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Xltek® EMU40EX™
with Natus Base p/n 013926

User and Service Manual

Publisher's Notice

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XLTEK EMU40EX with Natus Base User and Service Manual

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Introduction

The XltekⓇ **EMU40EX™** amplifier is a powerful and flexible EEG recording system. This rugged device was designed with extensive clinical input to meet the workflow and application needs for diagnostic EEG and Long Term Monitoring (LTM).

EMU40EX records a total of 46 channels: 40 referential EEG channels, 4 DC input channels for supplemental signal transducers and 2 SpO2 and Pulse Rate channels from its internal pulse oximeter.

The **EMU40EX** data stream acquired by the **EMU40EX** amplifier system is reviewed, analyzed, and archived using a Natus **NeuroWorks**® workstation. Standard TCP/IP or USB connectivity is supported for quick and easy installation. The Natus base unit offers TCP/IP and USB connectivity for quick and easy installation. This rugged device was designed with extensive clinical input to meet the workflow and application needs of the EEG, LTM, or PSG Lab.

EMU40EX features include:

- 40 referential channels, 4 DC channels, and 2 pulse oximeter channels (Sp02 and Pulse Rate)
- Ability to initiate an impedance test, change the threshold and view the results in the patient room
- Ambulatory Mode maintains data acquisition upon disconnection of the patient data cable
- Automatic fall-over to internal storage of full-resolution data for up to two hours
- Live display of EEG waveforms remains available over a secure Bluetooth connection during Ambulatory Mode
- Data acquired on the Breakout Box while in Ambulatory Mode is transparently and seamlessly transferred to the Base Unit after resuming wired-mode operation
- Standard TCP/IP and USB connectivity to Natus **NeuroWorks**® workstations
- DC inputs on Base Unit to interface a wide variety of auxiliary signal transducers
- Two Patient Event Button Switch interfaces: one on the Breakout Box for patient use, and another on the Base Unit for family or staff
- Photic stimulator interface for diagnostic EEG
- Small, lightweight patient-connected Breakout Box – 3.9 x 6.2 x 0.9 in (10.0 x 15.8 x 2.3 cm) and 0.73 lb (333 g)
- Rugged and durable design for reliable operation in clinical and research environments

WARNING: We strongly recommend that you read the **Contraindications, Warnings and Cautions** section of this manual before operating this amplifier.

Product Intended Use

The XLTEK EMU40EX EEG Headbox is an electroencephalograph that works in conjunction with XLTEK NeuroWorks software.

The XLTEK EMU40EX EEG Headbox is used to acquire, digitize, store and transmit physiological signals (such as EEG, pulse and oximetry signals) for EEG studies in research and clinical environments.

The XLTEK EMU40EX EEG Headbox requires competent user input, and its output must be reviewed and interpreted by trained medical professionals who will exercise professional judgement in using this information.

System Components

The **EMU40EX** amplifier system is provided with optional system components. Computers are intended to run the NeuroWorks software exclusively. Cameras are intended to acquire synchronized video of the patient during long-term monitoring. Isolation transformers are intended to provide power for all system components while ensuring the safety of operators and patients. Carts are intended to support and facilitate the use of the **EMU40EX** amplifier while keeping the system mobile. Patient Event Switches are handheld pushbutton switches used by the patient (or nearby attendant) to signal a significant clinical event (e.g. an aura or the beginning of a seizure).

Essential Peformance

Essential performances of the EMU40EX amplifer are identified in the standard IEC 60601-2-26:2012. Essential performance relates to the quality of the signal recorded from the amplifier. Specific essential performances are (1) accuracy of signal reproduction, (2) dynamic range and differential offset voltage, (3) input noise level, (4) frequency response, and (5) common mode rejection. The defitions of these essential performances can be found in the standard.

The standard ISO 80601-2-61 also applies as the amplifier is considered pulse oximeter equipment without an alarm system. The additional essential performance required of the amplifier as laid out in this standard includes SpO2 and pulse rate accuracy, to be verified by an electronic patient simulator; and indication of abnormal operation, including notification of signal inadequacy and probe faults. Evidence of SpO2 accuracy by controlled desaturation study to be covered by the manufacturer of the pulse oximeter probe or sensor used.

Essential Peformance Degradation

Professional healthcare trained personnel will observe essential performance degradation which includes but are not limited to:

- Loss of EEG signal/data
- Amplifier saturation indication on the computer monitor,
- Intermittent bursts of noise on random EEG leads.
- Loss of communications from the computer to the Natus base
- Pinbox disconnected events. (Quantum)
- Interruptions in signal transmission resulting from external electromagnetic events. (Ex: Electrocautery, Operation of wireless equipment in close proximity to the amplifier, etc.)
- Any form or random or intermittent system behaviour.

If any of the above are observed or if unusual system behaviour is observed contact Natus Technical support.

Using the Manual

This manual provides basic information and instructions that will enable you set up and operate the **EMU40EX** amplifier. When going through the procedures, we recommend that you read the whole section first, before starting the sequence. Please follow the instructions carefully.

In addition to reading this manual, we encourage you to explore the online Help to enable you to take advantage of everything that ***XLTEK*** has designed the **EMU40EX** amplifier to do. More detailed instructions relating to the operation and customization of the system are provided in the online **Help**.

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
	This symbol denotes a **warning** or important information that should not be missed. Read all warnings and cautions carefully before starting the system for the first time.
	A **note** that contains important supplemental information.
Bold	Names of control keys, function keys, options, and labels are shown in bold. Bold text is also used to emphasize important names or ideas.
Italic	Italic text is used for captions.

EMU40EX Safety and Standards Conformity

Standards of Compliance and Normative References

Multichannel Sleep/EEG Amplifier System, Model **EMU40EX**, detachable cord connected, portable 115/230Vac, 50/60Hz, 30W.

1. Type of protection against electric shock: Class I
2. Degree of protection against electric shock: Type BF
3. Degree of protection against ingress of water: IPX0
4. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous
6. Environmental Conditions: Normal: 10-40°C, 30-75% rH, 700-1060hPa

The **EMU40EX** and its accessories have been designed to comply with the following national and international standards.

Table 1 – Safety Standard of Compliance and Normative References

CAN /CSA-C22.2 No. 60601-1: 08(R2013) + C2:2011 ANSI/AAMI ES60601-1:2005/(R)2012 + C1:2009/(R)2012 and A2:2010/(R)2012 IEC 60601-1:2005 + C1:2006 and C2:2007, Third Edition CENELEC EN 60601-1:2006 + A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010, Edition 3.0	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366:2007, Edition 1.0	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-26:2012, Edition 3 CENELEC EN 60601-2-26L2003, Edition 2	Medical electrical equipment – Part 2-26: Particular requirements for the safety of electroencephalographs
EN ISO 80601-2-61:2011, Edition 1	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Table 2 – EMC Standard of Compliance and Normative References

