

Use of the NEUROVISION™ EMG MONITORING ENDOTRACHEAL TUBE

Intended Use:

The Neurovision™ EMG Monitoring Endotracheal Tube is intended to provide an open airway for patient ventilation while monitoring continuously for EMG activity and status assessment of the nerves supplying the laryngeal musculature. The tube may be used in connection with the Nerveäna® or any compatible EMG monitoring system with 42802 DIN compatible connectors.

Indications for Use:

For continuous EMG monitoring and status assessment of the nerves supplying the laryngeal musculature as well as providing an open airway for patient ventilation during surgical or parasurgical care using any compatible nerve monitoring system.

⚠ Warnings:

- Paralyzing agents, including anesthetic lubricants or topical sprays, may impair or reduce EMG responses rendering monitoring unreliable.
- Do not subject a patient with an implanted electronic device to electrical stimulation unless a medical specialist has first been consulted.
- Intubation beyond 24 hours is not recommended. Replace with a standard Endotracheal Tube if ventilation is needed beyond this period.
- Do not use flammable gases, high temperature generating devices or electro surgical electrodes when using an EMG stimulator to avoid combustion.
- Do not use cautery while stimulator is in contact with tissue or in surgical fields to avoid patient burns.
- Do not use if sterile package has been opened or is damaged.
- Cuff should be inflated slowly filling the minimum amount of air necessary to provide an effective tracheal seal.
- Cuff pressure and volume should be monitored regularly for any significant change. Deflation or an increase in pressure due to gas diffusion could injure the patient.
- Do not use a Neurovision™ EMG Monitoring Endotracheal Tube with a high electrical impedance measurement.
- Do not excessively bend the Neurovision™ EMG Monitoring Endotracheal Tube electrodes in order to maintain electrical integrity. Check electrode integrity after insertion.
- Do not connect electrode lead wires to any other types of equipment besides EMG recording/monitoring equipment in order to avoid electrical shock to the patient or user.
- Do not over inflate the Endotracheal Tube cuff, as this may damage the ET tube and cause blockage or airway damage.
- Do not remove an inflated Endotracheal Tube cuff from the trachea, as this may injure the larynx or vocal cords.
- Do not re-sterilize or reuse single use disposable devices. Device materials are not designed for re-sterilization and may result in device disintegration or patient infection.
- When using a stylet, verify that it does not protrude from the patient end or Murphy eye.
- Avoid insertion of a suction tube or stylet in a tube that has been distorted in any way. This has the potential to damage the Endotracheal Tube and cause airway blockage.
- Do not perform Magnetic Resonance Imaging (MRI) when using a Neurovision™ EMG Monitoring ET Tube.

Precautions:

- Communication between the surgeon and anesthesia provider is recommended to confirm expectations for pharmacological effects on neuromuscular activity.
- Clinicians should have experience with Intraoperative Neurophysiologic Monitoring if using the Neurovision™ EMG Monitoring Endotracheal Tube.
- Choose tube size in accordance with accepted clinical methods.
- Check cuff integrity and function of inflation system prior to use by filling slowly with air and then completely deflating.
- Check the patency of the main tube lumen after testing the cuff and prior to intubation.

Precautions Continued:

- Always inspect the tube, cuff, and monitoring connections for damage during insertion. Discard and replace if any damage occurs.
- Seat the connector firmly into the ventilator tube and verify it is secure. A swivel adaptor may be used.
- Confirm breath sounds along with correct placement of tube and proper ventilation of lungs.
- Confirm correct positioning and secure tube to eliminate movement out of position.
- Proper placement of the electrode recording area is critical. Review instructions for use prior to intubation.
- Deflate the cuff prior to repositioning the tube.
- Support the tube to avoid kinking where it makes contact with the teeth.
- Avoid injury by disposing of the devices in an appropriate sharps biohazard container.
- Avoid injury by using extreme care when handling and cleaning instruments with sharp points or edges.

Recommendations:

- Be aware that false negative responses may arise from over stimulating the nerve, deep anesthesia, poor electrode placement resulting in lack of contact between electrode and vocal cords or dislodgement of electrode placement while moving patient.
- A bite block is recommended when using the Neurovision™ EMG Monitoring Endotracheal Tube to prevent tube damage.

Limited Warranty:

Neurovision™ Medical Products, Inc., Warrants the Neurovision™ EMG Monitoring Endotracheal Tube to be free from problems in material or factory workmanship for one year at the shipment date.

To be eligible for this warranty the product must be used as indicated on product labeling and be unaltered or modified. The product must be accompanied by its packaging with the lot number and expiration date.

