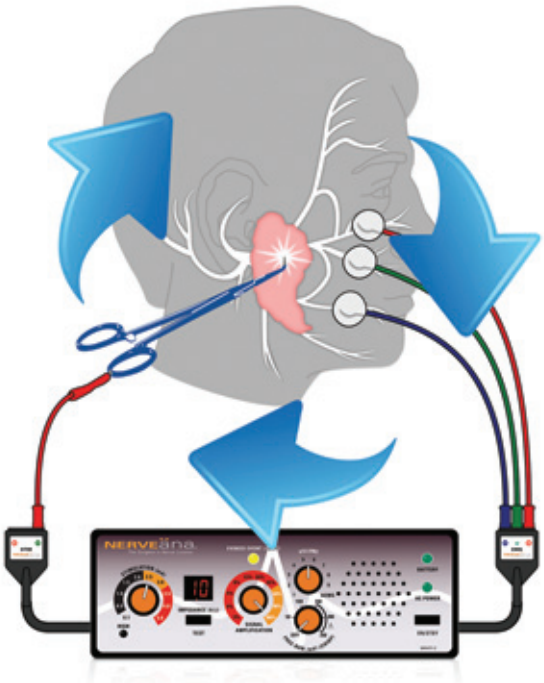
1) Locate the sterile Stimulator Pack *(NVSP)*. Remove the needle electrode *(white wire)*. Apply subdermaly to the patient's shoulder.
2) Plug the white connector into the color coded port on the STIM cable assembly.
3) Open the sterile inner pack and drop the red stimulator lead wire on the scrub table in a sterile manner.
4) Instruct the scrub nurse to pass the red connector end of the stimulator lead wire off of the sterile field.
5) Insert the red connector into the color coded port of the STIM cable assembly.
6) Direct the scrub nurse to connect the blue end of the stimulator lead wire to the post of the Scorpion™ instrument.
7) If using a Single Use – Scorpion™ Stimulator instrument skip #1 - #3. Open package and locate needle electrode *(white wire)* and apply subdermally to patient's shoulder. Open the sterile instrument package and drop the instrument with pre-attached red lead wire on the scrub table in a sterile manner. Proceed with #4 & #5 and skip #6.
8) If using a Drytouch® or Hummingbird™ probe, plug its black connector into the remaining open STIM port.
9) To verify stimulator function, first test on exposed muscle and listen for the "tic" confirmation before beginning nerve location or integrity monitoring.



DryTouch® SCORPION™ Hummingbird™

Chapter 2 Getting Acquainted with the Nerveäna®

The Nerveäna® combines a nerve stimulator and an electromyographic *(EMG)* monitor into an integrated surgical tool. A dissecting stimulating instrument continuously applies a stimulation pulse to soft tissue while the EMG monitor detects muscle response evoked by stimulation. Once an evoked EMG is detected the Nerveäna® produces an audio alarm so the surgeon is able to maintain attention on the surgical field. The Nerveäna® significantly reduces nerve location time and decreases surgeon stress by simplifying difficult dissections.



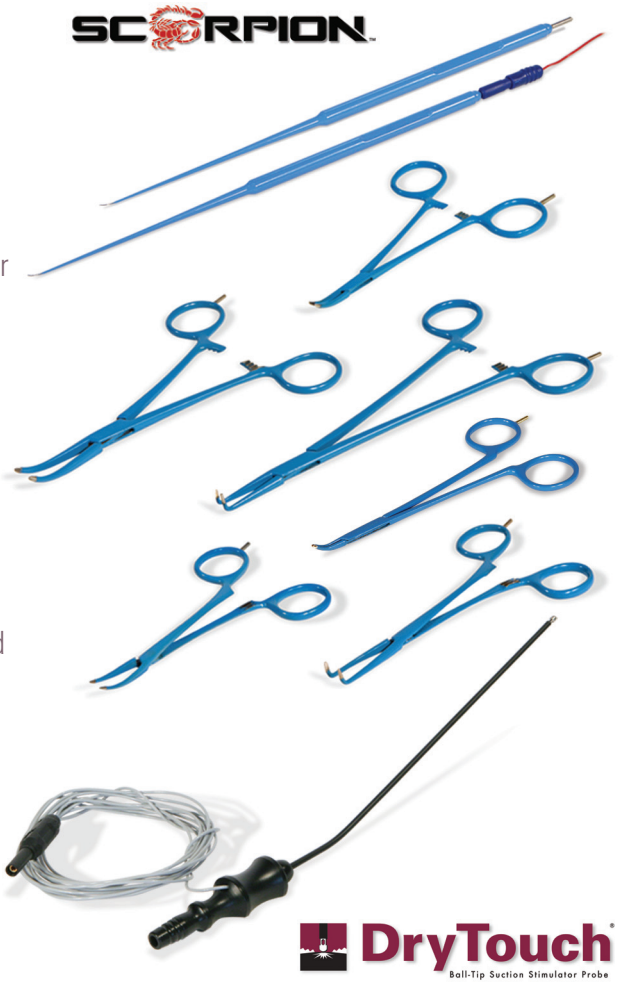
The Nerveäna® System

The Nerve Stimulator

The Nerveäna® delivers stimulations at a rate of four negative pulses per second. Every stimulation delivered to the patient is accompanied by a click audio tone and green flash from the Evoked Event light.

The stimulation intensity is controlled by the knob labeled Stimulation *(mA)* and has current settings of 0.1 - 5.0 milliampere *(mA)* marked by 0.5 mA intervals *(there is no 0 mA setting)*.

For evoked EMG, most surgery is begun with a 3.0 mA setting. The adjustable stimulation intensity function allows the surgeon to approach the target nerve at a higher setting with sufficient prospective warning to help prevent injury. The surgeon should stimulate directly on the identified nerve using the lower stimulator settings. The 3.5 - 5.0 mA intensity settings is used for transcutaneous, Vegus Nerve, or other far-field stimulation.



Scorpion™ Probes: *Rea-Type Monopolar Stimulators*

The Scorpion™ line of monopolar probes are surgical instruments for concurrent dissection and stimulation of tissue for nerve location. The stimulation pulse is applied to the body of the device via a pin that is attached to a disposable red lead wire running to the positive terminal of the stimulator cable assembly.

The body of the device has an insulating coating to prevent electrical shorting that extends to within 2 mm of the tips. The teeth of the forceps instruments are cut back above the exposed tips to provide full closure of the instrument.

Use of the Dissecting Stimulator

The forceps are used as a dissector by tunneling through the soft tissues with the tines of the instrument together, then gently separating the tines to spread the soft tissue. Always test the stimulator on exposed muscle for visible stimulation and for the audio "tic-tic-tic" alert before proceeding with nerve location.

