Nicolet EMG Tubal Insert Phones

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

CH REP Arazy Group Switzerland GmbH
Bruderholzallee 53
4059 Basel
Switzerland
swiss.ar@arazygroup.com

UK CA Natus Nicolet Uk Ltd
Baynards Green Trading Estate
Prospect House
Oxfordshire
Bicester
OX27 7SG
England, United Kingdom

CE **Rx only** LATEX

Associated product part numbers:

041-704000 and 085-746400

1 package of 041-704000 contains Impedance Probe Adapters, three red and three blue silicone tubes, two clips with Velcro® loop pads and disposable foam ear tips (fifty regular, four jumbo and ten baby ear tips).

1 package of 085-746400 contains 1 pair of cables with a DIN connector.

Description:

Nicolet Reusable Tubal Insert Phones 300 Ohm (or TIP300) are used as auditory evoked potential stimulators to present acoustic stimuli through the ear tips. The stimulus is presented to patients who are undergoing diagnostic assessment of the auditory pathways in clinical environments or during surgical procedures.

The Tubal Insert Phones are used with disposable foam ear tips, available in three sizes:

- ER3-14B – infant (10 mm)
- ER3-14A – regular size (13 mm)
- ER3-14C – jumbo size (18 mm)

The complete kit also includes:

- Three red and three blue sound delivery tubes
- Specialized impedance probe adapters
- Two clips with Velcro® loop pads

The Tubal Insert Phone Replacement Cable (p/n 085-746400) is a 16’ (4.9 mm) cable with a 9-pin DIN connector that connects the Tubal Insert Phones to a Nicolet EMG system.

Intended Use:

Tubal Insert Phones are reusable, non-sterile transducers intended to be used as an accessory to Electrodiagnostic testing systems during Auditory Evoked Potential procedures. The Tubal Insert Phones are used to present acoustic stimulation to the patient’s auditory pathways.

Intended Users and Patient Target Group:

Tubal Insert Phones are intended for use by skilled physicians or technologists trained in the specialty of evoked potential testing.

The target patient population is the pediatric and adult patient population requiring auditory evoked potential testing in the clinical environment or operating room.

Clinical Benefits:

Tubal Insert Phones are useful during AEP testing for patients in the clinical and operating room environment. Usage of AEP Tubal Insert Phones for diagnostic purposes 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 Tubal Insert Phones.

Operating Instructions for the Tubal Insert Phones:

- Attach the open-ended side of the red sound delivery tube to the red transducer and the blue sound delivery tube to the blue transducer.
- Apply one of the clips with Velcro® loop pads to the back of the left transducer and one to the right transducer to form an open loop.
- Insert the black tubing of an ER3 foam ear tip completely onto the adapter of the sound delivery tube, one for each tube.
- Drape the ear inserts around the back of the neck to the front of the chest, with the red transducer at the right ear and the blue transducer at the left ear.
- Gently roll the foam ear tips to a small diameter. Insert the foam tips at the entrance of the ear canal and allow the foam to expand into place. Ensure that the ear tip securely fits into the ear.
- Connect the Tubal Insert Phone cables into the audio jack input: insert the blue/left stereo phone plug into the Left (L) jack and the red/right stereo phone plug into the Right (R) jack.

Operating Instructions for the Tubal Insert Phone Replacement Cable:

- Gently grasp the cable connector and remove it from the transducer by pulling gently. Select the same color cable connector (as the one removed). Firmly insert the new cable connector into the transducer housing socket until fully seated. Insure the color is correct: the blue replacement cable goes into the blue transducer and red replacement cable goes into the red transducer.

Cleaning Instructions:

- Disconnect the Tubal Insert Phones from the EMG system base before cleaning.
- 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.
- Tubal Insert Phones and Foam Ear Tips 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.
Reusing foam ear tips could lead to patient cross infection. • Foam ear tips are single use and should not be reused between patients.
Modification of the tube length could lead to evoked potential latencies resulting in misdiagnosis or delay in diagnosis. • Do not modify or cut the sound delivery tubing.
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.
	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.
	Swiss Medical Device Ordinance (MedDO)	Swiss Medical Device (MedDO).	Indicates the Authorized Representative in Switzerland	Indicates the Authorized Representative in Switzerland.
	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.
	EU Medical Device Regulations 2017/745	EU Medical Device Regulation.	CE marking	Signifies European technical conformity.

031618 Rev D 12/2022