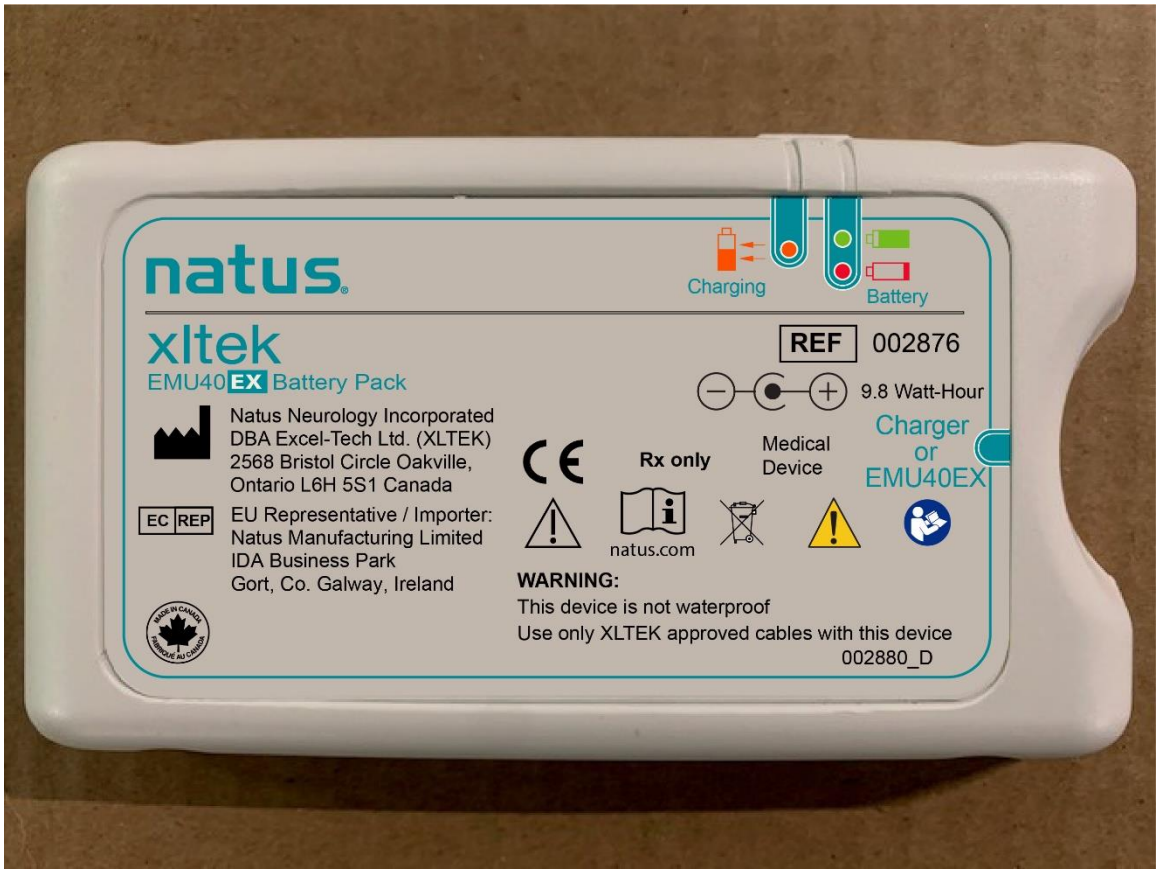
EMU40EX Battery Pack

User Manual



Publisher's Notice

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CE **Rx only** LATEX

Associated Product Part Numbers:

002874 and 002876

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TABLE OF CONTENT

WARNINGS AND PRECAUTIONS

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.

WARNING

System components immersed or in contact with liquids may cause electrical shock.

- The Battery Pack is classified as an IP0 – ordinary degree of protection against ingress of water according to IEC 529. The Battery Pack is not water proof. Prevent detergent solution or cold sterilization agents from seeping into the electronics of the system.

Battery pack stored by plugging into the charging source reduces the battery life.

- Do not store the battery pack plugged in to the charging source.

Cleaning the device while it is connected to an EMU40EX amplifier or a charger could lead to electric shock to the user.

- Do not clean the device when it is connected to an amplifier or a charger.

CAUTION

Unauthorized use of the battery pack can affect function and performance.

- Use with EMU40EX Breakout Box only.

Unauthorized modification of the battery pack can affect function and performance.

- Do not attempt to disassemble the Battery Pack. It does not have any serviceable parts.

⚠ **CAUTION**
Disposal of battery pack in the fire could lead to explosion. • Do not dispose the Battery Pack by burning.
Device used at higher temperature than the intended leads to functional failure. • Do not use the Battery pack under ambient temperature higher than +40C°.
Device exposed at higher temperature than the intended leads to functional failure. • Do not expose the Battery Pack to temperatures higher than +60C°. It may cause fire or permanent damage to the Li-ion battery.
Battery Pack completely discharged for a long time before storing could lead to failure of battery. • Do not keep the Battery Pack completely discharged for a long time. Optimal is to pre-charge it to 50~75% before storage (i.e. charge it for about 2 hours).
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.
Modifications to the device can affect function and performance. • Do not modify device or use unauthorized accessories supplies or components.