Nerve tissue has greater integrity than other soft tissues approached by this method. Bands of stronger connective tissue that are raised between the tines of the instrument may be tested by observing for muscle movement or EMG activation when continuous EMG monitoring is in use. Tissue that does not stimulate may be cut at the surgeon's judgment.

Once the nerve is identified, continuous or prolonged exposure of nerve tissue to stimulation should be limited to the lowest setting that evokes an EMG response. The stimulation should be removed from the nerve after activation and the intensity reduced prior to further exploration. After the nerve is exposed, only intermittent stimulation on the lowest possible intensity should be done to assure the surgeon of continued functional integrity.

Applying unipolar cautery or electrosurgical equipment to the dissecting stimulator should be avoided as the heat generated may melt the insulation on the instrument. Bipolar electrocautery and the ultrasonic cautery cause significantly less noise and may be used between the tines of the dissecting stimulator. The device should not be used in any fashion other than specified in these instructions.

Use of the Dissecting Stimulator must be done in conjunction with active EMG monitoring and/or active visual observation for target muscle movement. Muscle movement commonly is seen before the EMG reaches threshold settings and gives a warning tone. Only a supra-threshold muscle response *(compound action potential)* will trigger the alarm in the Nerveäna®. This locating system must be considered only as an aid to the surgeon and not as an excuse to relax vigilance or care in prevention of nerve injury. No device can replace sound surgical judgment.

Scorpion™ Probes Sterilization Instructions

The insulated coating on the Dissecting Stimulator is extremely rugged and difficult to remove from the instrument. Short cycle cooling times causes the insulation to crack from the rapid rise in temperature. We recommend only the following steam sterilization methods with our coated instruments.

Neurovision Medical Products sells instrument trays for use in sterilization and storage. An appropriate sized polyethylene/Tyvek *(or equivalent)* sterilization pouch of the appropriate size may be used to sterilize single instruments. Ensure that the pack is large enough to contain the instrument without stressing the seals or tearing the packaging.

Instructions for Steam Sterilization of Stimulating Instruments

Steam Autoclaving with Prevacuum

If a wrapping method is used, make certain that the instruments are individually wrapped or sealed in a sterile pack. Other metal objects should never come in contact with the insulating material. Such points of contact may cause melting of the insulation. Position all hinged instruments with latches open and with tips spread and all surfaces exposed.

We recommend the following values/parameters but we also suggest following the manufacturer's instructions for steam sterilization:

Cycle Sterilizing	Sterilizing Time	Drying Time
PREVAC 270°F *(132°C)*	4 min.	30 min.

It is important that the longest drying cycle possible is employed, to prevent build-up of moisture inside the instrument. A minimum 30 minute drying time is required. Corrosion, pitting or intermittent operation are usual signs of a moisture induced problem.

Flash Autoclaving *(immediate use sterilization)*

Flash autoclaving will reduce the useful life of the instrument particularly when it is constructed of various materials, encompassing different expansion rates. Flash autoclaving is not recommended for typical use.

Chemical Sterilizing, Sterrad and Sterris sterilization processing are not recommended for stimulating instruments.

The Nerveäna® System

The EMG Monitor

Evoked *(Beep)* Alarm - A Nerve Locator

The Nerveäna® is designed to detect muscle movement with surface recording electrodes. The electrodes record electromyographic *(EMG)* signals generated by contracting muscle. The Nerveäna® is designed to detect evoked movement which occurs when the nerve innervating the monitored muscle is activated by the machine's stimulation pulse.

Free-Run *(Chirp)* Alarm - A Nerve Monitor

The Free-Run EMG alarm allows the surgeon to monitor the nerve for a response caused in the absence of electrical stimulation.

EMG Electrodes

The Nerveäna® uses two types of surface electrodes as sensors for evoked muscle activity: a hydrogel electrode for skin application and a unique laryngeal surface electrode developed by Neurovision Medical Products for detecting EMG signals from the vocal cords.

The EMG electrodes are placed as appropriate for the procedure to be performed *(see setup instructions)*.

Care should be taken to follow the specific use information for each electrode found with the electrode packaging.

Laryngeal Surface Electrode

Hydrogel Electrode

Laryngeal Surface Electrode

Chapter 3 Nerveäna® Controls and Functions

The Nerveäna® control panel

For a tabular summary of all audio and visual indications see chapter 4.

Stimulation - *Current Controls*

This knob sets the stimulation current delivered by the stimulating instrument. The settings range from .1 mA to 5.0 mA.

Signal Amplification - *Alarm Trigger Level*

The Nerveäna® will only alarm if the muscle action exceeds the detection level set by the signal amplification knob. The higher setting corresponds to more sensitive EMG detection *(a weaker muscle response will trigger the alarm)*. This knob should be placed at the highest setting *(100%)* at the beginning of each surgical procedure and is adjusted downward only if needed.

On / Standby

The On / Standby button switches the Nerveäna® on and off. The on status is indicated by the Evoked Event light being lit. When turned off, the event light is not lit.

Volume Control

This is the master volume control for all audio signals.

Free-Run Alarm *(Chirp)* Knob

The Free-Run Alarm Knob is turned off at the extreme counter-clockwise position. When the Free-Run Alarm is set in the off position, only the evoked nerve location beep alarms will be active. Turning clock-wise past the off position activates the Free-Run alarm feature. A chirp alarm tone activated by an adjustable voltage threshold for integrity monitoring. The Free-Run alarm threshold varies between 1 and 250 microvolts and is adjusted upward by turning the knob clockwise.

EMG Monitor Alarm Test

Depressing the Test button with the Signal Amplification knob set at 100% generates an internal simulated evoked EMG signal *(compound action potential)* that verifies the function of the EMG detection circuitry. A successful test is indicated by repeated alarms and the Evoked Event light flashing red. If depressing the test button generates no alarm while the Signal Amplification is set to 100%, the machine is improperly configured or malfunctioning and should not be used.

Electrode Off Alarm

When an electrode connected to the EMG monitor is not in contact with the patient, a burst of four beeps will sound every minute. Nerve location by the Nerveäna® is not possible when there is an electrode off. This condition is considered abnormal operation of the monitor and should be corrected. If the operator continues to use the stimulator with the EMG detector in this non-functional condition, the audio ticks that indicate stimulus delivered are modified to a distinctive double tick.

Impedance Measurements

Each time the test button is depressed for several seconds, a digital impedance measurement of the electrode is performed. The results are displayed by three numbers serially flashing in the two digit display labeled Impedance ***(kΩ)***. Impedance measurements are used only for troubleshooting purposes.

