



Nicolet LED Goggles

Instructions for Use:



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Rx only



Associated product part number:

842-106504

Description:

Nicolet LED Goggles are used as a visual stimulator to present flash stimuli via LEDs enclosed in Goggles. The flash stimulus is presented to patients who are undergoing diagnostic assessment of the ocular system in clinical environments.

Intended Use:

LED Goggles provide timed, visual stimuli for the purpose of generating Visual Evoked Potentials (VEP) from a patient. The VEP is a measurement of averaged waveforms acquired from the patient's scalp evoked through goggle stimuli. The resulting waveforms are used to determine the integrity of the visual neural pathways.

Intended Users and Patient Target Group:

The LED Goggles are intended for use by skilled physicians and technologists trained in the specialty of evoked potential testing.

The target patient population is the pediatric and adult patient population requiring visual evoked potential testing.

Clinical Benefits:

Goggles are useful during VEP testing for patients who may not be able to attend to a stimulus presented via a monitor, such as patients with behavioral disorders or infants and children. Usage of VEP goggles 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 LED Goggles.

Operating Instructions:



- Place the LED Goggles over the patient's eyes with one LED stimulator cup over each eye. Ensure that each eye orbit is sufficiently sealed to minimize exterior light from entering the eye area.
- Secure the LED Goggles band comfortably around the head.
- Connect the LED Goggles cable into the Nicolet EMG system base at the Goggles 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.
- The cleaning procedure must be in accordance with your local facility's guidelines. The user/operator shall clean the device after every use.

- LED Goggles 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.
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • Information on how the hazardous situation is avoided.

Warnings and Precautions:

 WARNING
System components immersed or in contact with liquids may cause electrical shock.
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • This device is intended to be used by qualified healthcare professionals.

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
- ISO 15004-2: 2007 Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection
- 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
	-	-	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.		
	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.

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.
	-	-	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.
	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.

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