ABOUT EMU40EX BATTERY PACK

Thank you for purchasing the EMU40EX Battery Pack from XLTEK, one of the world's top manufacturers of neurodiagnostic equipment and software. XLTEK is an ISO13485 certified company committed to providing you with technologically advanced products that are practical and easy to use.

We encourage your feedback and suggestions regarding any aspect of the NeuroWorks system, documentation, accessories, and support services.

The Battery Pack for EMU40EX Breakout Box is a portable power source consisting of the following four parts:

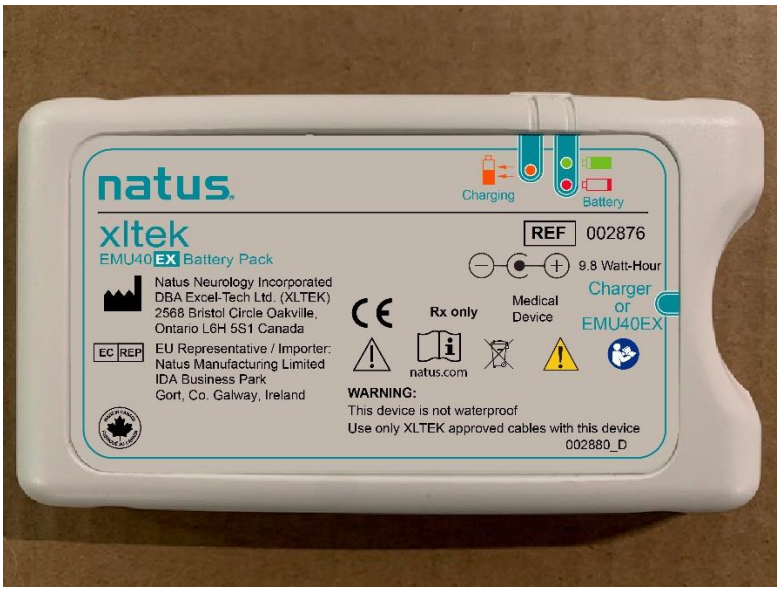

Fig.1. Battery Pack

Fig.2. USB Power Adapter

Fig.3. USB power Cable

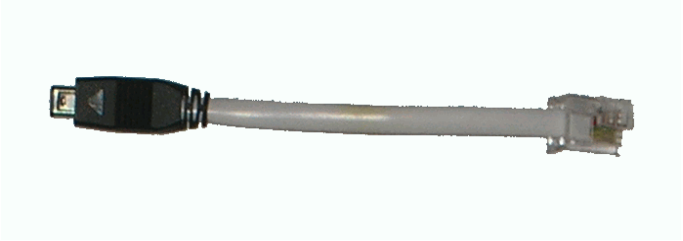

Fig.4. EMU40EX Power Cable

INTENDED USE

The EMU40EX Battery Pack is intended for use with EMU40EX Breakout Box only, which is used in combination with NeuroWorks®/SleepWorks™ software to allow a qualified medical practitioner trained in electroencephalography or polysomnography to acquire, display, archive, review, and analyze physiological signals. It can be used with patients of all ages, but it is not designed for fetal use.

INTENDED USERS AND PATIENT TARGET GROUP

The intended users of the EMU40EX battery pack are trained medical professionals or someone instructed by a trained medical professional. At minimum, it is expected that the user has a basic understanding of clinical EEG and PSG, conducting an EEG or PSG study, proficiency with computers and modern operating conventions. The user is typically trained on the use of the NeuroWorks/SleepWorks software to operate the system or conduct a study acquisition using the EMU40EX amplifier.

CLINICAL BENEFITS

The EMU40EX batter pack extends the period that a patient may be in an ambulatory position or not physically connected to an amplifier base through a cable to facilitate the continuous recording of a patient's physiological parameters.

CONTRAINDICATIONS AND SIDE EFFECTS

There are no known contraindications or side effects for procedures performed with the EMU40EX battery pack.

CHARGING THE BATTERY PACK

- Connect the Battery Pack (Fig.1) to USB Power Adapter (Fig.2) or to a computer USB port using USB Power Cable (Fig.3).
- Check that "Charging" **yellow light** is on. If **yellow light** is off, it means, that charger does not detect sufficient power and will not charge properly. Check cable connections and try again.
- Leave the Battery connected to the power source until continuous **yellow light** ("Charging") is turned off and continuous **green light** ("Battery") is turned on.
- Unplug USB Power Cable (Fig.4) from the Battery Pack. All lights should be off. The Battery Pack is now ready to use.