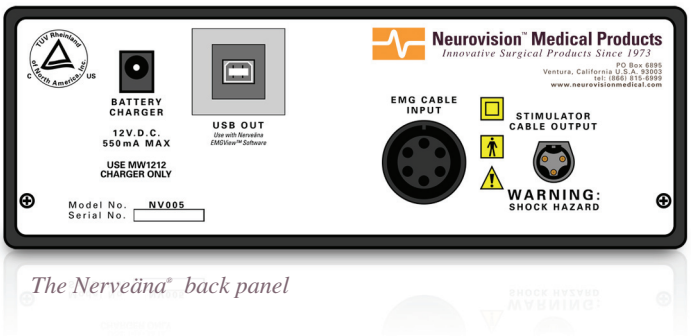
Checking Electrode Impedance

To check the impedance of the EMG surface electrodes, depress and hold the test button for at least six seconds. The first number shown on the digital display is the impedance across the positive *(+)* and negative *(-)* electrode leads. After the test button is released, a second and third number are displayed providing first the impedance of the positive *(+)* and then the negative *(-)* lead to the ground electrode.

The following table is a guide for optimum impedance ranges *(measured in kOhm)*. The Nerveäna® can operate properly outside of these ranges but if performance problems occur with the EMG detector, impedance should be checked and adjusted to match these guidelines.

Nerveäna® Impedance Guidelines

Electrode	Reading 1 *(kΩ)*	Reading 2 *(kΩ)*	Reading 3 *(kΩ)*
Using Laryngeal Electrodes	0.2-1.2	2.0 or less	2.0 or less
Using Hydrogel Electrodes	less than 20	less than 20	less than 20



The Nerveäna® back panel

Electrical Power

The Nerveäna® is designed to run from an internal battery. A large battery capacity allows operation for about ten hours before recharging is needed. The machine will operate from wall current if necessary. The light labeled Battery indicates the status of the battery. A green light indicates a sufficiently charged battery. A yellow light indicates a low battery level. A red light, accompanied by a long beep, indicates a critically low battery level.

The power supply/charger included with the Nerveäna® should be plugged into the port on the back left of the device labeled Battery Charger. The green light labeled AC Power indicates that the Nerveäna® is connected to an external power source. If the device is connected to an external power source, this light will be on regardless of whether the Nerveäna® is turned on or not. If the batteries are charging, the Battery light will be either yellow or red indicating the status of the batteries. If the battery is fully charged, the Battery light will be green when disconnected from wall power.

To ensure a full battery charge, the regulated power supply and charger should be attached to the Nerveäna® overnight prior to use. If needed, the Nerveäna® can run in Alarm mode from an external power source during surgery.

EMGView® Software for PC

The Nerveäna® is designed to connect to a PC for a graphic display of the waveforms, the saving of recorded information or to perform diagnostic checks on the machine. The port labeled USB Out, found on the back of the Nerveäna® fits a standard USB cable. The cable out is in turn connected to a PC. Neurovision's EMGView® software for Windows PCs must be installed on the computer prior to use.

The Nerveäna® Fixed Height Cart

EMGView™

Software for Nerveäna®

The Nerveäna® Adjustable Height Cart

Chapter 4 Surgical Technique and the Nerveäna®

Nerve Locator Safety

The Nerveäna® is designed to be a surgical tool in the hands of a competent surgeon. The nerve locating function of this device is not a substitute for prudent surgical technique and judgment. The Nerveäna® can only provide positive location of a nerve. Negative location *(i.e. determining that the target tissue is not nerve)* is beyond the ability of current technology. The possibility of device malfunction, pharmacologic or physical depression of nerve conduction, unknown electrode displacement, or other system dysfunction can never be excluded.

Surgeons who are hesitant to use unfamiliar electronic nerve locating equipment may gain experience by waiting to initiate use of the Nerveäna® until the nerve has been found anatomically. With the nerve in sight, the equipment can be turned on and tested against the various tissues.

A wide range of settings for the stimulator and EMG detector and the ability to use many surgical instruments as stimulators allow the surgeon to customize use of the Nerveäna® to accommodate their surgical technique.

Operation of the Nerveäna®

Set up the Nerveäna® system according to the instructions found in Chapter 1 of this manual or the small reference provided with each Single-Use Surgery Kit. Verify that no long acting paralytics have been administered that would inhibit EMG response. Do not use Nerveäna® equipment in the presence of flammable anaesthetic mixture, with air, oxygen or nitrous oxide.

Proceed with the surgery by normal anatomic dissection. Confirm the delivery of stimulation by observing fine twitches in muscles brought into contact with the dissecting stimulator. When the soft tissue depth to the target nerve becomes less than 5 mm, alarms may begin to replace the clicking sound of the dissecting stimulator.

The Nerveäna's® alarm indicates that stimulation pulses excited the target motor nerve and produced an evoked EMG response in the muscles monitored by the EMG electrodes. The Nerveäna® will only alarm if the muscle action exceeds the detection level set by the Signal Amplification Knob. The higher percentage setting corresponds to more sensitive EMG detection *(a weaker muscle response will trigger the alarm)*.

Operation of the Nerveäna® *(Cont.)*

The surgeon may choose to lower the Signal Amplification or Stimulation intensity as the nerve is approached to limit the number of alarms. Mapping of the nerve's location prior to direct visualization is possible by narrowing the area of soft tissue that produces alarms.

After visualization of the nerve has been achieved, lower the stimulation setting and proceed with the dissection. Whenever working near the nerve, use the lowest intensity stimulation that will evoke an EMG response. At this setting the nerve should require direct contact with the dissecting stimulator to induce alarms. Rapid dissection through areas more distant from the nerve can be facilitated by using the dissecting stimulator on higher stimulation settings.

More precise information on irritiaive response of the nerve can be utilized for the remainder of the dissection if the Free-Run alarm mode is activated and use of the stimulator is discontinued. In this mode, a Chirp alarm is produced if the EMG electrodes detect a signal larger than the alarm threshold set by the Free-Run Alarm Knob.

Additional Considerations

When the Signal Amplification is set low, fine motor movements of the monitored muscle are sometimes seen prior to generation of an alarm. Occasional false alarms may occur when the monitored muscle is mechanically moved or because of movement of the patient and wires. Stimulation of a large motor nerve branch can sometimes cause retrograde conduction that evokes a muscle response and an alarm even though the target nerve was not directly stimulated. Blood vessels in the dissection field can conduct the stimulating current to the nerve and when stimulated produce a response similar to nerve tissue. A wet surgical site will dissipate or shunt the stimulation current. For the most effective use of the stimulator keep the stimulated site free of blood and other fluids. If a malfunction occurs, stop using the Nerveäna® and consult the troubleshooting guide of this manual.

