



## Natus External Battery Pack

### Instructions for Use:



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Rx only



### Associated Product Part Numbers:

PN	Description
021255	External Battery Pack with Packaging
019755	External Battery Pack Power Supply
019756	Quantum Ext Battery Cable

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

# **1 Introduction**

## **1.1 Description**

The Natus External Battery Pack is composed of three parts:

- The rechargeable external battery
- The power adapter used to recharge the external battery
- The Quantum cable that connects the battery pack to the Natus Quantum Breakout Box when it is used in ambulatory mode. The cable is connecting to the breakout box instead of the Breakout to Base cable.

The External Battery Pack includes LEDs that indicate the level of charge when the respective button is pressed.

## **1.2 Intended Use**

The External Battery Pack is intended to be used as an accessory with Natus EEG or Sleep breakouts such as Quantum<sup>®</sup> Amplifiers or Trex<sup>™</sup> HD Ambulatory Systems when these are used in ambulatory mode. It provides extended recording time.

## **1.3 Intended Users and Patient Target Group**

The External Battery Pack 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.

## **1.4 Clinical Benefits**

Extending the recording time during ambulatory EEG or Sleep studies allows more data to be collected. The clinical benefit for the patient is improved diagnosis.

## **1.5 Contraindications and Side Effects**

There are no known contraindications and side effects for using the External Battery Pack.

## **1.6 Essential Performance**

The External Battery Pack will ensure continuous operation of the breakout box when it is used in ambulatory mode. The user can swap battery packs to extend the recording time even further.

## 1.7 Operating Principle of the External Battery Pack

Prior to using the External Battery Pack with patients, the user shall ensure it is charged using the External Battery Pack Power Supply.

When transitioning to ambulatory mode, a charged battery pack is connected to the breakout box, which will store data in its internal memory.



### 1.7.1 Essential Performance Degradation

Professional healthcare personnel may observe essential performance degradation. In such cases, inspect these things:

- Cables
- External Battery Pack, specifically the Power IN/OUT connector
- Charge level after charging (as indicated in this manual)

If issues with these things or if unusual system behavior are observed, contact Natus Technical support.










## 1.8 Manual Conventions

Various symbols and typographical conventions are used throughout the manual. The following table illustrates them and describes their meanings and functions.

Symbol/Convention	Description/Function
	<b>Refers to a hazardous situation that could result in minor or moderate injury or material damage if not avoided.</b> <ul style="list-style-type: none"><li>• Information on how the hazardous situation is avoided.</li></ul>
	<b>Refers to a hazardous situation that could result in death or serious injury if not avoided.</b> <ul style="list-style-type: none"><li>• Information on how the hazardous situation is avoided.</li></ul>
	A note that contains important supplemental information.

Symbol/ Convention	Description/Function
<b>Bold</b>	Names of control keys, function keys, options, and labels are shown in bold. Bold text is also used to emphasize important names or ideas.
<i>Italic</i>	Italic text is used for captions.

## 2 Warnings and Precautions

	<p><b>Misaligned connector pins may lead to damage of system components at power-on.</b></p> <ul style="list-style-type: none"> <li>Refer to the Natus Quantum User and Service Manual for connection diagrams.</li> </ul>
	<p><b>Overcharging the battery may lead to fire, injury, or damage of the battery.</b></p> <ul style="list-style-type: none"> <li>Use only Quantum External Battery Pack Power Supply.</li> </ul>
	<p><b>Lack of proper ventilation while using the battery may lead to fire, injury, or damage of the battery.</b></p> <ul style="list-style-type: none"> <li>Charge battery only in clean, well-ventilated, non-hazardous locations.</li> </ul>
	<p><b>Unauthorized modification or servicing could lead to loss of device safety, function, or performance.</b></p> <ul style="list-style-type: none"> <li>Do not perform any unauthorized modifications.</li> </ul>
	<p><b>Cleaning the device while it is connected to an amplifier or a charger may cause electric shock.</b></p> <ul style="list-style-type: none"> <li>Disconnect the device before cleaning.</li> </ul>
	<p><b>Use of petroleum-based or acetone solutions, or other harsh solvents, to clean the system could lead to loss of device safety, function, or performance.</b></p> <ul style="list-style-type: none"> <li>Refer to the cleaning instructions.</li> </ul>
	<p><b>System components immersed or in contact with liquid may cause electrical shock or damage the device.</b></p> <ul style="list-style-type: none"> <li>Do not immerse, drip, or spray liquid onto the device.</li> </ul>
	<p><b>Device dropped or damaged in transit or use may lead to loss of function.</b></p> <ul style="list-style-type: none"> <li>Inspect the device before each use and do not use if damaged.</li> </ul>
	<p><b>Improper disposal of battery or its incineration may lead to injury or contamination of environment.</b></p> <ul style="list-style-type: none"> <li>Refer to the disposal instructions.</li> </ul>

### 3 Safety and Standards Conformity



#### 3.1 Standards of Compliance and Normative References

The External Battery Pack has been designed to comply with the following national and international standards.

