OBM Neonatal Hydrogel Sensor

Instructions for Use:

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CE **Rx only**

Associated product part numbers:

OBM00042 and CZA00037

Description:

Natus OBM Neonatal Hydrogel Sensors are disposable surface electrodes used as a non-invasive method of conveying electrical signals from a patient to the Olympic Brainz Monitor or other amplifiers used for EEG, PSG, evoked potential, or EMG tests.

Intended Use:

The intended use of disposable surface recording electrodes is to stimulate or record the electrical activity to or from muscles and motor and sensory nerves during nerve conduction studies, evoked potential studies, or inter-operative monitoring.

Intended User and Target Patient Group:

The product may be used with neonatal patients or infants (defined as birth to 28 days post-delivery, and corresponding to a post-conceptual age of 24 to 46 weeks), under the direction of a physician.

Clinical Benefits:

Facilitates obtaining the recording of an EEG/PSG study to detect any irregularities indicative of various brain or sleep disorders.

Contraindications and Side Effects:

There are no known contraindications or side effects for procedures performed with Natus Neonatal Hydrogel Sensors. See Warnings or Precautions below.

Operating Instructions:

- Open the pouch just before use.
- Prepare the skin prior to application making sure that the site is clean and dry.
- Remove the electrode from its backing cloth.
- Apply to the patient making sure to place even pressure across the electrode.

Understanding Warnings and 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.
Device reused on another patient leads to cross infection or loss of performance. • Do not reuse or sterilize.
Data cannot be recorded due to improper placement leading to delay in procedure. • Assure proper connections and check signal quality before using.
Device left in place for prolonged periods of time may be associated with skin redness. • Do not use the device for prolonged periods of time.
Repositioning of sensor can degrade the signal quality. • Sensors should be replaced if the adhesive no longer provides a uniform connection to the skin surface.

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

Compliance Standards:

- ISO 10993: 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
- EN 60601-1:2006/A1:2013 and IEC 60601-1:2005/A1:2012 Ed. 3.1 clause 8.5.2.3

Disposal Instructions:

Following use, dispose of adhesive electrodes with infectious waste.

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 5.1.2	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.
	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 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 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Use-by date	Indicates the date after which the medical device is not to be used. Note: This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown.
	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 5.3.7	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 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	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.
	ISO 15223-1 Symbol 5.3.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Keep away from sunlight	Indicates a medical device that needs protection.

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