Protektor32 Auditory Transducers

Instructions for Use:

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CE **Rx only**

Associated product part numbers:

005032 and 005562

Description:

Protektor32 Auditory Transducers provide acoustic stimulation for Auditory Evoked Potentials (AEP) during surgical procedures. Protektor32 Auditory Transducers are designed to be used specifically with the Protektor32 system. The Auditory Transducers are plugged into the base of the system and the stimulus characteristics are controlled by software operation of the system application.

Intended Use:

The Protektor32 Auditory Transducers are reusable, non-sterile transducers intended to be used as an accessory to IOM testing systems during Auditory Evoked Potential procedures. The Auditory Transducers are used to present acoustic stimulation to the patient's auditory system.

This device is intended to be used by qualified medical practitioners, trained in Electroencephalography, Evoked Potentials and Electromyography, who will exercise professional judgment when using the information.

Intended User and Patient Target Group:

The Protektor32 Auditory Transducers are intended for use by skilled 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 operating room or clinical environment.

Clinical Benefits:

Auditory Transducers are useful during AEP testing for patients in the operating room or clinical environment. Usage of Auditory Transducers 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 Protektor32 Auditory Transducers.

Operating Instructions:

Auditory Stimulation Headphones (005032)

- Place the Auditory Stimulation Headphones over the patient's ears. The headphone represented with red color shall be placed over the patient's right ear. The headphone represented with the blue color shall be placed over the patient's left ear.
- Connect the Auditory Stimulation Headphones cable into the Protektor32 system base at the Headphones connector.

Auditory Stimulation Ear Inserts (005562)

- Attach appropriately sized disposable foam ear tips to the Auditory Stimulation Ear Inserts at the black tip of each tube.
- Drape the Auditory Stimulation 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 tips to a small diameter. Place the foam tips at the entrance of the ear canal and allow the foam to expand into place. The foam tips are one-time use and must be discarded after each patient use.
- Connect the Auditory Stimulation Ear Inserts cable into the Protektor32 system base at the Headphones connector.

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.
System components immersed or in contact with liquids may cause electrical shock. • Do not immerse, drip, or spray liquids onto the device.
Device is sterilized which leads to loss of function. • Protektor32 Auditory Transducers cannot be sterilized.

Environmental Specifications:

Operating Conditions:

- Temperature: +10° (+50°F) and +40°C (+104°F)
- Relative Humidity: 30% to 75%
- Pressure: 700 hPa to 1060 hPa

Storage Conditions:

- Temperature: -40°C (-40°F) to +70°C (+158°F)
- Relative Humidity: 10% to 100%
- Pressure: 500 hPa to 1060 hPa

Compliance Standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-40 Requirements for the basic safety and essential performance of electromyographs and evoked response equipment
- CISPR 11:2015 - Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment
- CFR47 FCC Part 15, Subpart B:2016 - Radio Frequency Devices
- ICES-003, Issue 6:2016 - Information Technology Equipment (ITE)

- IEC 62304:2006 (First Edition) + A1:2015 – Medical Device Software
- IEC 62366: 2007 (First Edition) + A1: 2014 – Usability
- Medical Devices Directive (MDD) - 93/42/EEC
- ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

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 DBA Excel-Tech Ltd. (Xltek) 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 DBA Excel-Tech Ltd. (Xltek) 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 5.1.6	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.
	ISO 15223-1 Symbol 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 60601-1 Table D.1 #11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Operating instructions	
	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	Medical device does not contain 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.

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