**Table 1 – Safety Standard of Compliance and Normative References**

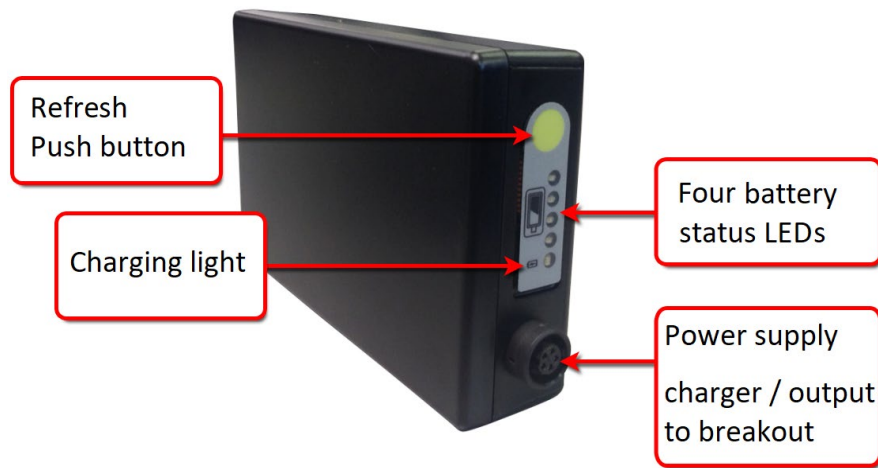
<ul style="list-style-type: none"> <li>• CAN /CSA-C22.2 No. 60601-1: 14(R2018)</li> <li>• ANSI/AAMI ES60601-1:2005/(R)2012</li> <li>• IEC 60601-1:2005 + C1:2006 + C2:2007 + A1:2012, Edition 3.1</li> <li>• CENELEC EN 60601-1:2006 + A1:2013</li> </ul>	<p>Medical electrical equipment – Part 1: General requirements for basic safety and essential performance</p>
<p>IEC 60601-1-2, Edition 4.0</p>	<p>Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– collateral standard: electromagnetic compatibility – requirements and tests</p>
<p>IEC 62133-2:2017</p>	<p>Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems</p>
<p>ISO 10993-1:2018</p>	<p>Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process</p>
<p>ETSI EN 300 019-2-1</p>	<p>Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-1: Specification of environmental tests; Storage</p>
<p>ETSI EN 300 019-2-2</p>	<p>Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-2: Specification of environmental tests; Transportation</p>
<p>ASTM D4169-16</p>	<p>Standard Practice for Performance Testing of Shipping Containers and Systems for Vibration</p>

## 4 Specifications: External Battery Pack

Specification	Value(s)
Size (cm)	7.0 x 12.1 x 2.5 (h x w x d)
Weight	<300g
LED Indicators	1 Charging Indicator; 4 Status Indicators
Capacity	Nominal 6.6AH
Charging Voltage	12 V
Charging Time	300 min (5 hrs)
Nominal Output Voltage	7.2 V
Certification	IEC-62133 and UL 2054
Environmental Specifications	
Operating Conditions	<ul style="list-style-type: none"> <li>• Temperature: +10°C to +30°C (+50°F to +86°F)</li> <li>• Relative Humidity: 30% to 75%</li> <li>• Atmospheric Pressure: 700 hPa to 1060 hPa</li> </ul>
Storage Conditions	<ul style="list-style-type: none"> <li>• Temperature: -25°C to +60°C (-13°F to +140°F)</li> <li>• Relative Humidity: 10% to 95%</li> <li>• Atmospheric Pressure: 500 hPa to 1060 hPa</li> </ul>
Symbol	Description
	External Battery Pack is charging.
	Power Pack charge status. This mark along with the four LEDs to the left of the Refresh Push Button will show state of charge of the battery. See <a href="#">External Power Pack LED Indicators</a> for charging details.

