Natus Quantum® Breakout to Base Cable

Instructions for Use:

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CE **Rx only** LATEX

Associated Product Part Numbers:

013414 and 013348

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Description:

The Natus Quantum® Breakout to Base Cables consist of Medical Grade Cable and Plastic Self-Latching Connectors providing security against shock or pull on the cable. It connects the breakout box to the Natus Base Unit.

The Natus Quantum Breakout to Base Cable is available in two convenient length options:

- PN 013414: 16 ft (5 m)
- PN 013348: 33 ft (10 m)

Intended Use:

The Natus Quantum Breakout to Base Cable is intended to be used as an accessory with Natus breakouts such as Quantum to connect the breakout box to the Natus Base Unit.

Intended Users and Patient Target Group:

The Natus Quantum Breakout to Base Cable is intended to be used by trained medical professionals and is designed for use in clinical environments such as hospital rooms, epilepsy monitoring units, intensive care units, and operating rooms. It can be used with patients of all ages but is not designed for fetal use.

Clinical Benefits:

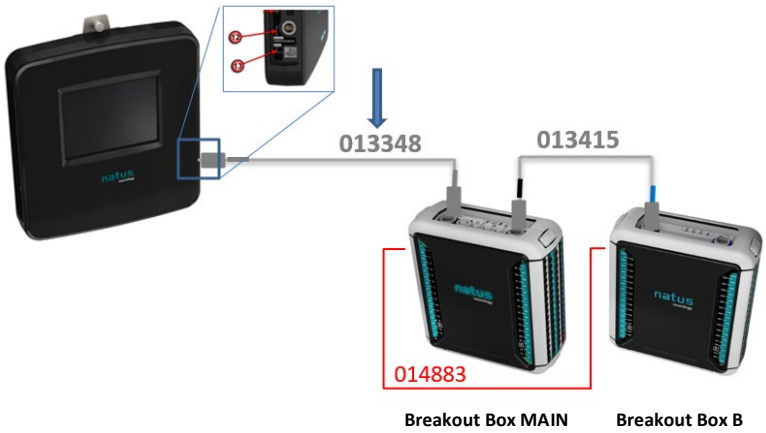
The Natus Quantum Breakout to Base Cable is a mandatory item for NeuroWorks®/SleepWorks™ to record EEG and Sleep data amplified in the breakout through Base Unit. It does not have clinical benefit itself, but it is needed to take advantage of the clinical benefits of the amplifier device.

Contraindications and Side Effects:

There are no known contraindications or side effects for using the Natus Quantum Breakout to Base Cable.

Operating Instructions:

Connect the Breakout Box such as Quantum(*) to Natus Base Unit with the Breakout to Base Cable PN 013414 or PN 013348 as shown in the picture.



(*) Other Natus breakouts can be connected as well: Natus Brain Monitor, Natus Brain Monitor iX, and Embla Dx.

Cleaning Instructions:

1. Clean with a commercial wipe such as CaviWipes™ or Sani-Cloth® to remove visible soil.
2. Wipe the article using a lint-free cloth and air dry.
3. The cleaning procedure must be in accordance with your local facility's guidelines. The user/operator shall clean the device after every use.

Understanding Warning and Caution 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

Misaligned connector pins may lead to damage of system components at power-on.

- Refer to the Natus Quantum User and Service Manual for connection diagrams.

⚠ CAUTION
Device dropped or damaged in transit or use may lead to loss of function. • Inspect the device before each use and do not use if damaged.
Unauthorized modification or servicing could lead to loss of device safety, function, or performance. • Do not perform any unauthorized modifications.

Environmental Specifications:

Operating Conditions:

- Temperature: +10°C to +30°C (+50°F to +86°F)
- Relative Humidity: 30% to 75%
- Atmospheric Pressure: 700 hPa to 1060 hPa

Storage Conditions:

- Temperature: -25°C to +60°C (-13°F to +140°F)
- Relative Humidity: 10% to 95%
- Atmospheric Pressure: 500 hPa to 1060 hPa

Compliance Standards:

- ISO 10993-1: 2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ETSI EN 300 019-2-1 Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-1: Specification of environmental tests; Storage
- ETSI EN 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 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: 2014 – EMC Fourth Edition: Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests, 4th Edition

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:

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.

Instructions to Access the eIFU:

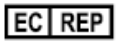
A copy of the Instructions for Use in PDF format is in the associated product area:

- Neurology: https://neuro.natus.com/neuro-support

Search for “Natus Quantum Breakout to Base Cable IFU” (refer to the Product Part Numbers) and choose the version for your local language for the instructions to use.

The files can be printed, saved, or searched using Adobe Reader. A copy of Adobe Reader can be downloaded directly from Adobe Systems (www.adobe.com).

Glossary of Symbols:

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
Medical Device	Not applicable	Not applicable	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 that the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	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 that the medical device 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 5.1.1	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 5.1.3	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 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	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 5.4.3 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).

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	IEC 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	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.
	IEC 60601-1 Table D.1 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
	IEC 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.
	MDR 2017/745	EU Medical Device Regulation	CE marking	Signifies European technical conformity.
	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 5.3.9	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Atmospheric pressure limitation	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Swiss Medical Device Ordinance (MedDO)	Medical Device Ordinance SR 812.213	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 (SI 2002 No 618, as amended) (UK MDR 2002)	UKCA Mark	Signifies United Kingdom technical conformity.