Understanding the Audio and Visual Indications

The Nerveäna® is designed such that the primary communication with the surgeon is by audio tones. The surgeon's attention remains focused on the surgical site while using the nerve locator. Visual indicators are provided primarily to assess the function of the machine.

Audio Indications

Silence

In the absence of electrical stimulation and with the Chirp alarm disabled, the Nerveäna® is silent. Note that the evoked detection alarm will not sound unless the stimulator is in use.

Ticks

When stimulating with the dissecting stimulator, a ticking sound at a rate of 4 clicks per second is heard with each delivery of a stimulation pulse. If no tick is heard when the stimulator is in contact with the patient, a check of the stimulator lead wire and ground connections should be done to correct the problem.

In rare cases, the stimulator will deliver a current below that specified by the stimulator setting. In this instance, the Nerveäna® will replace the typical ticking sound with a distinctive lower pitched tock sound. *(See the troubleshooting section for more information on this problem.)*

If one or more of the EMG sensor's electrodes is disconnected, a double tick will replace the typical single tick sound. *(See the troubleshooting section for more information on this problem.)*

Alarms

If the Nerveäna® detects an evoked response from the monitored muscles a distinctive Beep alarm will be repeated 4 times per second, replacing the stimulator clicks.

If the Free-Run alarm knob has been turned clockwise, the Chirp alarm is activated. Chirp alarms indicate that a voltage threshold, set by the knob position, has been exceeded and a soft chirp occurs. Chirp is activated independently of the evoked stimulation alarm Beep and is superseded by evoked stimulation Beep alarm.

If the Nerveäna's® EMG detector has been disconnected from the patient, a rapid train of 4 alarms lasting one second will sound every minute. All leads from the machine to the electrodes should be checked and the problem corrected before continuing the surgery.

A Sustained Alarm lasting 2 seconds indicates low battery power. The Nerveäna® should be connected to line power when in this condition to ensure continuous use.

Summary of Audio Indications

Nerveäna Condition	Audio
System Ready and Idle	Silent
Full Stimulation Delivered	Ticks *(higher pitch)*
Partial Stimulation Delivered	Tock *(lower pitch)*
Stimulation Delivered with EMG Off	Double Ticks
Evoked EMG Detected	Repeating Beep Alarm *(replaces ticks)*
Voltage Threshhold Exceeded	Repeating Chirp Alarm
EMG Detector Disconnected	Train of 6 Alarms *(once per minute)*
Critically Low Battery	Sustained Alarm

Summary of Visual Indications

Nerveäna Condition	Light	Color	State
Battery Charged	Battery	Green	Steady
Low Battery	Battery	Yellow	Steady
Critically Low Battery	Battery	Red	Steady
120 V Power Supply Connected	AC	Green	Steady

Clinical Indicator	Light	Color	State
System Waiting for EMG Input	Event	Yellow	Flashing
Stimulation Detected *(no alarm)*	Event	Green	Flashing
EMG Detected *(alarm)*	Event	Red	Flashing
EMG Detector Disconnected *(electrodes or cables)*	Event	Red	Steady

Chapter 5 Procedure Notes

Thyroidectomy and Parathyroidectomy

The laryngeal surface electrode *(Dragonfly® or Cobra®)* must be properly placed and remain in contact with the vocal cords. Random alarms may indicate the LSE is out of position but often the problem is not identified until the nerve is obviously being stimulated without triggering the Nerveäna's® alarm. Correction of the problem requires repositioning of the electrode by laryngoscopy and according to the laryngeal electrode instruction found in the appendix of this manual.

Stimulation of the inferior thyroid artery can sometimes cause false alarms and the vessel can be mistaken for the nerve due to its proximity.

The Nerveäna® can be used to find the superior laryngeal nerve. When dissecting the superior pole of the thyroid contraction of the external cricothyroid muscle can usually be observed as the nerve is approached. Alarms may not occur but the mass response of the muscle is readily discernible.

Muscle movement with nerve stimulation can be used to identify the branch of the recurrent laryngeal nerve to the inferior pharyngeal constrictor muscle.

Parotidectomy

Unnecessary stimulation of a located nerve is to be avoided. However, the Nerveäna's® lowest stimulation levels do not cause neuropraxia of the facial nerve.

Small nerve branches that are typically sacrificed in standard dissection may be encountered and preserved using the Nerveäna®.

Retraction on the gland, a dry surgical site or cool temperatures may cause temporary neuropraxia of the facial nerve and it may not stimulate. The surgeon may choose to avoid retraction until nerve location is performed or to dissect out a peripheral branch and work toward the main trunk *(neuropraxic portion)* of the nerve. Neuropraxia monitoring can be performed with the Free-Run alarm feature.

For benign mixed and Warthin's tumors, the surgeon may choose to dissect the mass with a cuff of normal tissue, using the nerve location power of the Nerveäna® to identify branches of the facial nerve only in the zone of surgery.

Submandibular Gland Excision

The Nerveäna® is an aid in the location of the marginal mandibular nerve in submandibular gland excision. Often the facial branches to the platysma are located and displaced out of the surgical field preserving function of the corner of the mouth. Some difficulty in distinguishing between stimulation of the facial nerve branches and the platysma muscle directly may be encountered.

Additionally, the EMG detector of the Nerveäna® can be utilized to locate the hypo glossal nerve by placing needle electrodes into the tongue.

Neck and Skull Base Procedures

The Nerveäna® can be used in various operations of the neck. To target a particular nerve, align the array of three surface electrodes over the muscle innervated by the target nerve.

For example, in a typical neck dissection, the trapezius muscle is monitored by surface electrodes arrayed over the junction of the trapezius and the neck, just behind the crest of the shoulder.

The accessory cranial nerve can be identified on either side of the sternocleidomastoid muscle or at the skull base. The branch to the SCM can be specifically identified or the trapezius branch dissected separately.

Location of the accessory nerve in a posterior triangle lymph node biopsy can be done by use of the Nerveäna®, but use of local anesthesia requires additional care to prevent nerve paralysis by the local injection.

Otologic Surgery

In ear surgery, the Nerveäna® can be used for facial nerve location in the mastoid bone and in the middle ear. Monitoring may include the Beep for evoked CAP detection or the Chirp for nonevoked voltage threshold detection and the most sensitive monitoring of the nerve. Waveform evaluation may be used with a PC. The drill instrument must be activated as a stimulator for proactive nerve location. Neurovision Medical Products makes a variety of otologic stimulation probes for use in middle ear or mastoid surgery.

