Nicolet Comfort Probes

Instructions for Use:

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Associated product part numbers:

515-016300 and 515-018800

515-016300 RS10 Kit consists of RS10 Comfort Probe, EMG Stimulus Probe Holder, EMG Probe Mount, Adult Angled Stimulus Head for Comfort Probes, Adult Straight Stimulus Head for Comfort Probes, Touch Proof Stimulus Head for Comfort Probes and Wing Nut.

515-018800 WR50 Kit consists of WR50 Comfort Plus Probe, EMG Stimulus Probe Holder, EMG Probe Mount, Adult Angled Stimulus Head for Comfort Probes, Adult Straight Stimulus Head for Comfort Probes, and Touch Proof Stimulus Head for Comfort Probes.

Description:

Bipolar Stimulation Probes

The Nicolet Comfort Probes are bipolar stimulation probes which are accessories to Electrodiagnostic testing systems during NCS/EMG/EP electrical stimulation procedures. These stimulation probes are used to apply bipolar electrical stimulation current to the patient's skin. A convenient Probe Holder (071-422900) is provided with the Comfort Probes.

Comfort Probe RS10 (515-016300) The Comfort Probe provides electrical stimulation using the Nicolet EMG software interface, control panel or footswitch. It is compatible with Nicolet EDX® and VikingQuest systems. It is also compatible with Natus UltraPro S100 system when using an adaptor cable (included in Comfort Probe RS10 kit, part 842-695000).	 Comfort Probe
Comfort Probe Plus WR50 (515-018800) The Comfort Probe Plus provides the ability to control stimulation through buttons and a wheel located on the probe. The user may start/stop stimulation, adjust stimulation intensity, change stimulation duration, activate the next trace, and switch stimulus polarity directly from the probe. It is compatible with the Nicolet EDX system.	 Comfort Probe Plus

Probe Heads

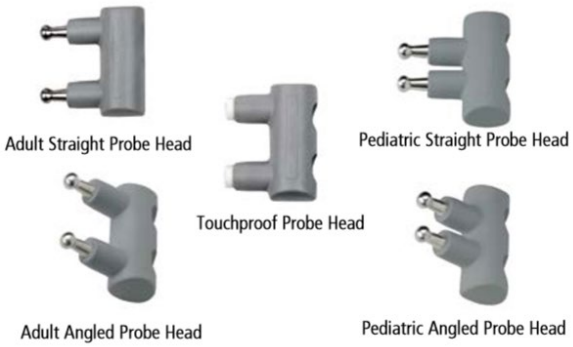
A range of stainless steel stimulus probe heads are available for use with the Nicolet Comfort Probes.

Adult Probe Heads (071-423500 and 071-423600) have 0.8" (20 mm) spacing between tips.

Pediatric Probe Heads (071-423700 and 071-423800) have 0.4" (10 mm) spacing between tips.

Angled Probe Heads (071-423600 and 071-423800) are angled between the tip and probe connector.

The Touchproof Probe Head (071-500600) has 0.8" (20 mm) spacing between tips and is used to connect external electrodes for stimulation.



Intended Use:

The Nicolet RS10 and WR50 Comfort Probes are reusable, non-sterile probes intended to be used as an accessory to Electrodiagnostic testing systems during electrical stimulation procedures. The probes are used to apply bipolar electrical stimulation to the patient's skin.

Intended Users and Patient Target Group:

The bipolar stimulation probes are intended for use by skilled physicians and technologists trained in the specialty of Electrodiagnostic testing.

The target patient population is the pediatric and adult patient population requiring NCS/EMG/EP electrical stimulation procedures.

Clinical Benefits:

Bipolar stimulation probes are useful accessories during NCS/EMG/EP electrical stimulation procedures. Usage of the probes during such diagnostic procedures is at the discretion of the clinical provider.

Contraindications and Side Effects:

There are no known contraindications or side effects for procedures performed with the Nicolet RS10 Comfort Probe and the WR50 Comfort Probe Plus.