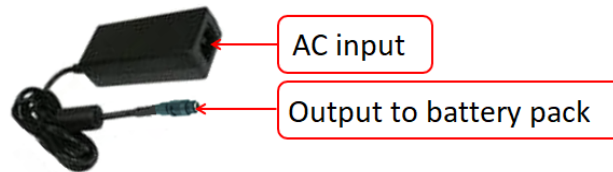
## 5 Product Images and Description

### 5.1 External Battery Pack



**Fig 1 – External Battery Pack**

### 5.2 External Battery Pack Power Supply



**Fig 2 – External Battery Pack Power Supply**

### 5.3 Trex HD and Quantum Breakout Box Cables

<p>Trex HD External Battery cable, PN 019727</p>	
<p>Quantum External Battery cable, PN 019756</p>	

## 6 Using the External Battery Pack

### 6.1 Charging the External Battery Pack

1. Inspect the power pack. If there are any cracks or damage, do not charge the power pack. Properly dispose of the power pack and replace.
2. Keep batteries and power supplies in a cool, well-ventilated location free of particulates or other airborne contamination.
3. Plug the power cord into an AC power source (110-220 V).
4. Insert the plug from the power supply into the connector on the power pack. Rotate the plastic sleeve to lock it in place. Charging will begin.
5. LEDs situated under the charging icon illuminate while charging and indicate the state of the charge. See [External Power Pack LED Indicators](#) for additional charging details.
6. Charging is complete when the amber LED changes to green.



The charging time to full capacity is approximately 5 hours.

### 6.2 External Power Pack and Charging Details

The battery provides approximately 500 charge/discharge cycles over the course of a two-year expected life. The life of the power pack will be significantly reduced if exposed to excessively high/low temperatures.

- Do not charge a power pack that is below 32°F (0°C). Allow battery pack to warm to room temperature first.
- Optimal power pack charging temperature is 68°F to 77°F (20°C to 25°C). Charging temperatures out of this range will reduce power pack life cycle and capacity.
- New power packs, or power packs that have been in storage for an extended period, should go through a charge-discharge-charge cycle prior to use, to calibrate the gas gauge.
- Operational time will be reduced when operated at environmental temperature extremes, and due to naturally occurring aging of the power pack.

### 6.3 Using the External Battery Pack While Recording in Ambulatory Mode

The External Battery Pack connects to the breakout box in ambulatory mode to provide extended study duration.



It is recommended that the power pack be charged to full capacity prior to each use.

The following scheme shows how the External Battery Pack provides power to the breakout box when ambulatory recording begins.



**Stationary /  
Connected mode**



**Stationary →  
Ambulatory  
transition**

1. Disconnect the breakout box from the Natus base unit (Quantum) or from the acquisition unit (Trex HD).
2. Connect a fully charged External Battery Pack to the breakout box using the appropriate cable.
3. Refer to the Quantum or Trex HD user manual for placement of the External Battery Pack in the respective Pouch.

**Ambulatory /  
Disconnected mode**



Natus Base Unit



When the External Battery Pack is providing power to the breakout box, the green external power LED light remains on.

**6.4 External Power Pack LED Indicators**

The percentage of remaining capacity of the power pack can be seen on the end of the unit while connected to the breakout box. The number of LEDs illuminated indicates power pack capacity.

If the power pack is being charged, the state of the charge will be indicated by the same four (4) LEDs.

Battery Status	Indicator Status
75~100%	Four lights
50~75%	Three lights
25~50%	Two lights
1~25%	One light
0%	No light
Charging In Progress	Amber charging light
Charging Complete	Green charging light

If the power pack is not connected to the breakout box, the power pack charge status can be viewed by pressing the Refresh Push Button.



**NOTE:** To preserve battery life, the LED status lights are designed to turn off while powering the breakout box and during storage. The indicators may be reactivated by pressing the Refresh Push Button.



**NOTE:** The External Battery Pack consumes a small charge while idle or in storage. It is recommended that the battery pack be used within 24 hours after it is charged to full capacity. A longer storage or idle time may reduce the battery life during operation.

## 6.5 Disconnecting the External Power Pack

To disconnect the power pack:

1. Rotate the plastic sleeve of the power supply cable to unlock it.
2. Remove the power supply plug from power pack connector.
3. Unplug the power cord from the wall.

## 6.6 Storing the External Power Pack

To maximize power pack capacity, store power packs connected to the power supply in a cool, dry area that is protected from exposure to hazardous contaminants. If desired, power packs can also be stored disconnected from the power supply.

## 7 Maintenance



Ensure that no cable is connected to it when the External Battery Pack is cleaned.

To keep the External Battery Pack in good working condition, follow a regular schedule of user performed maintenance. Regular maintenance performed by the user does not involve access to the interior of the External Battery Pack. For service problems that require corrective maintenance and/or internal component service, call Natus Technical Support or contact your local Natus representative.

### 7.1 Cleaning



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.

## 7.2 Disposal

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](https://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.



## 8 Troubleshooting

### 8.1 Troubleshooting Checklist

- Inspect your cables.
- Check the power to the External Battery Pack.

## 9 Disclaimer

Any serious incident that has occurred in relation to the device should be reported to Natus Medical Incorporated DBA Excel-Tech Ltd. (Xitek) 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.

## 10 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 External Battery Pack 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](http://www.adobe.com)).

## 11 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.
<b>Rx only</b>	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 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Serial number	Indicates the manufacturer's serial number so that a specific medical device 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.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	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).
	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.

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