Contact Neurovision Medical Products for more information on activating a drill as a nerve locating stimulator and for using the Nerveäna® in ear surgery.

Appendix

Dragonfly® Single Channel Laryngeal Surface Electrode Intubation Instructions

Reliable performance of Dragonfly® electrodes requires proper positioning. Please follow these instructions carefully and avoid using long-acting paralytics.

Applying electrode:

1) Choose any non-silicon ET tube and the appropriate electrode based on the ET size chart below:

ET Tube ID Size	Dragonfly® Electrode Item Code
2.0 - 5.5	LSE500MSP
6.0 - 7.0mm	LSE500MS
7.5 - 10.0mm	LSE500M

Before application, the tube should be kept clean and free of any lubricants or other materials that may inhibit electrode adhesion.

2) Determine the location where the vocal cords will be in contact with the ET tube after intubation. The middle of the electrode will be applied at this location with the wires directed toward the mouth. *(fig 1)*

3) Turn over and straighten the ET tube to expose what will be the posterior side when intubated. Use of a straightened stylet facilitates hands-free straightening of the ET tube.

4) Align electrode's midline with the midline of the posterior portion of the tube. Press electrode down, wrapping it toward the top *(anterior)* side of the tube *(fig. 2)*. Press along the entire surface and edge to ensure proper adhesion.

Note: electrode plates should not touch after wrapping.

Dragonfly®
The Stick-On Electrode

Figure 1

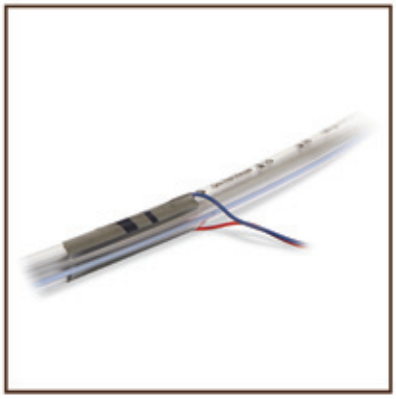


Figure 2

Dragonfly® Laryngeal Surface Electrode Intubation Instructions *(Cont.)*

Intubation*:

1) A small amount of lubricant may be applied to the electrode. Insert the ET tube under direct vision or with a video laryngoscope so that each vocal cord is touching its respective electrode plate and rests between the two blue positioning stripes. *(fig. 3)*

Note: the depth number on the ET tube against the maxillary central incisors before any further positioning of the patient.

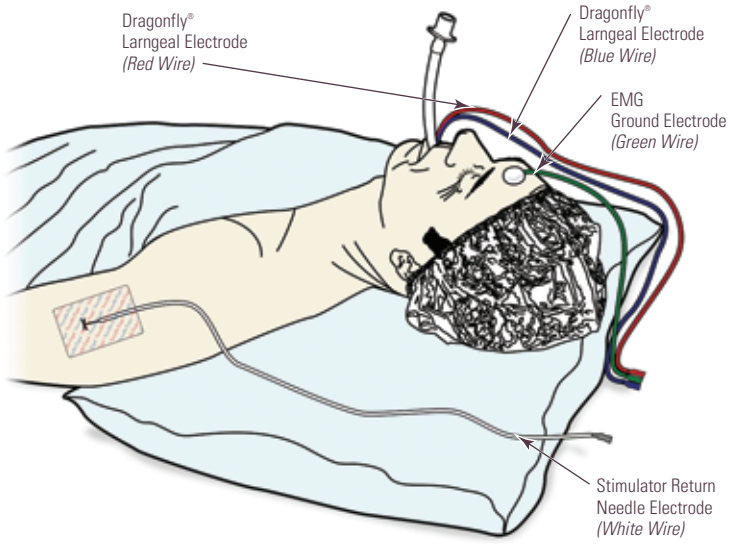
2) Tape the ET tube securely with 2 pieces of tape by wrapping each piece first around the tube and then securing it to the upper lip. *(fig. 4)*

3) Tightly secure the breathing circuits so the ET tube will not rotate or be displaced and then verify final electrode position by laryngoscopy with a #3 Miller Blade or with a video laryngoscope.

4) After final positioning of patient, align ET tube in the middle of the pharynx behind the tongue. The posterior portion of the ET tube should be directly opposite the central maxillary incisor gap at the depth number noted after initial positioning.

5) Attach the Blue and Red electrode lead wires to the + or - EMG terminals and apply the Green lead from and EMG reference to the remaining terminal.

* Intubation with Dragonfly® electrodes for longer than 8 hours is not recommended.



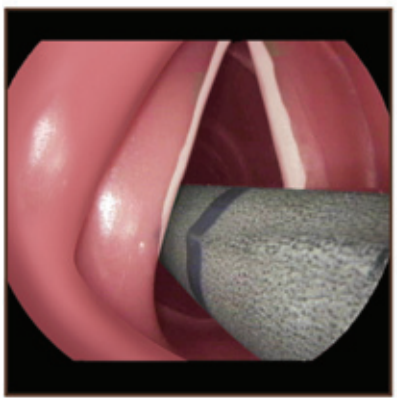


Figure 3

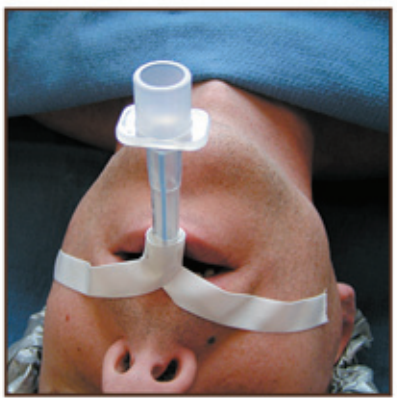
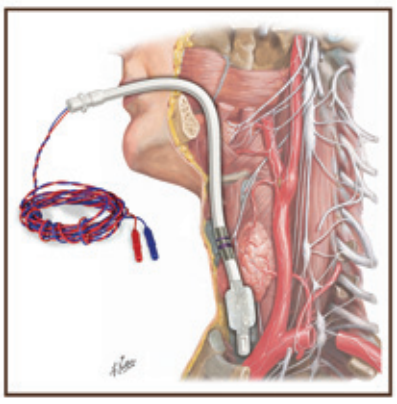


Figure 4



Appendix

Cobra® EMG Monitoring ET Tube Intubation Instructions

Reliable performance of Cobra® electrodes requires proper positioning. Please follow these instructions carefully and avoid using long-acting paralytics.

