Natus Quantum® 10-10/10-20 Pin Box

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

EU Representative / Importer
Natus Manufacturing Limited
IDA Business Park
Gort, Co. Galway, Ireland

Associated Product Part Numbers:
017048

Copyright © 2021 by Natus Medical Incorporated. All Rights Reserved. All product names appearing on this document are trademarks or registered trademarks owned, licensed to, promoted or distributed by Natus Medical Incorporated, its subsidiaries or affiliates.

CaviWipes is a trademark of Metrex Research, LLC. Sani-Cloth is a registered trademark of PDI, Inc.

Description:

The Natus Quantum® 10-10/10-20 Pin Box is a passive inbox replacing standard touch-proof connector pin boxes on a Quantum Breakout Box. It provides convenient connection for electrodes placed according to the International 10-20 or 10-10 placement scheme.

The 10-10/10-20 Pin Box features 32 additional referential inputs and 8 inputs that can be used either as individual referential inputs or four bipolar channels.
**Intended Use:**

The Natus Quantum 10-10/10-20 Pin Box is intended to be used as an accessory with the Natus Quantum Breakout Box to provide to the EEG technician an input layout according to the 10-10 and 10-20 input scheme during routine EEG or LTM studies with NeuroWorks® software.

**Intended Users and Patient Target Group:**

The Natus Quantum 10-10/10-20 Pin Box 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:**

This Natus Quantum 10-10/10-20 Pin Box provides easier connection of the electrodes during preparation of routine studies using the 10-10/10-20 scheme. The 10-10/10-20 Pin Box replaces the standard pin boxes with numerical channel numbers, and its graphical layout reflects directly the position of the electrode on the brain surface.

**Contraindications and Side Effects:**

There are no known contraindications or side effects for using the Natus Quantum 10-10/10-20 Pin Box.
Operating Instructions:

1. Connect the 10-10/10-20 Pin Box (#2 in the image below) to the Quantum Main Breakout (#1 in the image below) by seating and locking (#3 in the image below) the larger pin box module into place.

2. Once the larger pin box module has been connected, seat (#4 in the image below) and lock (#5 in the image below) the smaller input module into position.

3. Create or select a Quantum montage that uses the 10-10 or 10-20 labels. Please refer to the NeuroWorks or SleepWorks user manuals for additional information on how to create or select the montage.

4. Ensure the 10-10/10-20 Pin Box is enabled in the NeuroWorks/SleepWorks software by selecting **Edit | Settings | Acquisition** (tab).

   **Note:**
   Additional Breakout Boxes can be added for additional channels. Refer to the section “Connecting the Breakout Boxes to the Natus Base Unit” of the Quantum User and Service Manual for additional information.
5. Activate the 10-10 module for the Quantum by selecting the checkbox next to 10-10 MODULE under the Pinboard Usage section.

**Note:**
Refer to the section “Quantum Breakout Boxes MAIN and B” of the Quantum User and Service Manual to learn more about connectors on the Breakout Box.

**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**

System components immersed in or in contact with liquid may cause electrical shock or damage the device.
- Do not immerse, drip, or spray liquid onto the device.

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 EN300 019-2-1 Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-1: Specification of environmental tests; Storage
- ETSI EN300 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

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. (Xlitek) 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 10-10/10-20 Pin Box IFU” (refer to the Product Part Number) 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:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Standard Reference</th>
<th>Standard Title</th>
<th>Symbol Title</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>An indication of Medical Device</td>
<td>This product is a medical device.</td>
</tr>
<tr>
<td><strong>Rx only</strong></td>
<td>21 CFR Part 801.109(b)(1)</td>
<td>Labeling-Prescription devices</td>
<td>Prescription only</td>
<td>Indicates that the product is authorized for sale by or on the order of a licensed healthcare practitioner.</td>
</tr>
<tr>
<td><img src="latex.png" alt="latex" /></td>
<td>ISO 15223-1 Symbol 5.4.5 (Reference Annex B for the general prohibition symbol)</td>
<td>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</td>
<td>Not made with natural rubber latex</td>
<td>Indicates that the medical device is not made with natural rubber latex.</td>
</tr>
<tr>
<td><img src="waste.png" alt="waste" /></td>
<td>2012/19/EU</td>
<td>Waste Electrical and Electronic Equipment (WEEE)</td>
<td>Disposal at end of operating life instructions</td>
<td>Indicates that electrical and electronic equipment waste should not be discarded together with unseparated waste but must be collected separately.</td>
</tr>
<tr>
<td><img src="manufacturer.png" alt="manufacturer" /></td>
<td>ISO 15223-1 Symbol 5.1.1</td>
<td>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</td>
<td>Manufacturer</td>
<td>Indicates the medical device manufacturer.</td>
</tr>
<tr>
<td><img src="representative.png" alt="representative" /></td>
<td>ISO 15223-1 Symbol 5.1.2</td>
<td>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</td>
<td>Authorized representative in the European Community</td>
<td>Indicates the Authorized representative in the European Community.</td>
</tr>
<tr>
<td><img src="date.png" alt="date" /></td>
<td>ISO 15223-1 Symbol 5.1.3</td>
<td>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</td>
<td>Date of manufacture</td>
<td>Indicates the date when the medical device was manufactured.</td>
</tr>
<tr>
<td><img src="serialnumber.png" alt="serialnumber" /></td>
<td>ISO 15223-1 Symbol 5.1.7</td>
<td>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</td>
<td>Serial number</td>
<td>Indicates the manufacturer's serial number so that a specific medical device can be identified.</td>
</tr>
<tr>
<td><img src="cataloguenumber.png" alt="cataloguenumber" /></td>
<td>ISO 15223-1 Symbol 5.1.6</td>
<td>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</td>
<td>Catalogue number</td>
<td>Indicates the manufacturer's catalogue number so that the medical device can be identified.</td>
</tr>
<tr>
<td><img src="consultinstructions.png" alt="consultinstructions" /></td>
<td>ISO 15223-1 Symbol 5.4.3 Annex A #A.15</td>
<td>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</td>
<td>Consult instructions for use</td>
<td>Indicates an instruction to consult an electronic instructions for use (eIFU).</td>
</tr>
<tr>
<td>Symbol</td>
<td>Standard Reference</td>
<td>Standard Title</td>
<td>Symbol Title</td>
<td>Explanation</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------</td>
<td>----------------</td>
<td>--------------</td>
<td>-------------</td>
</tr>
</tbody>
</table>
| ![Symbol](83x650 to 115x679) | 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" |
| ![Symbol](83x567 to 115x589) | 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. |
| ![Symbol](85x439 to 113x459) | IEC 60601-1 Table D.1 #10 | 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](88x392 to 110x420) | 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. |
| ![Symbol](86x335 to 112x361) | MDR 2017/745 | EU Medical Device Regulation | CE marking | Signifies European technical conformity. |
| ![Symbol](86x277 to 112x303) | 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. |
| ![Symbol](86x224 to 112x250) | 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. |
| ![Symbol](86x171 to 112x202) | 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. |

---

034418_02 03/2021