IEC 60601-1-2:2007, Edition 3.0	Medical electrical equipment – Part 1-2: General requirements for safety – collateral standard: electromagnetic compatibility – requirements and tests
IEC 61000-4-2:2008, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test
IEC 61000-4-3 ed 3.0 with A1:2007+A2:2010	Electromagnetic Compatibility (EMC) Part 4-3: Testing and Measurement Techniques - Radiated, Radio-frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4:2012, ed 3.0	Electromagnetic Compatibility (EMC) Part 4-4: Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5:2014, ed 3.0	Electromagnetic Compatibility (EMC) Part 4-5: Testing and Measurement Techniques - Surge Immunity Test
IEC 61000-4-6 ed 2.0 with A1:2004 + A2:2006	Electromagnetic Compatibility (EMC) Part 4-6: Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-frequency Fields
IEC 61000-4-8:2009, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
IEC 61000-4-11:2004, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-11: Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests
IEC 61000-3-2:2014, ed 4.0	Electromagnetic Compatibility (EMC) Part 3-2: Limits - Limits for Harmonic Current Emissions
IEC 61000-3-3:2013, ed 3.0	Electromagnetic Compatibility (EMC) Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
CISPR 11 ed 5.0 with A1:2010	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement

Declaration of Compliance for IEC 60601-1-2

Table 1 - Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The **EMU40EX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **EMU40EX** should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The **EMU40EX** uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The **EMU40EX** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 - Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The **EMU40EX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **EMU40EX** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250ec	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **EMU40EX** requires continued operation during power mains interruption, it is recommended that the **EMU40EX** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC supply voltage prior to application of the test level.			

Table 3 - Electromagnetic Immunity– for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The **EMU40EX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **EMU40EX** should assure that it is used in such an environment			
Immunity test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **EMU40EX**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \times \sqrt{P}$ 150kHz to 80MHz $d=1.2 \times \sqrt{P}$ 80MHz to 800MHz $d=2.3 \times \sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site[1] should be less than the compliance level in each frequency[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **EMU40EX** is used exceeds the applicable RF compliance level above, the **EMU40EX** should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the **EMU40EX**.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the EMU40EX.			
The **EMU40EX** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **EMU40EX** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **EMU40EX** as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter (W)	**Separation Distance according to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Declaration of Compliance for FCC

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Warning: Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Contraindications, Warnings, and Cautions

Contraindications

The Xltek EMU40EX with the Natus Base shall NOT be used in the following conditions:

	Do **NOT** operate the system in the presence of flammable anesthetics.
	Check areas of use to avoid using the system in the presence of flammable gases.
	To ensure the validity of signals, do not operate the device near any sources of electromagnetic interference.
	***Natus*** systems are not AP or APG rated. **DO NOT USE** a ***Natus*** system in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
	The **Xltek EMU40EX with the Natus Base** is **NOT** designed to work with defibrillators. The system could be damaged when used with this device.

Warnings and Cautions

General Warnings

NOTE: It is recommended that all data be stored using redundant storage capabilities. This can help to minimize data loss in the event of a failure of the primary drive.

	Proper use of this device depends on the careful reading of all instructions and labels that come with or on the system. Inaccurate measurements may be caused by incorrect application or use.
	The equipment/system is intended for use by trained users. Please read the manual before installing any of the hardware, and refer to the appropriate section when you operate, store or re-install the system.
	Only use the **EMU40EX** system in conjunction with approved devices and accessories. Use of cables other than those specified or sold by the manufacturer on the equipment, may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2007
	The amplifier base unit is classified as an IPx0 – ordinary degree of protection against ingress of water according to IEC 60529. The amplifier Breakout is classified as body worn and has an IPx1 rating while inside the pouch (-61) and meets IEC 60601-2-26 spillage requirement without the pouch. The **EMU40EX** system is classified as a class I device according to IEC 60601-1.
	The computer used with an **EMU40EX** system must either be approved by ***XLTEK*** and supplied as part of an IEC 60601 approved system, or it must be approved to IEC 60950 or similar and kept outside of the patient environment (that is, the area within 1.5 meters of the patient laterally and within 2.5 meters of the floor in the area occupied by the patient).
	**WARNING:** Third-party software installed on the acquisition computer may interfere with the operation of the Natus software. Please consult Natus Technical Support before installing third-party software on the computer.
	Never use equipment that has parts missing or equipment that might contain loose parts inside of it (that is, inside an enclosed portion of the equipment). If you suspect a piece of equipment has missing or loose parts, contact Natus. Routinely inspect system cables and components for regular wear and tear.
	Perform the recommended maintenance. Refer to the *Maintenance, Cleaning, & Disposal* section for details.
	Turn off all system power and disconnect the power cord from the system and the wall before attempting to clean the unit. Cleaning must be done very carefully. Do not allow any liquid to seep into any of the connectors or into the internal electronics of the system. Refer to the Maintenance, Cleaning, & Disposal section for details.

	The **EMU40EX** cannot be cleaned of bio-contaminate. Attempts to remove bio-contaminate will damage the unit.
	Device accessories may include several kinds of disposable, sterile needle electrodes. These needles are labeled as **STERILE**, and the method of sterilization is documented on the packaging. These electrodes should not be used if the sterile packaging has been tampered with.
	The sale, distribution, or use of this device is restricted to, by, or on order of a physician.
	Printers and/or peripherals used with ***XLTEK*** devices should be marked and approved for use in their appropriate medical environment in accordance with the regulations of the country in which they are used.
	Do not attempt to connect any third-party devices to the Patient Breakout Box except those approved by ***XLTEK***.
	Do not dispose of this medical product as unsorted municipal waste. At the end of an **EMU40EX**'s life, please contact ***XLTEK*** at 1-800-303-0306 in order to arrange return shipping for your **EMU40EX** amplifier.
	**WARNING:** No modification of this equipment is allowed.
	Operation of this equipment with input signals in excess of a range of +/-10mV may cause incorrect results.
	**REPETITIVE STRESS INJURY HAZARD:** Sustained use of this product without ergonomic consideration may result in repetitive stress injury.
	Do **NOT** position Medical Electrical equipment in such a way as to make it difficult to operate the disconnection device.

Electrical Warnings and Cautions

	***XLTEK*** systems are intended for connection to a properly grounded electrical outlet only. Ensure that the **EMU40EX** Amplifier System is solely connected to a three-wire, grounded, hospital-grade receptacle.
	Ensure that the **EMU40EX** Amplifier System is solely connected to a three-wire, grounded, hospital-grade receptacle.
	Conductive parts of electrodes and their connectors are not to contact other conductive parts and earth.

	Do not place MULTIPLE PORTABLE SOCKET-OUTLETS (MPSOs) on the floor.
	Do not connect additional MPSOs or extension cords to the **EMU40EX** Amplifier System.
	**ELECTRICAL SHOCK HAZARD:** Do **NOT** turn on the system power until all cables have been connected, verified and visually inspected for any damage. **Failure to inspect the cables may result in electrocution. Verification of electrical safety should be performed routinely.**
	**ELECTRICAL SHOCK HAZARD:** Do **NOT** service the system. Refer servicing to qualified personnel only. Do **NOT** use repaired components without proper testing.
	Do not use the MPSO with the **EMU40EX** Amplifier System for supplying power to any equipment that is not part of the system.
	**ELECTRICAL SHOCK HAZARD:** Do **NOT** connect electrode inputs to earth ground. The Patient Breakout Box contains warning symbols reminding you that the connections are intended for isolated patient connections only. Connecting to an earth ground might result in electrocution.
	**ELECTRICAL SHOCK HAZARD:** Do **NOT** service the system. Refer servicing to qualified personnel only. Do **NOT** use repaired components without proper testing.
	For the use of an ELECTROENCEPHALOGRAPH without protective means to prevent burning of the PATIENT, information on the location of the ELECTRODES is provided.
	Do **NOT** connect non-medical equipment which has been supplied as part of the system directly to the wall outlet when the system is supplied, via MPSO, with a separating transformer.
	To avoid the possible hazards caused by the summation of leakage currents when all the parts of the system are interconnected, no equipment other than devices connected to the EMU40EX Amplifier system may be powered by the isolation transformer.
	The current rating of the isolation transformer must be sufficient to operate all of the devices powered by it. Refer to the current ratings of the isolation transformer and current rating for each individual device connected.
	When replacing the fuse for the **EMU40EX**, it must be replaced by a fuse with the same type and rating as the original fuse. Replacement fuses should be purchased from Natus directly.
	The **EMU40EX** amplifier system is classified as a class I device according to IEC 60601-1.