Choose a Tube:

ET Tube ID Size	Cobra Electrode Item Code
6.0mm	LTE700S
7.0mm	LTE700M
8.0mm	LTE700L

Positioning the electrode:

1) A small amount of lubricant may be applied to the electrode. Insert the ET tube under direct vision or with a video laryngoscope so that each vocal cord is touching its respective electrode. *(fig. 1)*

Note the depth number on the ET tube against the maxillary central incisors before any further positioning of the patient.

2) Tape the ET tube securely with 2 pieces of tape by wrapping each piece first around the tube and then securing it to the upper lip. *(fig. 2)*

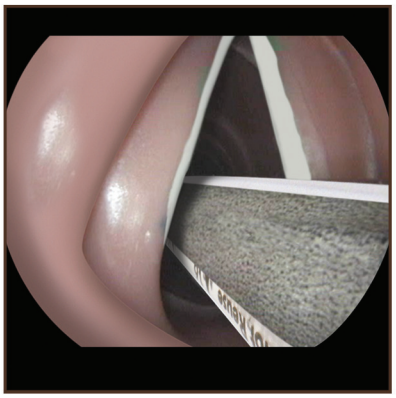


Figure 1

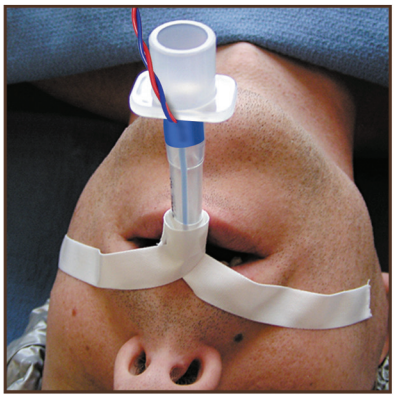
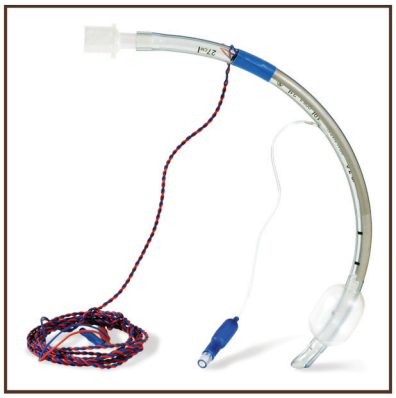
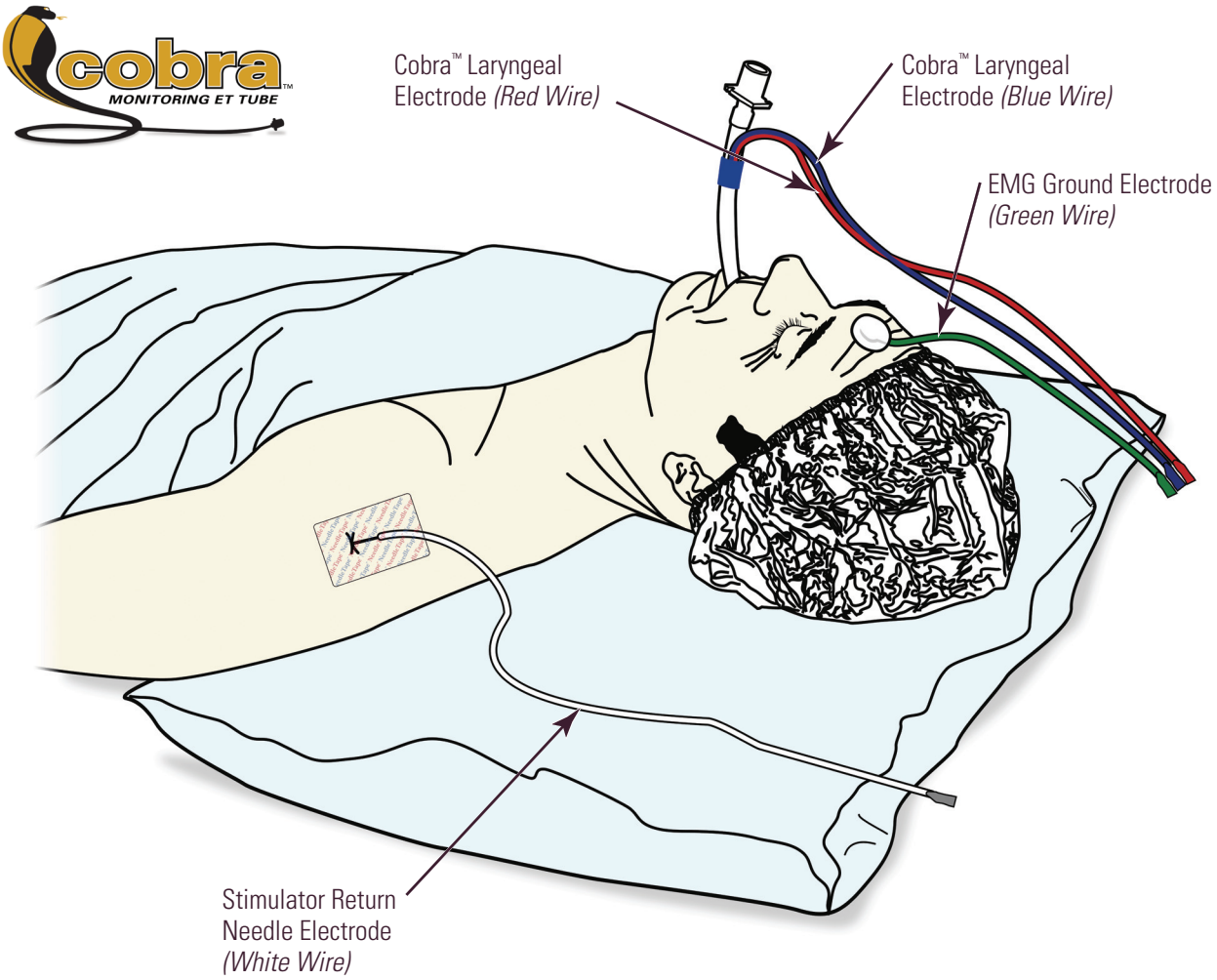


Figure 2



Appendix

Cobra® EMG Monitoring ET Tube Intubation Instructions *(Cont.)*



3) Tightly secure the breathing circuits so the ET tube will not rotate or be displaced and then verify final electrode position by laryngoscopy with a #3 Miller Blade or with a video laryngoscope.

4) After final positioning of patient, align ET tube in the middle of the pharynx behind the tongue. The posterior portion of the ET tube should be directly opposite the central maxillary incisor gap at the depth number noted after initial positioning.

5) Attach the red and blue electrode lead wires to the + and - EMG terminals and apply an EMG ground.

