Instructions for use of NEURO-PULSE™ Surgical Nerve Locator REF 0003

ILLUSTRATION

WARNING: DO NOT USE IN THE PRESENCE OF FLAMMABLE GASES/MATERIALS OR IN OXYGEN RICH ENVIRONMENTS. FIRE COULD RESULT.

WARNING: THIS PRODUCT IS STERILIZED UTILIZING ETHYLENE OXIDE. THESE PRODUCTS CAN EXPOSE YOU TO CHEMICALS INCLUDING ETHYLENE OXIDE (ETO), WHICH IS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER AND/OR BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM. FOR MORE INFORMATION GO TO **WWW.P65WARNINGS.CA.GOV**.

Caution: Use 0.5 mA initial setting. Limit nerve locator contact to one (1) second maximum.

After removing the Neuro-Pulse™ (See Illustration) from its sterile package, remove the rubber band that holds the wire in place, and the white foam from the probe and needle.

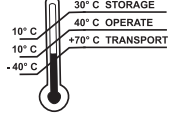
IMPORTANT: Test the unit by touching the probe and needle together. If properly functioning, this should activate the LED in the rear of the unit. After each change in the mA setting, it is recommended that this initial test be repeated.

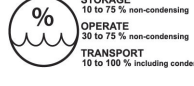
Insert the positive ground (the needle) into subcutaneous tissue near the proposed operative site. When the probe contacts exposed tissue, and the ground needle is in place, the LED indicator located at the back of the instrument will light. This shows that the circuit is completed through the tissue and the instrument is operative.

The LED indicator DOES NOT let the surgeon know when it has located a nerve, only that the circuit has been completed.

The Muscle Response is the indicator that an exposed nerve has been located.

Select the amperage by rotating the probe index until the marker is near aligned with the desired output setting, and the **engagement is felt**. Use the 0.5 mA setting initially. If the muscle does not respond, increase the amperage output as required. The 2 mA setting may be required to achieve muscle response in larger nerves.





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NOTE: Since normal muscle response is instantaneous, nerve contact should not be for more than one second. This instrument is not designed to determine the degree of viability of a nerve. It is only for identifying exposed motor nerves.

Medical Purpose / Indication
The intended use of the Nerve Locator is to identify the general location of exposed motor nerves while at the same time reducing the possibility of accidental nerve damage or severance.

Operating Principle
Nerve Locator is surgically invasive and is intended for transient use. The units are compact and portable and have three power settings (0.5 mA, 1.0 mA, 2.0 mA at 3.0 V). The yellow or red LED illuminates when the needle and probe comes in contact with tissue to indicate the device is active. The LED indicator DOES NOT let the surgeon know when a nerve has been located, only that the circuit has been completed. The Muscle Response is the indicator that an exposed nerve has been located.
These are single-use devices and are contraindicated for use at or around the heart or the central circulation system. They are further contraindicated for use in the presence of flammable gases and materials.

Patient Population
- No restriction

Site of Use and Site Conditions
- Site of use – No restrictions
- Site Condition – Aseptic

Intended User Profile
- Education
  - Trained medical professional
- Knowledge
  - Read and understand the supplied IFU
  - Understands hygiene
- Experience
  - Some training on techniques or training under surveillance/supervision
- Permissible Impairments
  - Mild reading/vision impairment or corrected vision to 20/20

Intended Conditions for Use
- Environment
  - Physician Procedure Room, Surgery center or Hospital, intended for professional use only
  - Sterile medical device
  - Single patient use
- Conditions of visibility
  - Clear and unobstructed view of point of use
  - Hand-Held
- Frequency of Use
  - Single Use - Single patient multiple activation
- Mobility
  - Hand-Held

IMPORTANT: After use, use proper disposal method.