	**WARNING: ELECTRICAL SHOCK HAZARD:** Do **NOT** turn on the system power until all cables have been connected, verified and visually inspected for any damage. Failure to inspect the cables may result in electrocution. Verification of electrical safety should be performed routinely.

Patient Environment Warnings and Cautions

NOTE: The patient environment is defined as the area within 1.5 meters of the patient laterally and within 2.5 meters of the floor in the area occupied by the patient.

	Connect all patient electrodes to fully electrically isolated devices only. Connecting patient electrodes to any other device or external outlet may result in personal injury.
	The Patient Breakout Box accepts only touch-proof style electrode inputs. Do **NOT** attempt to use any other style of patient electrode input.
	The Patient Event Switch attached to the Base Unit or Breakout Box is **NOT** intended for critical patient-safety-related incidents.
	If a computer is located in the patient environment and is connected to a network, a network isolator **MUST** be used.
	Do **NOT** touch any EMU40EX system accessible metal parts and the patient simultaneously.
	Do **NOT** touch any earth-grounded components of the EMU40EX system and the patient simultaneously.
	Connection of a patient to high-frequency surgical equipment and to electroencephalography equipment simultaneously may result in burns at the site of bio-potential input electrodes and possible damage to the biological amplifiers. Please consult the user documentation of the surgical equipment for instruction as to its proper use.
	As with all medical equipment, there is a risk of injury if the lanyard/belt and pouch(es) are used without ensuring they are secured to the patient properly. Refer to the *Adding the EMU40EX breakout box to a lanyard or belt* section for details.
	The EMU40EX Amplifier system does **NOT** include SpO2 or Pulse Rate alarms.
	If a video camera is present in the patient environment, it should be connected via Ethernet directly to the computer, and not to a network.
	User is not to position Medical Electrical equipment in such a way as to make it difficult to operate the disconnection device.

	No parts of the Medical Electrical equipment shall be serviced or maintained while in use with a patient.
	Patient connections are **NOT** intended for direct cardiac contact.
	Route patient cabling carefully to reduce the possibility of patient entanglement or strangulation.
	Do not use **EMU40EX** in the vicinity of MRI or CT systems.
	Do not allow loose electrodes to contact metal parts.

Pulse Oximeter Warnings

	The Masimo SET® Pulse Oximeter is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
	**Explosion hazard**. Do not use the MS board pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
	The EMU40EX Amplifier system does **NOT** include SpO2 or Pulse Rate alarms.
	A pulse oximeter should **NOT** be used as an apnea monitor.
	A pulse oximeter should be considered an **early warning device**. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition.
	Significant levels of dysfunctional hemoglobins (HbCO or MetHb) may cause inaccurate measurements.
	Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate measurements.
	Excessive illumination may cause inaccurate measurements or loss of pulse signal.

	Excessive patient movement may cause inaccurate measurements.
	Venous pulsations may cause inaccurate measurements.
	Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.
	Loss of pulse signal can occur when the patient has hypotension, severe vasoconstriction, severe anemia or hypothermia.
	Loss of pulse signal can occur when there is arterial occlusion proximal to the sensor.
	Loss of pulse signal can occur when the patient is in cardiac arrest or is in shock.
	Tissue damage can occur due to incorrect placement of sensor.
	Do not immerse patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize patient cables by irradiation, steam or ethylene oxide.

Pulse Oximeter Sensor Warnings

	Before using, carefully read the LNOP® sensor directions for use.
	Use only Masimo oximetry sensors for SpO_2 measurements. Other oxygen transducers (sensors) may cause improper pulse oximeter performance.
	Tissue damage can be caused by incorrect application or use of an LNOP® sensor; for example, by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity and correct positioning and adhesion of the sensor.
	Do not use Masimo pulse oximetry sensors during MRI scanning as this could potentially cause burns. The Masimo pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
	Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line may cause inaccurate measurements.

	Loss of pulse signal can occur when the sensor is too tight.
	See the cleaning instructions in the directions for use for reusable Masimo LNOP® sensors.
	Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the directions for use for reusable Masimo patient cables.

Wireless Option Warnings and Cautions

	The wireless feature of this amplifier/headbox presents a passive visualization of the EEG signal. This feature is not a substitute for other means of patient monitoring and supervision.
	Like other wireless devices, this feature is limited in operating range. The range will also be reduced substantially if there is any physical interference between the Base Unit and the Breakout Box. In either of these situations, the wireless data will not be received by the acquisition computer.
	The **EMU40EX** contains FCC ID: **R47F2M03GX** which complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
	The **EMU40EX** contains **F2M03GXA** which has passed the Bluetooth Qualification/Certification process as specified within the Bluetooth Specifications and as required within the PRD 2.0. **QDID: B012540**.
	There are no devices known to cause disturbance to the performance of the wireless radios in this device. However, precautions should be made to keep the EEG device a safe distance from any other wireless products. Refer to Table 4 in the Declaration of Compliance for IEC 60601-1-2 section. Should interference with the wireless radios in this device occur, relocate the devices causing the issue, or contact ***Natus Technical Support*** at **1-800-303-0306** or OTS@Natus.com.

Electromagnetic Interference (EMI) Warnings

	Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual and any other Accompanying Documents.
	The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2007
	The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.”
	Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

Conducted Immunity Warning

	Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the system and its components is adequate, sturdy, and safe. Natus is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces. Natus is not responsible for any injury or damage that may result from improper cable storage during transport.

Transportation Warnings

	Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the system and its components is adequate, sturdy, and safe. Natus is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces. Natus is not responsible for any injury or damage that may result from improper cable storage during transport.
	**TIPPING HAZARD:** During transport, the user should guide the cart using both hands, ensuring the wheel base is aligned so that a single caster leads in the direction of motion. Failure to lead the cart with one wheel could result in a tipping hazard when ascending or descending steps or thresholds.

Procedures and Warnings

Electrostatic Disacharge (ESD) Handling

Before performing any setup or placement procedures, read the precautions outlined in this section.

WARNING: Be sure to take the appropriate Electrostatic Discharge (ESD) precautions. Disconnect the cables before moving, cabling, or performing any set up procedures.

Some semiconductor (solid state) devices can be easily damaged by static electricity. Such components are commonly called Electrostatically Sensitive Devices (ESD). Do not touch the accessible conductive parts for the Connectors marked with the ESD symbol.

