Natus Quantum® Patient Event Button

Instructions for Use:

Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario, L6H 5S1 Canada
Tel: +1 905-829-5300
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 **UK Responsible Person**
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:

013762 and 013891

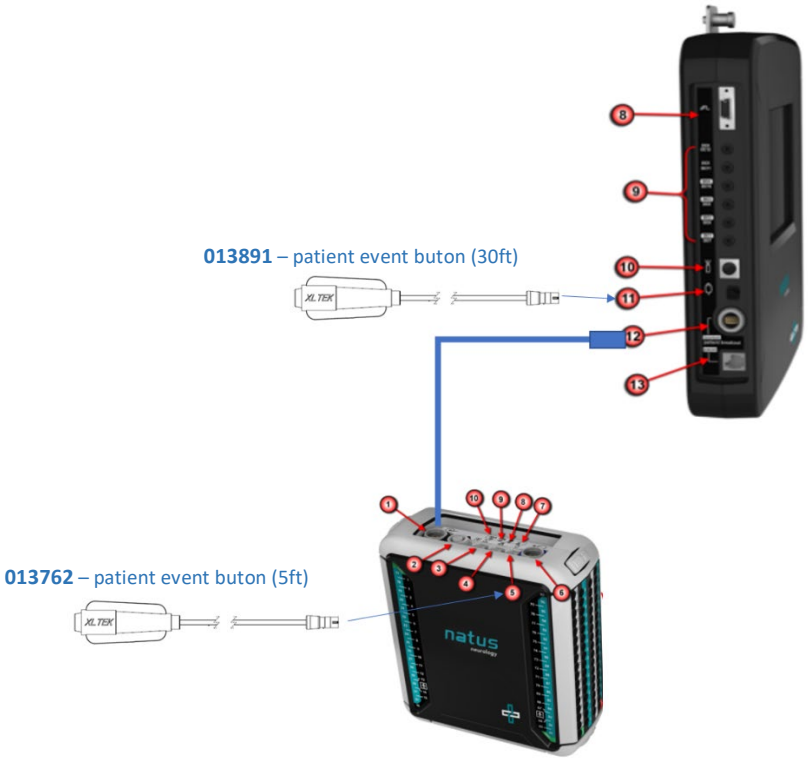
034408-EN_03 03/2022

Description:

The Natus Quantum® Patient Event Button provides patient feedback during EEG and sleep studies using the Natus NeuroWorks®/SleepWorks™ platform. When the button is pressed during a study, a notification is marked in the EEG recording and is captured as part of the overall study and included in the test results and report.

The Natus Quantum Patient Event Button is available in two convenient length options:

- PN 013762: 5 ft (1.5 m)
- PN 013891: 30 ft (9.1 m)



Patient Event Button PN 013762 connects to the breakout box and it convenient for use by the patient when carting the breakout box in the pouch.

Patient Event Button PN 013891 connects to the base unit and it convenient for use by either the patient or the medical staff when located close to the patient bed.

Intended Use:

The Natus Quantum Patient Event Button is intended to be used as an accessory with Natus hardware such as Quantum, Natus Brain Monitor, Embla Dx, and Natus Base to mark an event while recording EEG, Sleep, or LTM studies with NeuroWorks/SleepWorks software.

Intended Users and Patient Target Group:

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

Clinical Benefits:

Feedback from the Natus Quantum Patient Event Button allows healthcare professionals to compare what the patient feels or what is seen by others to what the EEG shows at the same time. This information can be useful criteria in interpretation of the test results. Usage of the Patient Response Button is for diagnostic purposes is at the discretion of the clinical provider.

Contraindications and Side Effects:

There are no known contraindications or side effects for using the Natus Quantum Patient Event Button.

Operating Instructions:

Ensure the Natus Quantum Patient Event Button is accessible to the patient or caregiver by: placing the wand in the patient's hands, placing it within reach on the bedside or side table, or inserting into an external slot on the patient-worn amplifier pouch.

Instruct the patient or caregiver to press the red pushbutton on the Patient Event Button wand as needed.

Note:

In the Quantum Breakout Boxes (MAIN and B) and Natus Base Unit, Patient Event Button connection is labeled with  . Refer to the Quantum User and Service Manual for more information.

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:

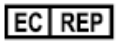
A copy of the Instructions for Use in PDF format is in the associated product area:

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

Search for “Natus Quantum Patient Event Button 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.
CH REP	Swiss Medical Device Ordinance (MedDO)	Medical Device Ordinance SR 812.213	Indicates the Authorized Representative in Switzerland	Indicates the Authorized Representative in Switzerland.
UK CA	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.