The manufacturer's obligation under this warranty is limited to replacing products provided that they are returned to Neurovision™ Medical Products, Inc., within one year of the original date of purchase. A handling/postage charge will be assessed. Customer must obtain an RMA number from Neurovision™ Medical Products' corporate offices prior to returning any products.

Neurovision™ Medical Products, Inc. expressly disavows any medical liability for the proper or improper use of this device. This liability rightly resides with the surgeon alone.

This warranty does not apply (*is void*) to any Neurovision™ EMG Monitoring Endotracheal Tube which has been repaired in any way or modified by unauthorized personnel, in the judgment of Neurovision™ Medical Products, Inc.

The foregoing warranty is in lieu of all other warranties express or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose or warranties arising from a course of dealing or usage of trade. NVM reserves the rights to change, amend, or modify any or all of the items under this warranty.



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Cobra® EMG Monitoring Endotracheal Tube Two Channel



Description:

Neurovision™ EMG Monitoring Endotracheal Tubes are made of polyvinyl chloride (PVC) and are available in various sizes. Each tube has a radiopaque stripe, ventilator tube connector, and a silver recording surface designed to record the activity of the vocal cord musculature when connected to an electromyographic (EMG) device. Each tube is sterilized by ethylene oxide (EO).



i Cobra® EMG Monitoring Endotracheal Tube Instructions for Use

Reliable performance of Cobra® electrodes requires proper positioning. Please read and follow all instructions.

Caution: use of paralytics inhibits EMG nerve monitoring.

Preparation:

1) Choose the appropriate Endotracheal Tube size:

Endotracheal Tube ID Size	Cobra® Electrode Item Code
6.0mm	LTE700DCS
7.0mm	LTE700DCM
8.0mm	LTE700DCL

2) Prior to intubation, test the cuff by slowly filling with a Luer tip syringe. Remove syringe from valve and check that cuff and inflation system retain air. Reattach syringe and remove all air from cuff.



Intubation*:

1) A small amount of water-based lubricant, may be applied to the electrode. Do not use petroleum-based lubricants. Use of a stylet is recommended for proper placement. Intubate using currently accepted medical techniques. Insert the Endotracheal Tube under direct vision or with a video laryngoscope so that each vocal cord is touching its respective silver electrode stripe. (fig. 1)

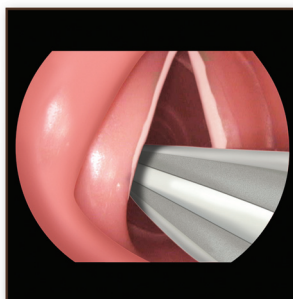


Figure 1



Figure 2

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

- 2) Tape the Endotracheal Tube securely with 2 pieces of tape by wrapping each piece first around the tube and then securing to the upper lip. (fig. 2) A Bite Block may also be used to secure the tube.
- 3) Inflate the cuff with the minimum amount of air necessary to create an effective tracheal seal.
- 4) After final positioning of patient, align Endotracheal Tube in the middle of the pharynx behind the tongue. The posterior portion of the Endotracheal Tube should be directly opposite the central maxillary incisor gap at the depth number noted after initial positioning.

5) Tightly secure the ventilator circuit so the Endotracheal 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. Support the tube to avoid kinking where it makes contact with the teeth.

6) Attach the pairs of red and blue electrode lead wires to the + and - terminals of the EMG recording device and apply the EMG ground and stimulator return electrodes to the sternum as shown in Figure 3.

* Intubation beyond 48 hours is not recommended. Replace with a standard Endotracheal Tube if ventilation is needed beyond this period.

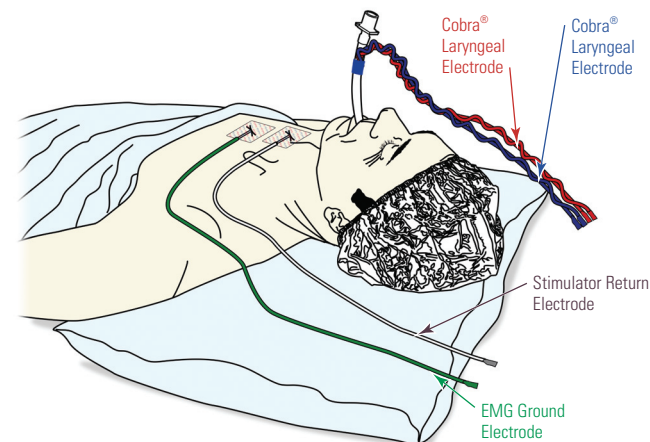


Figure 3

Extubation:

Extubate only after complete deflation of the cuff with a Leur tip syringe.