Follow these techniques to help reduce the incidence of component damage caused by static electricity:

- Immediately before handling any product components assemblies, drain the electrostatic charge from your body by touching a known earth ground.
- Minimize body motions when handling unpackaged replacement ESDs. Motions such as brushing clothes together or lifting your foot from a carpeted floor can generate enough static electricity to damage the product components.
- Avoid carpets in cool, dry areas. If provided, leave the product components in their anti-static packaging until ready to be installed.
- Take care when connecting or disconnecting cables. When disconnecting a cable, always pull on the cable connector or strain-relief loop, not on the cable itself.

WARNING: A damaged cable can cause a short in the electrical circuit. Prevent damage to the connectors by aligning connector pins before you connect the cable.

WARNING: Misaligned connector pins can cause damage to system components at power-on.

Conducted Immunity Procedures and Warnings

Conducted immunity is defined as the ability of an electronic product to tolerate the influence of electrical energy from other electronic products or electromagnetic phenomena.

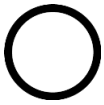
The electrical energy from other electronic devices located in nearby equipment are usually propagated through the connecting cables. The functionality of some semiconductor devices and high sensitivity amplifiers (EEG, EMG ECG) may be affected by induced parasitic signals.

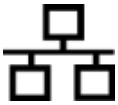
This effect could be described as noise and/or channel saturation on the EEG waveforms, together with off the scale values for auxiliary sensors.

Follow these techniques to help identify the sources, and to increase the immunity towards parasitical noise: o
Verify the power supply and all portable multiple socket-outlets are off the flo r and in a dry location.

- If parasitic noise is present on the EEG waveforms, try to identify possible culprits by disconnecting nearby equipment from the common power source.
- Lay out the interconnection cables as far as possible from the cables being used by nearby equipment.
- Verify the Power cord integrity. Do not use portable multiple socket outlets that are not properly grounded.
- Do not use power outlets without a protective ground
- When isolation transformers are used, ensure that the Medical System is properly grounded.

Description of Symbols

Symbol	Description
	**ATTENTION:** **Consult Accompanying Documents**
	Consult Accompanying Documents
	Consult Operating Instructions
	Pushing Prohibited
	Protective Earth (Ground)
	Type BF Equipment
	Dangerous Voltage
	Alternating Current
	Direct Current
	Power On
	Power Off
	**EU only**: Do Not Dispose as Unsorted Municipal Waste
	Class II Equipment (non-grounded enclosure)

Symbol	Description
	ESD Sensitive or Static Sensitive
DC13 I DC16	DC Inputs 13 to 16 Breakout Cable Connector
	Patient Event Button Connector
	Equipotential stud
	Non-Waterproof Device
	LAN Connection
	USB Connection
	Manufacturer Information
	Fragile
IPX0	No protection against ingress of water according to IEC 60529.
IPX1	Protection from dripping water from above the device for at least 10 minutes according to IEC 60529.

Specifications: EMU40EX Amplifier

Specification	Value(s)
Analog Specifications Channels	
Referential Channels	40
Differential Input Impedance	> 50 MOhms
Common Mode Input Impedance	> 25 MOhms
Common Mode Rejection Ratio	116 dB @ 60 Hz
Input Noise (peak to peak)	3.9 µV @ 0.1~70 Hz bandwidth
Input Noise (RMS)	0.65 µV @ 0.1~70 Hz bandwidth
EEG Channel Hardware Gain	250
Maximum Differential AC Input Before Clipping (Referential)	± 10 mV pk-to-pk
Maximum Operational DC Input Voltage Electrode Offset	± 200 mV
Input Bias Current	< 20 pA
Channel Crosstalk	-87 dB
Analog Specifications – DC Channels	
DC Channels (Base Unit, DC1 – DC4)	4 isolated
DC Input Range	± 5 V
Host Interface	
Network Interface Wired	TCP/IP (Fixed IP address or DHCP) Gigabit Ethernet (1000BASE-T, IEEE 802.3ab)
Direct Connection Interface	USB 2.0
User Interface	
Front Panel Control	Base Unit LCD Touchscreen
Patient Event Pushbutton Connection	1 on Base Unit, 1 on Breakout Box
Photic Stimulator Interface	1 Natus Photic Stimulator

Specification	Value(s)
Digital Specifications	
Sampling Frequency	256 Hz, 512, 1024 Hz
Sampling Resolution – EEG Channels	16 bits
Sampling Quantization – EEG Channels	300 nV
Sampling Resolution - DC Channels	16 bits
Sampling Quantization – DC Channels	150 µV
Modes of Operation	
Base Unit Fuse Type and rating	T 1.5A / 250V
Base unit power supply	100 – 230V, 50/60Hz
Storage Capacity	4 GB Internal Compact Flash Card
Mains Power Requirement (Base Unit)	100-230VAC; 50-60Hz 70VA
Power Consumption (EMU40EX Breakout Box)	1 W @12 V
Battery	Rechargeable 2 x AAA Ni-Mh battery
Battery Life	1 to 1.5 hrs. (depending on features enabled: wireless, oximeter)
Impedance Check	< 2.5, < 5, < 10, < 25 kOhms
Channel Test Signal	Programmable Sine: 5–20 Hz, 50–200 µV pk-to-pk Square: 0.25–1 Hz, 50–200 µV pk-to-pk
Wireless Specifications	
Operating Frequency	2.400 – 2.4835 GHz
RF Output Power	6 mW (+8dBm) 64 mW (+18dBm) [3]
Maximal distance range between transmitter / receiver (according to EMC environmental conditions).	Up to 30 meters

[3] Maximum radio power can be adjusted for each EMU40EX unit using provided software utility

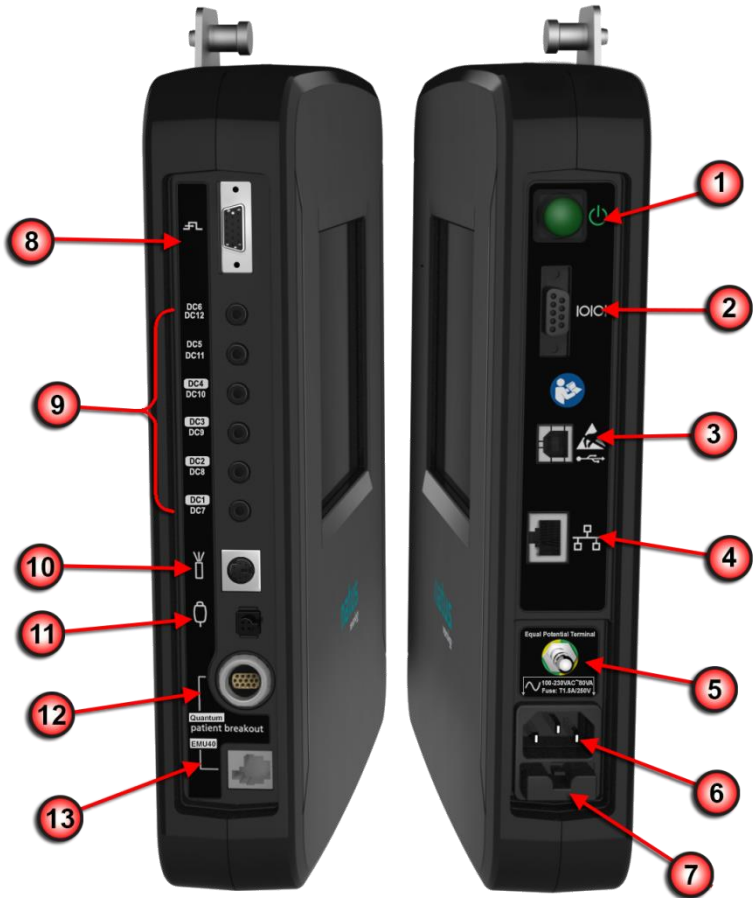
Specification		Value(s)
Environmental Conditions for Use		
Operating Environmental Limits		Temperature: 10° to 30°C
		Relative Humidity: 30%–75%
		Atmospheric Pressure: 700 hPa–1060 hPa
Transport and Storage Temperature Range		-25°C to 60°C
Transport and Storage Humidity Range		10%–95%
Transport and Storage Atmospheric Pressure Range		500 hPa to 1060 hPa
Dimensions		
Size (length x width x height)	Natus Base Unit	292.5mm x 266.6mm x 51.5mm (11.52” x 10.5” x 2.03”)
	EMU40EX Breakout	100mm x 158mm x 23mm (3.94’’ x 6.22’’ x 0.91’’)
Weight	Natus Base Unit	2.14kg (4.72lb)
	EMU40EX Breakout	333g (0.73lb)

