

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

Symbol	Symbol Title
	Manufacturer
	Authorized representative in the European Community
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using ethylene oxide
	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
	Do not re-use
	Consult instructions for use
	Caution

For a complete guide of ISO standards visit: www.iso.org/obp

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 <i>*icon may also appear in black, meaning does not change</i>
	WEEE Directive Mark: do not dispose, collect separately <i>IS EN 50419:2006</i>
IP31	IP Classification: Protected against solid foreign objects of ≥ 2.5 mm. Protection against vertically falling water drops.
Other / Unique Marks to Neurovision Medical Products	
Symbol	Symbol Title
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	European Conformity mark
	Not made with natural rubber latex

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nerveäna®

Muting Sensor

Instructions For Use



Neurovision Medical Products
353 Sanjon Road
Ventura, CA 93001 USA
tel: (866) 815-6999
fax: (877) 330-1727
neurovisionmedical.com

Australian Sponsor
Emergo Australia
Level 20 Tower II
Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia

DESCRIPTION:

Muting Sensor is an accessory to Nerveäna® which provides muting of the free-run ('CHIRP') alarm during use of electrocautery.

INSTRUCTIONS FOR USE:

1. Check Muting Sensor battery by pressing button labeled 'TEST' on front of device. LED should be green.
If LED is yellow or red, replace three AAA batteries (slide back cover off to remove batteries). (See Figure 1)



Figure 1

2. Use garment clip to secure Muting Sensor near active lead of electrocautery cable.
3. Insert active lead of electrocautery cable into groove on front of Muting Sensor.
4. Secure cable in place by rotating oval latch to cover wire in groove. (See Figure 2)



Figure 2

5. Locate port for fiber optic cable on end of Muting Sensor, remove gray protective plug, if needed, and insert cable. (See Figure 3)



Figure 3

6. Insert other end of fiber optic cable into 'MUTING IN' port on rear panel of Nerveäna® (directly below the USB connector). (See Figure 4)

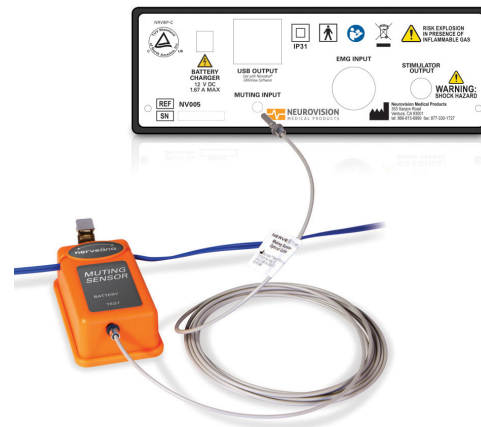


Figure 4

7. Turn on Nerveäna® and rotate free-run ('CHIRP') knob to appropriate detection threshold.
8. Confirm proper muting of chirp alarm with first use of electrocautery.
Muting Sensor silences chirp alarm while monopolar electrocautery is detected.
9. After use, wipe Muting Sensor and cable with disinfectant wipes. Keep all moisture out of inside of device.

INDICATIONS FOR USE:

Nerveäna® nerve locator and monitor is intended for use in intraoperative nerve monitoring using electromyography (EMG) and electrical stimulus of motor nerves.

Muting Sensor is intended for use when muting of the free-run ('CHIRP') alarm is desired.

WARNINGS:

- Product is for use by a licensed physician only.

PRECAUTIONS:

- Inspect device for defects prior to use and discard if any defects are found.
- Do not sterilize Muting Sensor or fiber optic cable.
- Do not immerse Muting Sensor or cable in any fluids.
- Do not crimp fiber optic cable when storing or handling.
- Do not roll any equipment over the fiber optic cable.
- Do not position Nerveäna® or Muting Sensor near electro-surgical generator.
- Do not place bipolar electrocautery cables in groove of Muting Sensor.

RECOMMENDATIONS:

- Clinicians should have experience with Intraoperative Neurophysiologic Monitoring.
- Contact Neurovision Medical Products, Inc. for any questions concerning the care or use of this product.



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