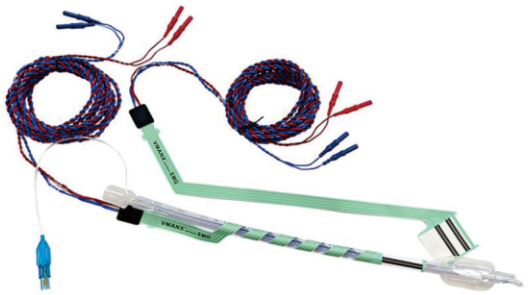
Specification Sheet for Medical Laryngeal Electrode Film Sensor



1. Product Overview & Keywords

- EMG-Laryngeal Surface Electrodes are a high-precision, single-use electromyography (EMG) laryngeal electrode film sensor manufactured using advanced electronic printing technology.
- This product is specifically designed for Intraoperative Neuromonitoring (IONM).
  It is primarily used in thyroid, parathyroid, and other neck surgeries to monitor
  the functional integrity of the Recurrent Laryngeal Nerve (RLN) and the Superior Laryngeal Nerve in real-time. It is a key medical device for preventing postoperative complications such as hoarseness and breathing difficulties.

ISO13485

ISO9001

IATF 16949

2. Product Core Keywords

- Intraoperative Neuromonitoring (IONM)
- Recurrent Laryngeal Nerve (RLN)
- Electromyography (EMG) Sensor
- Laryngeal Electrode Film
- Single-use Electrode
- Biocompatible
- Thyroid Surgery
- Nerve Integrity Monitoring
- Surface Electrode
- Visualized EMG Signals

3. Electrical Performance Parameters

Parameter Item	Specification	Test Conditions / Notes
Electrode Contact Impedance	≤ 2 kΩ	Measured in standard saline solution at 1kHz frequency
Operating Frequency Range	10 Hz - 10 kHz	Suitable for EMG signal acquisition
Common Mode Rejection Ratio (CMRR)	≥ 110 dB	Typical value, ensuring interference immunity
Baseline Noise	≤ 5 μV	Input shorted, bandwidth 10Hz - 10kHz
Maximum Input Voltage	±5 V	-
Signal Sensitivity	100 - 5000 μV adjustable	Must be matched with acompatible IONM main unit
Cable Length	Standard 2.5m (customizable)	With standard interface (e.g., DIN, D-sub)
Insulation Resistance	≥ 100 MΩ	500 VDC

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4. Working Mechanism

The sensor operates based on electromyographic principles.

- Signal Acquisition: When surgical instruments approach, retract, or stimulate the recurrent laryngeal nerve during surgery, the nerve generates electrical impulses.
- Muscle Response: These electrical impulses are conducted to the innervated laryngeal muscles (e.g., thyroarytenoid muscle), causing muscle contraction and generating weak electromyographic (EMG) signals (typically at the microvolt level).
- Signal Capture: The product is affixed to the surface of the endotracheal tube (ETT) cuff. Its biocompatible conductive ink-printed electrodes precisely capture these weak EMG signals generated by the laryngeal muscles.
- Signal Transmission: The captured analog electrical signals are transmitted via the integrated high-shielded cable to the connected IONM system main unit.
- Signal Processing & Feedback: The IONM main unit amplifies, filters, and converts the signals into visualized waveforms and audible audio feedback, providing real-time information to the surgeon and anesthesiologist. This enables continuous monitoring of nerve function and early risk warning.

5. Instructions for Use (Brief Steps)

- Preparation: Remove the sensor from its sterile packaging. Ensure the packaging is intact and the product is within its expiration date.
- Electrode Installation: Aseptically and smoothly wrap the film sensor around the cuff area of the selected endotracheal tube (ETT). Ensure the electrode contacts have full contact with the cuff surface, with the cable oriented toward the patient's oral end.
- Cable Securement: Use the provided adhesive tape or follow hospital standard operating procedures to properly secure the sensor cable along the ETT to prevent intraoperative displacement.
- Connection to Main Unit: Connect the sensor cable interface to the corresponding channel of the IONM system's Patient Interface Box, ensuring a firm connection.
- Cuff Inflation: Inflate the ETT cuff following routine procedures. As the cuff expands, it presses the electrodes on the film sensor firmly and stably against the patient's mucosal tissue near the vocal folds.
- System Check: Perform a system self-test or impedance check on the IONM main unit to confirm all electrode channels are connected properly and impedance values are within the acceptable range.
- Intraoperative Monitoring: Once surgery begins, set appropriate parameters on the IONM main unit to monitor EMG signals in real-time.