Product Images

EMU40EX System

*Figure 1: **EMU40EX** System: Base Unit, Breakout Box and Battery Pack*

Base Unit



1	Power Button. Labeled with ⏻.
2	Reserved for future use. Labeled with IOIOI.
3	Can be used to connect the Base Unit directly to a PC and/or Laptop. Labeled with ⚠ ⇢.
4	Can be used to connect the Base Unit to a TCP/IP network. Labeled with 品.
5	Ground equipotential terminal.
6	Connects the Base Unit to the mains power supply.
7	Fuse Compartment. Labeled with: ∼ Fuse: T 0.5A/250V; 100-230VAC; 50-60Hz 70VA
8	Reserved for future use. Labeled with 品.
9	Can be used to connect DC signals from external devices. Labeled with DC1-DC12. ***Only*** DC1-DC4 are available ***when EMU40EX Breakout Box is connected.***
10	Natus Photic Stimulator Connector. Labeled with ⏚.
11	Patient Event Button Connector. Labeled with ⏚.

12	Used to connect the Base Unit to the Quantum Patient Breakout Box. ***Not available when EMU40EX Breakout Box is connected.***
13	Used to connect the Patient Breakout Box for the **EMU40EX**. Labeled with EMU40
	NOTE: Only one type of breakout box should be used at a given time. You cannot use an EMU40EX breakout in conjunction with another breakout box.

EMU40EX Breakout Box

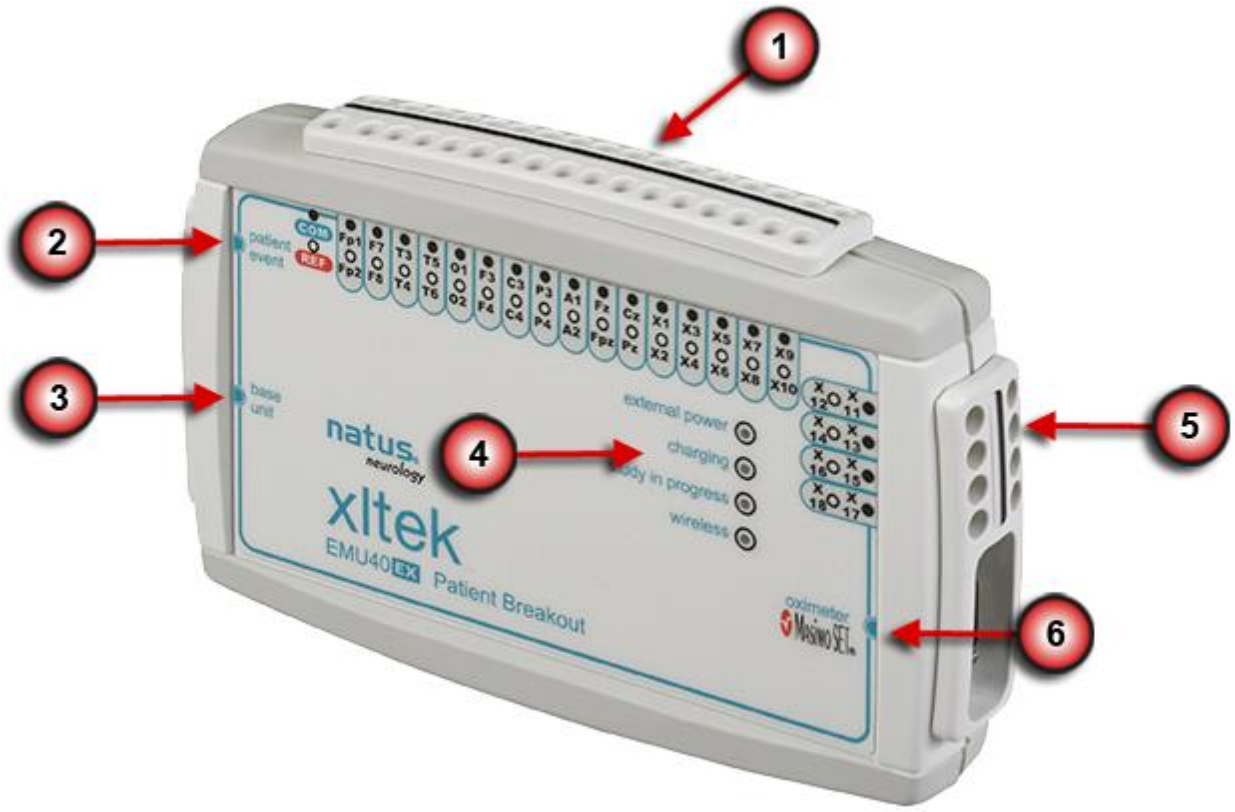


*Figure 5: **EMU40EX** Breakout Box*

1	Standard 10-20 Channel Inputs
2	Patient Event Connection (on side)
3	Base Unit or External Battery Pack Connection (on side)
4	Status LEDs
5	8 Additional Channels
6	MASIMO SET® Pulse Oximeter Connection

Unpacking

When you unpack your **EMU40EX**, make sure the following items are included:

- ***Natus* Base Unit**
- **EMU40EX** Breakout Box
- **EMU40EX** Breakout Cable
- Ethernet Cable
- Power Cord
- Patient Event Switch

Optional Accessories:

- **EMU40EX** Battery Pack
- EEG Accessory Kit

NOTE: The **EMU40EX** system should be used only with cables, transducers, electrodes, sensor, and switches that are supplied or approved by ***Natus.***

Setting Up

The **EMU40EX** amplifier is designed to work with computer system running **Natus Database** and **NeuroWorks** EEG software.

