natus

Reusable EMG Disc Electrodes

Instructions for Use:

Natus Neurology Incorporated
3150 Pleasant View Road
Middleton, Wisconsin 53562 USA
Tel: +1 608-829-8500
Website: natus.com

EC REP EU Representative / Importer
Natus Manufacturing Limited
IDA Business Park
Gort, Co. Galway, Ireland

CE **Rx only**

Associated product part numbers:

6030-TP, 6030-3-TP and 019-401200

Description:

Reusable EMG Disc Electrodes are used to assess the propagation properties of normal and diseased nerves. Electrodes are expected to maintain a continuous connection for monitoring electromyogenic and physiologic data signals.

Intended Use:

Reusable EMG Disc Electrodes are used in neurodiagnostic testing in conjunction with electrodiagnostic equipment for recording electromyographic (EMG), electroencephalographic (EEG), evoked nerve potentials (EP) and electronystagmographic (ENG) signals.

Intended User and Target Patient Group:

The product is for use only under the direction of trained medical professionals in acquiring electrophysiologic signals.

Clinical Benefits:

Facilitates obtaining an EMG recording to detect any irregularities indicative of muscle disorders.

Contraindications and Side Effects:

There are no known contraindications or side effects for procedures performed with the Natus Reusable EMG Disc Electrodes. See Warnings or Precautions below.

Operating Instructions:

- Prepare the skin prior to application making sure that the site is clean and dry.
- Prepare the skin with alcohol or an abrasive agent. Place a small amount of conductive gel in the desired area.
- Apply the electrode to the patient's skin, making sure to place even pressure across the electrode.
- A Velcro® strap or adhesive tape can be used to hold the electrode in place.
- Connect the electrode to an amplifier using the appropriate connector.
- Check that clear, strong signals are being transmitted following connection.

Cleaning Instructions:

- Clean with a commercial wipe such as CaviWipes™ or Sani-Cloth® to remove visible soil.
- Wipe the article using a lint-free cloth and air dry.

Understanding Cautions Statements:

⚠ **CAUTION**
Refers to a hazardous situation that could result in minor or moderate injury or material damage if not avoided. • Information on how the hazardous situation is avoided.

Warnings and Precautions:

⚠ **CAUTION**
Device dropped or damaged in transit/use could lead to loss of function or delayed diagnosis. • Inspect the device prior to each use and do not use if damaged.
Improper usage of Electrode can lead to Data loss. • Users should check signal quality before and after connection of EMG electrodes.

⚠ CAUTION
Excessive force applied to electrode may cause skin damage or redness. • Avoid excessive force on the electrode when applying and during use.
Prolonged electrode use can cause patient skin redness or damage. • Periodically check for patient skin redness due to electrode, and either stop using the electrode or move the electrode to a new location.
Modifications to the device can affect function and performance. • Do not modify this equipment without authorization of the manufacturer.

Environmental Specifications:

Operating Conditions:

- Temperature: +10°C (+50°F) to +30°C (+86°F)
- Relative Humidity: 20% to 80%
- Pressure: 70 kPa to 106 kPa

Storage Conditions:

- Temperature: 0°C (+32°F) to +30°C (+86°F)
- Relative Humidity: 20% to 80%
- Pressure: 50 kPa to 106 kPa

Disposal Instructions:

Natus is committed to meeting the requirements of the European Union WEEE (Waste Electrical and Electronic Equipment) Regulations 2014. These regulations state that electrical and electronic waste must be separately collected for the proper treatment and recovery to ensure that WEEE is reused or recycled safely. In line with that commitment Natus may pass along the obligation for take back and recycling to the end user, unless other arrangements have been made. Please contact us for details on the collection and recovery systems available to you in your region at natus.com

Electrical and electronic equipment (EEE) contains materials, components and substances that may be hazardous and present a risk to human health and the environment when WEEE is not handled correctly. Therefore, end users also have a role to play in ensuring that WEEE is reused and recycled safely. Users of electrical and electronic equipment must not discard WEEE together with other wastes. Users must use the municipal collection schemes or the producer/importers take-back obligation or licensed waste carriers to reduce adverse environmental impacts in connection with disposal of waste electrical and electronic equipment and to increase opportunities for reuse, recycling and recovery of waste electrical and electronic equipment.

Equipment marked with the below crossed-out wheeled bin is electrical and electronic equipment. The crossed-out wheeled bin symbol indicates that waste electrical and electronic equipment should not be discarded together with unseparated waste but must be collected separately.

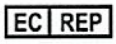
Disclaimer:

Natus Medical Incorporated is not responsible for injury, infection or other damage resulting from the use of this product.

Any serious incident that has occurred in relation to the device should be reported to Natus Medical Incorporated and the competent authority of the Member State in which the user and/or patient is established.

Refer to the Natus website for an electronic copy of this document.

Glossary of Symbols:

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
Medical Device	-	-	An indication of Medical device	This product is a medical device.
Rx only	21 CFR Part 801.109(b)(1)	Labeling-Prescription devices.	Prescription only	Indicates the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1 Symbol 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Symbol 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	ISO 15223-1 Symbol 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Symbol 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Batch or Lot code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Symbol 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Date of manufacture	Indicates the date when the medical device was manufactured.
 natus.com	ISO 15223-1 Symbol 5.4.3 Annex A #A.15	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Consult instructions for use	Indicates an instruction to consult an electronic instructions for use (eIFU).
	ISO 60601-1 Table D.2 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use	Refer to instruction manual/ Booklet. NOTE on ME EQUIPMENT "Follow instructions for use"
	ISO 15223-1 Symbol 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 60601-1 Table D.1 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	ISO 15223-1 Symbol 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Temperature limit	Indicates the (storage) temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Symbol 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Humidity limitation	Indicates the range of (storage) humidity to which the medical device can be safely exposed.
	ISO 15223-1 Symbol 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Symbol 5.4.5 (Reference Annex B for the general prohibition symbol)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Not made with Natural Rubber Latex	Indicates a medical device that is not made with natural rubber latex.
	2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)	Disposal at end of operating life instructions	Indicates that electrical and electronic equipment waste should not be discarded together with unseparated waste but must be collected separately.

Product Part Numbers	Product Description
6030-TP	10mm diameter, 1.0m (39"), (1.5mm DIN), 1 pair/pkg
6030-3-TP	10mm diameter, 1.0m (39"), (1.5mm DIN), 1 pair/pkg
019-401200	30mm diameter, 0.75m (30") lead, (1.5mm DIN), 1/pkg

017W078 Rev 05 10/2020