NOTE: Complete charging cycle may take about 3½ hours when using USB Power Adapter (Fig.2) and 5~6 hours when using PC USB port. Charging the Battery Pack from USB port is not recommended due to longer charging time.

USING THE EMU40EX HEADBOX WITH THE BATTERY PACK

- Connect Battery Pack (Fig.1) to EMU40EX Breakout Box using EMU40EX power cable (Fig.4).
- **Green light** ("Battery") will keep flashing as long as the battery is at least 20% full.
- When the Battery Pack is discharged to less than 20% of its capacity, flashing light "Battery" changes its color to **RED**. This is a warning for you to complete the study or to change the power source in less than 1 hour.
- Even after the Battery Pack is discharged and all lights are off, there may still be some power available stored in the internal battery of the EMU40EX Breakout Box.

USEFUL TIPS

- In order to check condition of the battery simply connect the EMU40EX Power Cable (Fig.4). There is no need to connect the headbox for this check. Three cases are possible:
  1. "Battery" LED is off the battery is completely discharged.
  2. "Battery" LED is flashing GREEN the battery is more than 20% full.
  3. "Battery" LED is flashing RED the battery is less than 20% full.
- Please do not leave EMU40EX Power Cable (Fig.4) plugged if you do not intend to use the Battery Pack for a long time. When the EMU40EX Power Cable is unplugged, the Battery Pack automatically enters low-power standby mode prolonging battery life.
- All lithium batteries are "perishable products". Their life expectancy is limited to 500 charge-discharge cycles or 5 years due to chemical degradation of active electrodes. You may see very slow degradation of the lithium cell performance even if it is not used.
- Lithium battery will last much longer when using more **shallow charge-discharge cycles** rather than **full-charge — full-discharge cycles.** Battery life in charge-discharge cycles is specified for the latter (worst) case. Use fresh or fully charged batteries before beginning a study.
- If you are not going to use Battery Pack for a few weeks or longer, **please pre-charge it approximately to 50~75%.** This is optimal for long-term storage. Do not store a totally discharged battery as this may render the battery pack inoperable.
- Do not continuously leave the battery pack charging. Overcharged cell leads to faster electrode degradation.
- If you need longer continuous operation two (or more) batteries can be used to prolong disconnected operation of EMU40EX headbox. This is limited by the memory storage capacity of the EMU40EX headbox.

MAINTENANCE

- The battery pack should not be immersed in water or any other fluid.
- Clean with a commercial wipe such as CaviWipes™ or Sani-Cloth® to remove visible soil or use a lint-free cloth dampened with tap water to wipe the surface area.
- Dry using a lint-free cloth and air dry.
- Do not allow any liquid or cleaning solutions to come into contact with the LED electronics, contacts, or connectors.
- Do not use alcohol-based or harsh abrasive cleaners.

SPECIFICATIONS

Battery technology ..... 3.7V, Single cell, Li-polymer
Equivalent Li content ..... 0.76g (for transportation regulations)
Electrical capacity ..... 2500~2700mAh
Energy capacity 9.8Watt-hours
Input charging voltage ..... 5~12VDC
Charging current ..... limited to 500~1000mA @ 4.2V
Charging time ..... 3½ hrs

Charge retention/storage > 80% at
- Humidity ..... 65±20RH
- -20 to +20°C ..... 1 year
- -20 to +45°C ..... 3 months
- -20 to +60°C ..... 1 month

Output voltage ..... 10.7±0.5VDC regulated
Output current ..... limited to <700mA
”Charging” indicator ..... yellow LED
”Battery” indicator ..... green/red LED
Operating Conditions
- Temperature ..... 10°C to 40°C (50°F to 104°F)
- Relative Humidity ..... 30% to 75%
- Atmospheric Pressure ..... 700 hPa to 1060 hPa

Storage Conditions
- Temperature ..... -40°C to 70°C (-40°F to 158°F)
- Relative Humidity ..... 10% to 100%
- Atmospheric Pressure ..... 500 hPa to 1060 hPa

Expected Cycle Life ..... >500 full cycles keeping >70% of initial capacity
Physical dimensions ..... 131×72×21mm (5.15”×2.8”×0.79”)
Weight 130g
Regulatory Compliance ..... RoHS, UL 1642, CSA 22.2 No. 601-1, IEC 601-1

COMPLIANCE STANDARDS

- ISO 10993-1: 2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- EN ETSI 300 019-2-1 Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-1: Specification of environmental tests; Storage
- EN ETSI 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
- UL1642 and IEC 62133-2:2017 Standard for Safety for Lithium Batteries
- IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Fourth Edition Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

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

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.

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 “EMU40EX Battery Pack User Manual” (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 5.1.6	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 5.1.7	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 5.4.3 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.

A Total Service Solution

Natus Systems are backed by a comprehensive & extendable warranty.

Our support team is available around-the-clock. Our technical staff provides phone and remote PC support, while our nationwide network of service engineers can be dispatched quickly when required.

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033980 Rev 1 03/2021