Connecting to the computer

USB-Style Connection

To connect the EMU40EX to the XLTEK computer:

1. Use the supplied **USB 2.0** cable to connect the **Natus Base Unit** to the computer.
2. Insert the **Patient Event Switch** into the Patient Event connection on the Base Unit or Breakout.
3. If a **Photic Stimulator** is needed, insert the Photic Stimulator into the Photic Stimulator connection on the Base Unit.
4. When you are ready to run a study, connect the patient leads and transducers to the **EMU40EX** Breakout Box.

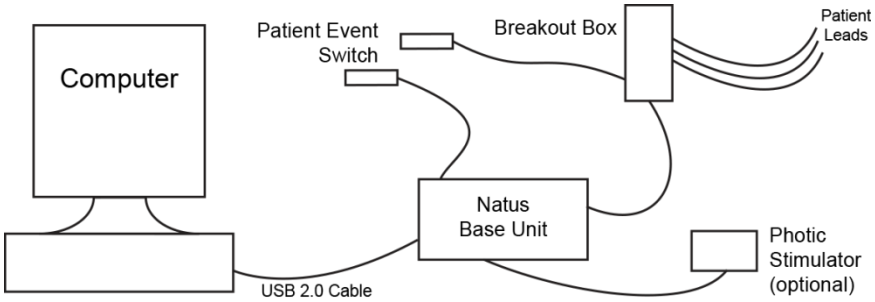


*Figure 6: USB-Style Hardware Connections for an **EMU40EX** System*

Ethernet-Style Connection

1. Connect the computer to the LAN (Local Area Network).
2. Connect the **Natus Base Unit** to the LAN.
3. Insert the Patient Event Switch into the Patient Event connection on the Base Unit or Breakout.
4. If a Photic Stimulator is needed, insert the Photic Stimulator cable into the Photic Stimulator connection on the Base Unit.
5. When you are ready to run a study, connect the patient leads and transducers to the **EMU40EX**.

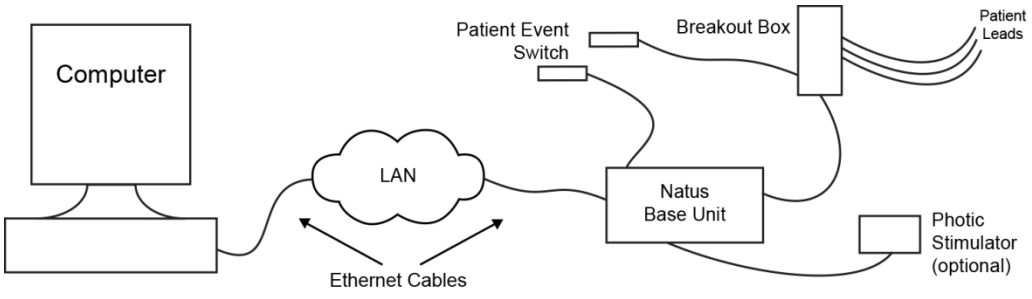
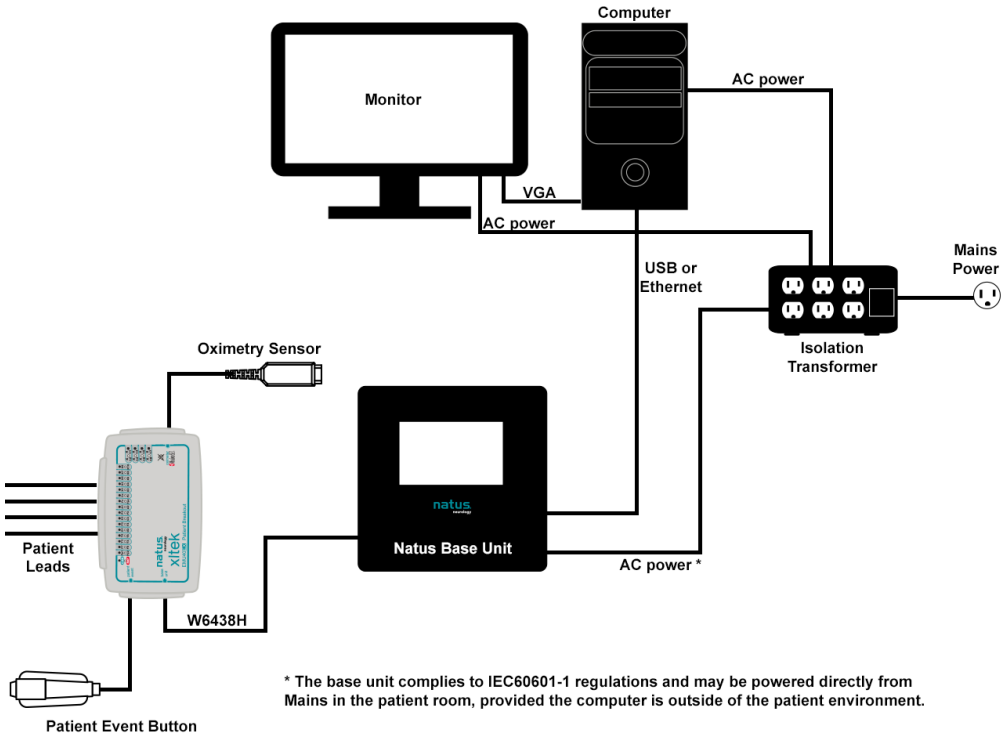


*Figure 7: Ethernet-Style Hardware Connections for an **EMU40EX** System*

NOTE: ***XLTEK*** has designed the **EMU40EX** amplifier for EEG/LTM studies. For more information on running studies, refer to the online **Help**.

Connection Setup for the Base Unit

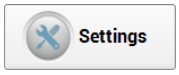
1. Confirm that the Base Unit is mounted via the Quick Disconnect Bracket to either a system cart or wall mount track.
2. Connect the amplifier Base Unit to the acquisition computer using a network or via USB. The Base Unit can be connected to a standard switched gigabit network jack (recommended) or to a secondary gigabit network interface card on the acquisition computer.
3. Connect the power cable, Base Unit to **EMU40EX** Breakout Cable, patient event switch, and any additional accessories as required.



NOTE: Setup and Installation of the **EMU40EX** amplifier system should be performed by Natus qualified personnel only.