* Intubation with Cobra™ EMG Tube is permissible for up to 8 hours.

Instructions for Maintaining, Cleaning, and Sterilization Non-disposable Stimulation Instruments

Cleaning Procedures

Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning. *System components used on or near tissues of patients who are known or suspected to be infected with Cruetzfeldt-Jakob disease *(a.k.a. TSE, CJD)* should be discarded.

Containment/Transportation

1. Universal precautions for handling contaminated/biohazardous materials should be observed.
2. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

Preparation of Cleaning Agents

Prepare neutral pH enzyme and cleaning agents *(Enzo® Clean or equivalent)* at the use-dilution and temperature recommended by the manufacturer.

Manual Cleaning Procedure

1. Use the neutral pH enzyme soaking solution that has been prepared.

2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Use a small, soft-bristled brush to gently clean the device *(particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas)* until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush *(i.e. pipe cleaner brush).*

Note: *The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).*

3. Remove the device from the enzyme solution and rinse in purified water *(from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled)* for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.

4. Prepare the neutral pH cleaning *(detergent, Prolystica® 2x Enzymatic Cleaner concentrate or equivalent)* solution and place in a sonication unit.

5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.

6. Rinse instrument in purified water *(from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled)* thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.

7. Repeat Steps 5 and 6 with freshly prepared cleaning solution.

8. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

Disinfection

Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

See sterilization section in chapter 2.

Inspection/Function Testing

1. Carefully inspect each device to ensure that all visible blood and soil has been removed.
2. Visually inspect for damage and/or wear.
3. Check the action of moving parts *(such as hinges and box-locks)* to ensure smooth operation throughout the intended range of motion.
4. Check instruments with long slender features *(particularly rotating instruments)* for distortion.

Note: If damage or wear is noted that may compromise the function of the instrument, contact Neurovision Medical Products for a replacement.

Warnings ⚠

- Never rely on the Nerveäna® to determine any structure is not nerve.
- Avoid cauterization on the dissecting stimulator. Bipolar cautery may be used between the tines.
- Do not cauterize or stimulate near the EMG electrodes.
- Never use the Nerveäna® with longer acting paralytics or local anesthetic.
- Avoid leaving the stimulator in prolonged contact with a motor nerve.
- Never assume that sensor electrodes are properly positioned.
- Application of high frequency surgical equipment near the stimulation probe may result in burns at the stimulator ground or damage to the Nerveäna® stimulator.
- Operation of Nerveäna® in close proximity to shortwave or microwave therapy equipment may produce instability in the
- stimulator output.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Do not subject a patient with implanted electronic device to stimulation.
- Do not use Magnetic Resonance Imaging (MRI) or another electric stimulation during device use.

Cleaning Procedures for Nerveäna®

Clean the Nerveäna® unit with a soft cleaning cloth or disposable wipe using alcohol or disinfecting solution. Do not allow liquid to enter the unit while cleaning. Clean the EMG and STIM cable assemblies with alcohol or tape remover as needed. Clean the Scorpion® probes with the instrument disinfection procedures and sterilization instructions in Chapter 4 and Appendix.

Environment Warning

Do not use Nerveäna® equipment in the presence of flammable anaesthetic mixture, with air, oxygen or with nitrous oxide.

Parts and Accessories

Replacement parts and accessories are available for the Nerveäna® system. Please contact Neurovision Medical Products for more information.

Troubleshooting

Stimulator Problems	Solutions
No tick sound is heard when using the dissecting stimulator.	Check connections of all cables from the stimulating instrument to the back of the machine. Ensure needle electrode is placed and properly connected to cable assembly.
No muscle movement is seen when stimulating.	Muscle should rapidly twitch when in contact with the stimulator. Turn up stimulation intensity until movement is seen. If the problem persists follow solutions above.
The low tick tone replaces typical clicking sound.	The low tone indicates that the level of stimulation delivered is lower than specified by the stimulation intensity setting . Check the needle electrode to ensure is making good contact with the patient.

EMG Problems	Solutions
No lights or sound when power switched on.	If not connected to line power, the problem is likely a dead battery. After connecting the machine to line power, depress and release the on/stand by button and try to restart the machine.
Electrode Off Alarm	The Nerveäna® may produce bursts of beeps at one minute intervals indicating that electrode impedance has gone above the operational levels of the detector. If all EMG cable and lead wire connections are made and all electrodes appear securely in place as described in their respective instructions, see the impedance measurement section below.
The low tick tone replaces typical clicking sound.	The Nerveäna® is designed to detect only evoked EMG. If alarms appear to be random and not correlated to simulation, follow the steps described for electrode off alarm. If the problem persists, contact Neurovision Medical Products.

Checking Electrode Impedance

To check the impedance *(contact)* of the EMG surface electrodes, depress and hold the test button for at least six seconds. The first number shown on the digital display is the impedance across the positive *(+)* and negative *(-)* electrode leads. After the test button is released, a second and third number are displayed providing first the impedance of the positive *(+)* and then the negative *(-)* lead to the ground electrode.

The following table is a guide for optimum impedance ranges *(measured in kOhm)*. The Nerveäna® can operate properly outside of these ranges but if performance problems occur with the EMG detector, impedance should be checked and adjusted to match these guidelines.

Nerveäna® Impedance Guidelines

Electrode	Reading 1 *(kΩ)*	Reading 2 *(kΩ)*	Reading 3 *(kΩ)*
Using Laryngeal Electrodes	0.2-1.2	2.0 or less	2.0 or less
Using Hydrogel Electrodes	less than 20	less than 20	less than 20

Nerveäna® Technical

Specifications Stimulator

Repetition Rate	4 pulses per second *(± 1%)*
Pulse Width	158 ± 5 microsecond
Current	0.1 mA - 5.0 mA *(0.5mA steps) (larger ± 0.2 mA or ±10%)*
Load	0-1000 Ohms ± 1%, (constant) pulse current, regulated
Compliance	36V min, 40V max
Isolated	Designed to meet or exceed IEC 60601-1

EMG Monitor

Lowest Gain	x367, A/D range = ± 6.8 mV *(± 5%)*
Highest Gain	x18,608, A/D range = ± 134 microvolt *(± 5%)*
Bandwidth	20 ± 3 Hz - 3,000 ± 300 Hz
Notch Filter	2-pole 60 Hz *(or 50 Hz)*, by crystal controlled clock
A/D converter	10 bit, at 18,000 samples per second
Input Impedance	10 MegOhm each input to reference
Compliance	± 300 mV
Isolated	Designed to meet or exceed IEC 60601-1

Impedance Monitor

Display Range	0.0k - 99k Ohm, over range indication (2 high bars)
Accuracy	larger of ± 0.1k Ohm or 10%
Current	< 10 uA peak at 30 Hz *(or 25 Hz)*

Data Input/Output

Isolated USB	Requires proprietary PC program; Attach to the USB port of PC only.