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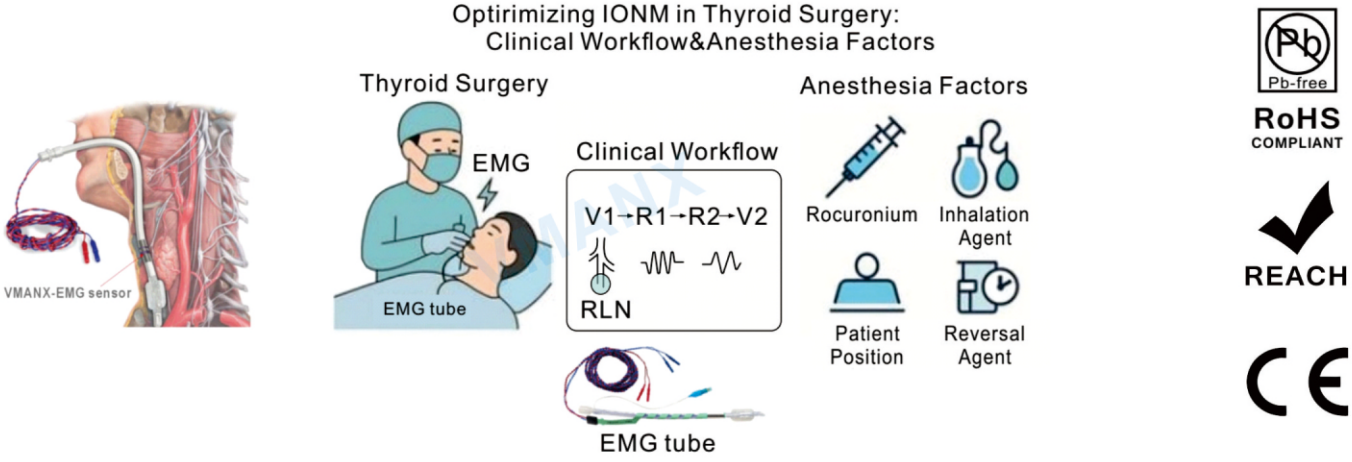
6. Precautions & Warnings

- Single-Use Only: This product is a single-use sterile medical device. Reuse is strictly prohibited. Reuse carries the risk of cross-contamination and device performance failure.
- Sterile Condition: Inspect the packaging for damage before use. If the packaging is compromised, the sterile integrity of the product may be breached, and it should be discarded immediately.
- Compatibility: Before use, verify that this sensor is compatible with the model of endotracheal tube and the IONM main unit system you are using.
- Correct Installation: Ensure the electrode film is installed smoothly without wrinkles, allowing for even mucosal contact after cuff inflation. Improper installation may lead to poor signal quality or monitoring failure.
- Avoid Sharp Objects: Avoid scratching the film electrodes and leads with fingernails or sharp instruments during handling and installation.
- Patient Safety: Exercise care during insertion and removal of the endotracheal tube to prevent accidental injury to the patient's airway from the sensor.
- Post-Procedure Disposal: Used products should be disposed of according to medical waste regulations.

7. Quality & Compliance

- Quality Management System: VMANX designs and manufactures this product under a quality management system certified to ISO 13485 (Medical Devices Quality Management System) and IATF 16949 (Automotive Quality Management System, applied for high-reliability electronic components).
- Regulatory Compliance: The product complies with the European Union Medical Device Regulation (EU MDR 2017/745) and the US FDA 21 CFR Part 820 Quality System Regulation requirements.
- Biocompatibility: All patient-contacting components of the product have passed biocompatibility tests required by the ISO 10993 series standards (e.g., cytotoxicity, sensitization, irritation) and are safe and reliable.

8. Product Usage Schematic



Application scenario diagram

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