Setting the IP Address

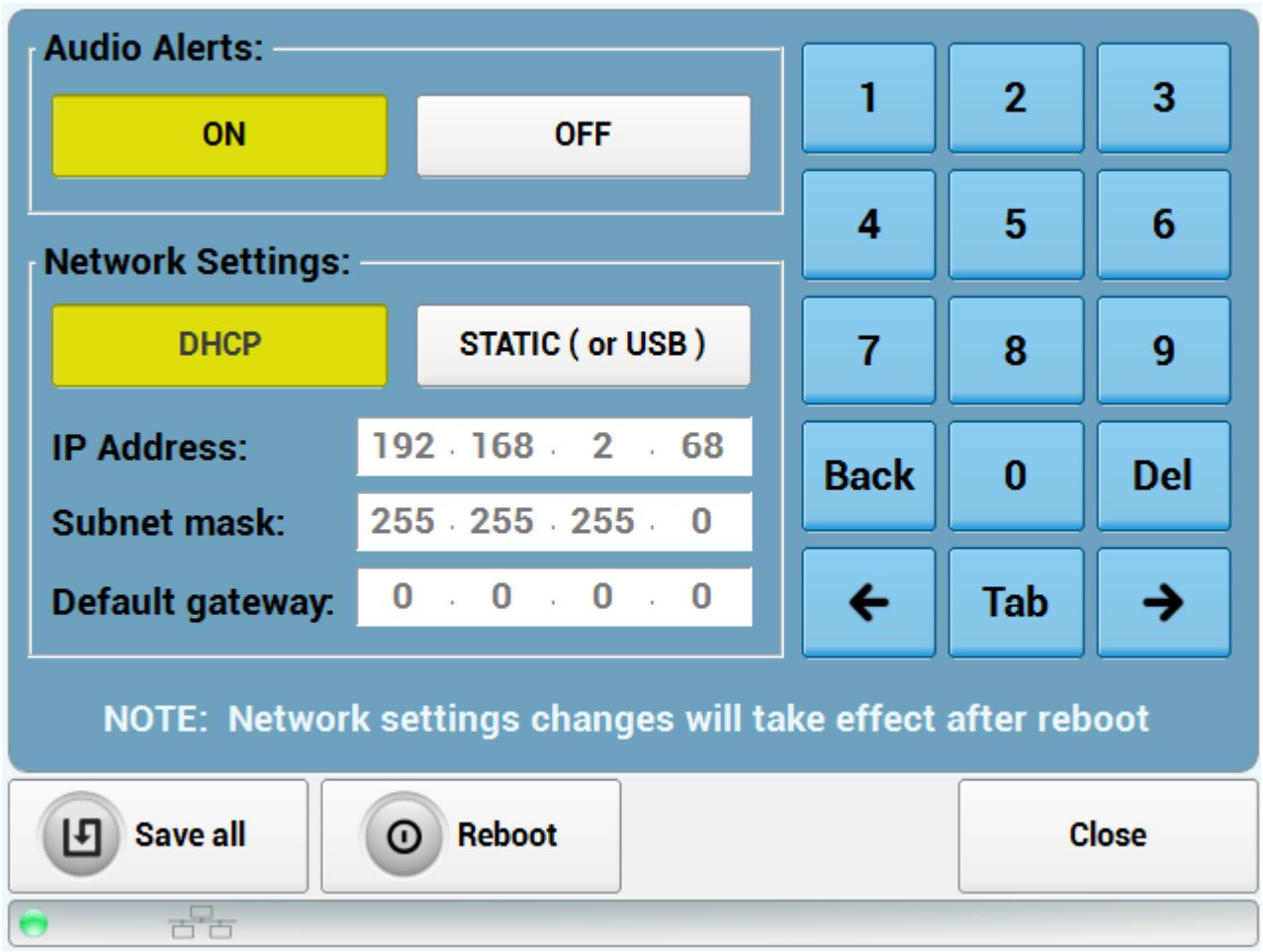
1. To power-up the Base unit, press and hold power button for 3 seconds. The following user interface appears.

2. Press the **Settings**  button on the touchscreen to access the IP Configuration.

NOTE: The amplifier supports both DHCP and static TCP/IP address configuration. Selecting DHCP will allow the amplifier to receive TCP/IP addresses automatically from the DHCP server.

The NeuroWorks software can scan and find available amplifiers for acquisition.

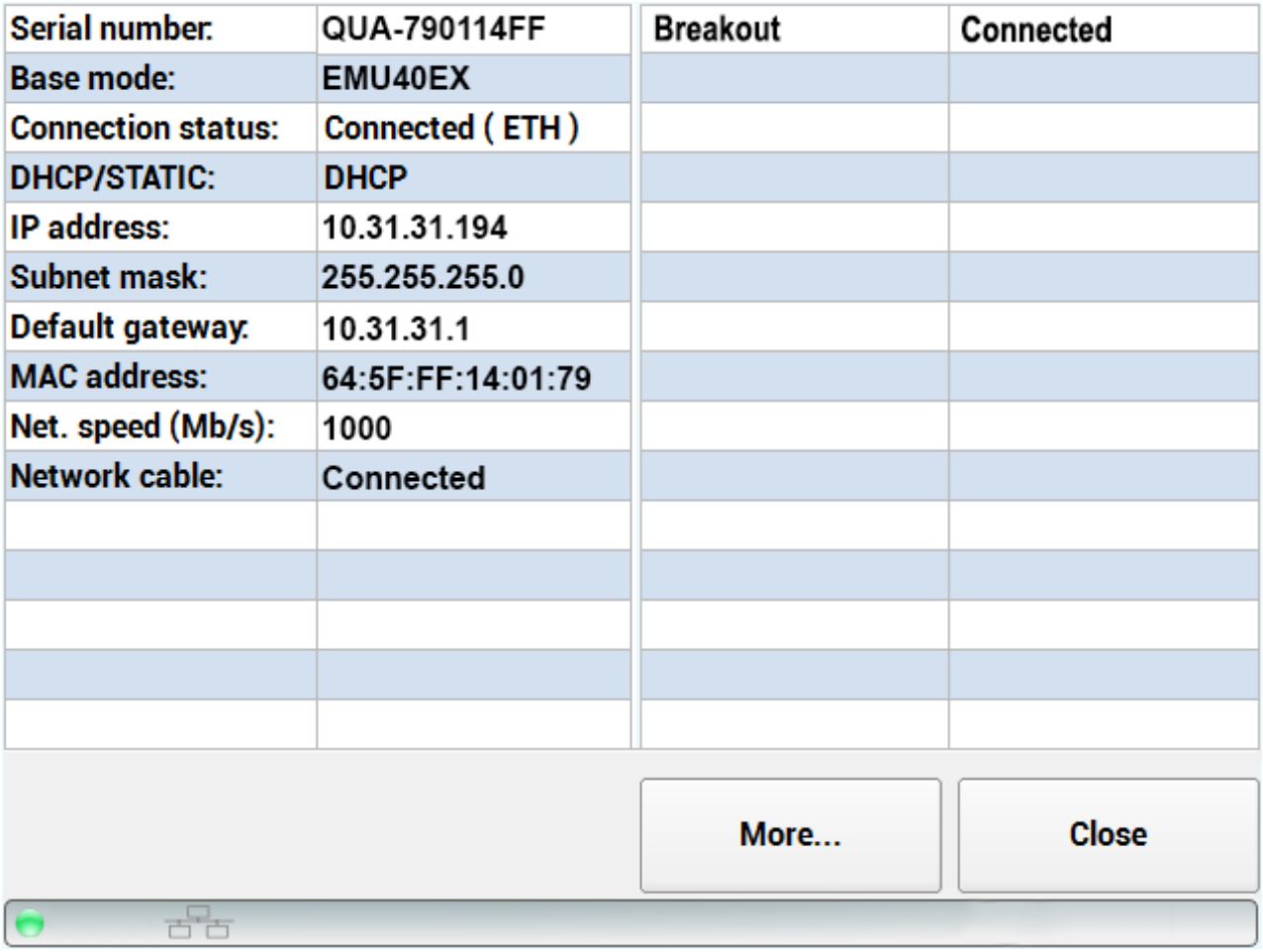
3. Select **On** or **Off** for **Audio Alerts**.
4. Select **DHCP** under **Network Settings** otherwise, the DNS server will enable manual entry of the **IP address** and **DNS server** for the Base Unit.