Power

Battery	6V, 3.4 Amp-Hour, SLA
Discharge	10 hours *(full charge)*
Charge Rate	240 ± 25 mA, followed by sustaining 2.5 mA trickle
Charge Time	Approximately equal to time discharging
DC Input	12 VDC ± 20%, 550 mA max
AC Adapter	In: 100-200 VAC, 50/60 Hz, 0.5A. Out: 12 VDC, 1.0 A

Environment

Condition	The permissible Environment for shipping, storage and use
Temperature	10˚-40˚ C
Relative Humidity	30-75%
Atmospheric Pressure	700-1060 h"

Maintenance Schedule:

Routine, basic maintenance should be conducted by at a minimum of every four *(4)* months by the Biomedical Department.

Basic maintenance consists of:

1. Turning on the system and depress the TEST button. Positive circuitry check is exhibited by a consistent beep alarm with corresponding red light flashing on the EVOKED EVENT LED.
2. Leave unit on for at least 60 seconds to confirm four *(4)* beeps, which indicates ELECTRODE OFF warning system is functioning properly.
3. Generally inspect the EMG, Stimulator and USB ports for damage. Rotate knobs on the front face to assure functionality.
4. nspect all cable assemblies for damage, including plug port damage or fraying of cables.

Storage:

If the unit is stored for over three months, consult the manufacturer about battery removal or recharge battery overnight once per month.

Disposal of Unit:

The Nerveäna® unit contains a lead acid battery and other possible electronic waste. Do not dispose in general waste.

www.nerveana.com

Limited Warranty:

Neurovision Medical Products, Inc., (herein, the "Manufacturer") warrants the Nerveäna® Nerve Monitoring System to be free from defect in material or factory workmanship during the course of normal use for a period of one year from the date of purchase by the customer. The Nerveäna® Nerve Monitoring System is comprised of the Nerveäna® Unit and the following accessories: Stimulator cable, EMG cable, power supply, power cable, Muting Sensor, PC Monitoring System with EMGView® Software, and Rolling Stand Cart. The Manufacturer will service/repair or replace all products under warranty. The Nerveäna® System has no user serviceable parts. Unauthorized service of the Nerveäna® System will void this product warranty.

To initiate a repair or replacement, or for answers to technical support questions, please contact the Manufacturer or the exclusive distributor in your area. The Manufacturer's Customer Service Department will facilitate your request for a Return Merchandise Authorization (RMA) number and provide shipping instructions. In good faith, the Manufacturer will attempt to provide the customer with a Nerveäna® System on loan during the service or repair term. The customer shall provide a No Charge Purchase Order to the Manufacturer for the use of a loaner Nerveäna® System.

Once the one year Limited Warranty period has ended, servicing/repairs will only be available for the Nerveäna® Unit (all accessories are excluded). Please contact the Manufacturer for all service/repair requests that fall outside of the warranty period. Neurovision Medical Products, Inc., reserves the right to refuse the service or repair of any Nerveäna® Unit.

Warranty of Repair and Service:

The Manufacturer warrants the service and repair of each product to be free from defect in material and factory workmanship under normal use for a 30-day period following the date of return of the serviced product. Any defects resulting from improper or inadequate service/repair by the Manufacturer (as solely determined by the Manufacturer) during this 30-day period will be repaired by the Manufacturer. Costs of such repair and service (both labor and materials) will be borne by the Manufacturer except for the cost of shipping or freight which shall be the responsibility of the customer. Any and all Nerveäna® Systems repaired due to defects in material or factory workmanship will continue to be covered by the Manufacturer during the one year Limited Warranty as set forth above.

Extended Warranty:

One, two, three, and four year extended warranties are available for purchase within two years of the Nerveäna® Unit purchase date. Under extended warranty, the Manufacturer will service/repair or replace the Nerveäna® Unit and cables (STIM, EMG, power cable, and power supply) per the same terms of the Limited Warranty as stated above. All other accessories are excluded from extended warranty coverage. Please contact the exclusive distributor in your area for pricing.

Neurovision Medical Products

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www.neurovisionmedical.com, e-mail sales@neurovisionmedical.com

An ISO 13485 Certified Company

Electromagnetic Compatibility

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The following cables and other ACCESSORIES of the NV005 System are replaceable by Neurovision Medical Products Inc. and are likely to affect compliance of the System with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY) : Stimulator cable, EMG cable, power supply, power cable.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NV005 System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMC PRECAUTIONS:

Application of high frequency surgical equipment near the stimulation probe may result in burns at the stimulator ground or damage to the Nerveäna® stimulator.

Do not cauterize or stimulate near the EMG electrodes.

Operation of Nerveäna® in close proximity to shortwave or microwave therapy equipment may produce instability in the stimulator output.

Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

Do not subject a patient with implanted electronic device to stimulation.

Do not use Magnetic Resonance Imaging (MRI) or another electric stimulation during device use.

Guidance and Manufacturer's Declaration – Emissions
All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration - Emissions
The NV005 is intended for use in the electromagnetic environment specified below. The customer or user of the NV005 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The NV005 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The NV005 is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Complies	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity
All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration – Immunity
The NV005 is intended for use in the electromagnetic environment specified below. The customer or user of the NV005 should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/O's	±2kV Mains ±1kV I/O's	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NV005 requires continued operation during power mains interruptions, it is recommended that the NV005 be powered from an uninterruptible power supply or a battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V 0.15 MHz-80 MHz 6 V[1] in ISM between 0.15 MHz and 80 MHz[2] 80 % AM at 1 kHz	3 V 0.15 MHz-80 MHz 6 V[1] in ISM between 0.15 MHz – 80 MHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

1) r.m.s. before modulation is applied.
2) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

Guidance and Manufacturer's Declaration – Immunity to RF wireless communications equipment ME Equipment and ME Systems

Guidance and Manufacturer's Declaration – Immunity
The NV005 is intended for use in the electromagnetic environment specified below. The customer or user of the NV005 should ensure that it is used in such an environment.

Test Frequency	Band [1]	Service [1]	Modulation [2]	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
385	380 - 390	TETRA 400	Pulse modulation [2] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM [3] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation [2] 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [2] 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [2] 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [2] 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation [2] 217 Hz	0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[1] For some services, only the uplink frequencies are included.

[2] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[3] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.