Operating Instructions for Bipolar Stimulation Probes:

- Select a probe head and insert the probe head securely into the connection points on the probe.
- Connect the probe to the EMG system at the probe connection on the system base.
- Prepare the stimulation site prior to application making sure that the site is clean and dry.
- Place the probe tips at the patient site making sure to place even pressure across the stimulating probe tips.
- Initiate the stimulus.
- Check that clear, strong signals are being transmitted following connection.

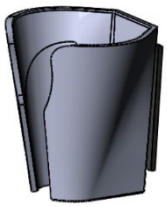
For additional detailed instructions on using the Comfort Probe bipolar stimulation probes, please refer to the user guide for the corresponding EMG system.

Operating Instructions for Probe Holder:

The 071-422900 Probe Holder is provided with the Comfort Probes for convenience. To mount the Probe Holder:

- Select a suitable flat surface for mounting the Probe Holder. The selected area should be clean and dry.
- Remove the protective strip from the adhesive (tape) on the back of the Probe Holder.
- Press the Probe Holder firmly into place.

- Allow the tape's glue to dry for at least 1 hour.

	
071-422900 Probe Holder	WR50 Comfort Probe Plus Mounted in Probe Holder

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.
- The cleaning procedure must be in accordance with your local facility's guidelines. The user/operator shall clean the device after every use.
- The stimulation probe and probe heads cannot be sterilized.

Understanding Warnings and Cautions Statements:

WARNING

Refers to a hazardous situation that could result in death or serious injury if not avoided.

- Information on how the hazardous situation is avoided.

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:

WARNING

System components immersed or in contact with liquids may cause electrical shock.

- Do not immerse, drip, or spray liquids onto the device.

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.

Device when used by untrained user could lead to patient injury, incorrect diagnosis or delayed diagnosis.

- This device is intended to be used by qualified healthcare professionals.

Unauthorized modification, servicing or use of non Natus approved supplies or components could lead to loss of device function or performance.

- Do not modify device or use unauthorized accessories supplies or components.

Environmental Specifications:

Operating Conditions:

- Temperature: +15.6°C (+60°F) to +32.2°C (+90°F)
- Relative Humidity: 20% to 80% (non-condensing)
- Altitude: 0 to 10,000 ft (0 to 3 km)

Storage Conditions:

- Temperature: -17.7°C (0°F) to +55°C (+132°F)
- Relative Humidity: 10% to 90% (non-condensing)
- Altitude: 0 to 35,000 ft (0 to 10.668 km)

Compliance Standards:

- ISO 10993-1: 2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ETS 300 019-2-1 Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-1: Specification of environmental tests; Storage
- ETS 300 019-2-2 Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-2: Specification of environmental tests; Transportation
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems for Vibration
- IEC 60601-1:2005+A1:2012+Cor1:2014 - General Safety Ed. 3.1
- IEC 60601-1-2:2014 – EMC Fourth Edition

- IEC 60601-2-40:2016 – Particular requirements for the basic safety and essential performance of electromyography and evoked response equipment
- IEC 60601-1-6:2013 – Collateral Usability

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
MD	-	-	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.
EC REP	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.
REF	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.
LOT	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.
	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 60601-1 Table D.2 #2	Medical electrical equipment — Part 1: General requirements for basic safety and Essential performance.	General warning sign	Indicates a hazard of potential personal injury to patient or operator.
	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.
QTY	-	-	Quantity	Number of parts in a package.
	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.
CH REP	Swiss Medical Device Ordinance (MedDO)	Swiss Medical Device (MedDO).	Indicates the Authorized Representative in Switzerland	Indicates the Authorized Representative in Switzerland.
UK CA	UKCA Medical Device Regulation (SI 2002 No 618, as amended) (UK MDR 2002)	UKCA Medical Device Regulation.	UKCA Mark	In compliance with the United Kingdom technical conformity.
CE	EU Medical Device Regulations 2017/745	EU Medical Device Regulation.	CE marking	Signifies European technical conformity.

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