5. Press **Save** to finalize changes to the IP configuration.
6. Press **Close** to return to the main screen.

7. From the Main Screen, confirm system setup by pressing the **Info** button 

to view the information screen.



8. On the information screen, ensure that the **IP address** is set as intended, and that the connection information related to the Breakout show that all components are recognized by the system.

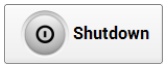
NOTE: If **DHCP** was not used the **DHCP/STATIC** item will indicate **STATIC**.

9. Press **Close** to exit the info screen.

The amplifier is now setup and ready to use.

Touchscreen Icons

When properly installed and connected to the PC, the Natus Base displays several icons at the bottom of the touchscreen which indicate the connectivity status of the breakout boxes, the headbox, and the base units. The following table shows the different connection status indicators.

Icon	Description
	Shows the number of breakout boxes (1) that are connected to the base unit.
	Indicates that the headbox is connected to the PC via USB and has established a connection with the software.
	Indicates that the headbox is connected to the PC via an Ethernet cable. If the color is BLUE, the PC software is connected to the head box and is typically running a study.
	If the color is BLACK, the Ethernet cable is connected but the software has not established a connection with the headbox.
	If it is TRANSPARENT, then no network cable is plugged in.  NOTE: If a USB connection is used, the above connection will be shown until the software establishes a direct connection to the headbox, at which point it will be changed to  . A physical connection to a USB cable cannot be detected by the hardware.
	Displays the settings for the Natus Base
	Displays the information about the Breakout connected.
	Turns the LCD Screen off.
	Shuts the Natus Base off.

Amplifier Usage and Features

Getting Started

NOTE: In the event of a power failure, the current recording will resume using the last programmed settings upon the restoration of power.

Placement of the Operator and Patient

It is expected that the operator of the system will stand or sit in front of the computer, but not continuously. The patient is typically lying in a bed located beside the system cart or amplifier and is in no way supported by the equipment.

Amplifier units are patient-worn. Refer to the section ***Adding the EMU40EX Breakout Box to a Harness or Belt*** for details on the placement of the Breakout Box on the patient.

At no point should the system be leaned against or rested upon. Refer to the ***Transport System Specifications and Maintenance*** section for placement, details, and cautions for the different cart transportation options.

Refer to the corresponding *Instructions for Use* for all system components prior to use. This should include, but is not limited to: cameras, computers, stimulators, and software.

Beginning a study

Once the equipment has been installed by your Natus qualified representative and a patient has been connected to the **EMU40EX** system, a new EEG study can be started. For details on beginning a new EEG study, consult the ***NeuroWorks*** manual.

NOTE: In order to record a study the Base Unit must be connected to a PC and the Base Unit must be connected to the Breakout Box as described in ***EMU40EX Breakout Box to Base Unit Data Link***.

Powering Down the System

Utilize the following steps to ensure your system is powered down completely and safely.

1. Close any active studies in the *NeuroWorks* software.
2. Shut the computer down; ensuring to follow the proper shut down procedure.
3. On the base LCD press and hold the Shutdown button for 3 seconds.
4. Unplug the power cord from the wall.Adding the EMU40EX Breakout Box to a belt or a lanyard

Placing the **EMU40EX** Breakout Box on the patient can be accomplished by using either the belt or the lanyard setup.

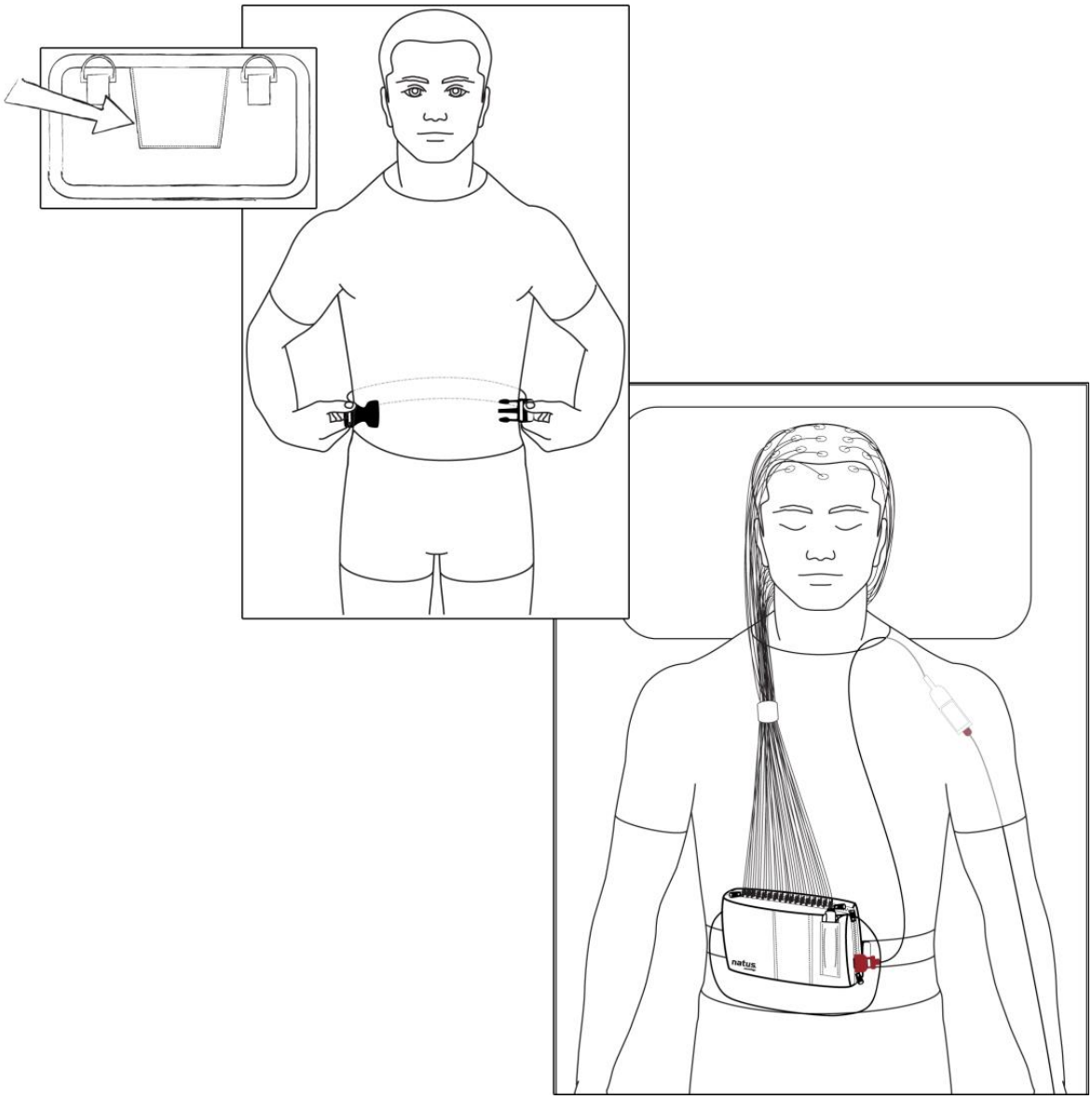
The pouch and belt or lanyard system must be worn over top of the patient's clothes or hospital garment.

Adding the EMU40EX Breakout Box to a Lanyard or Belt

Belt Setup

To use the belt setup:

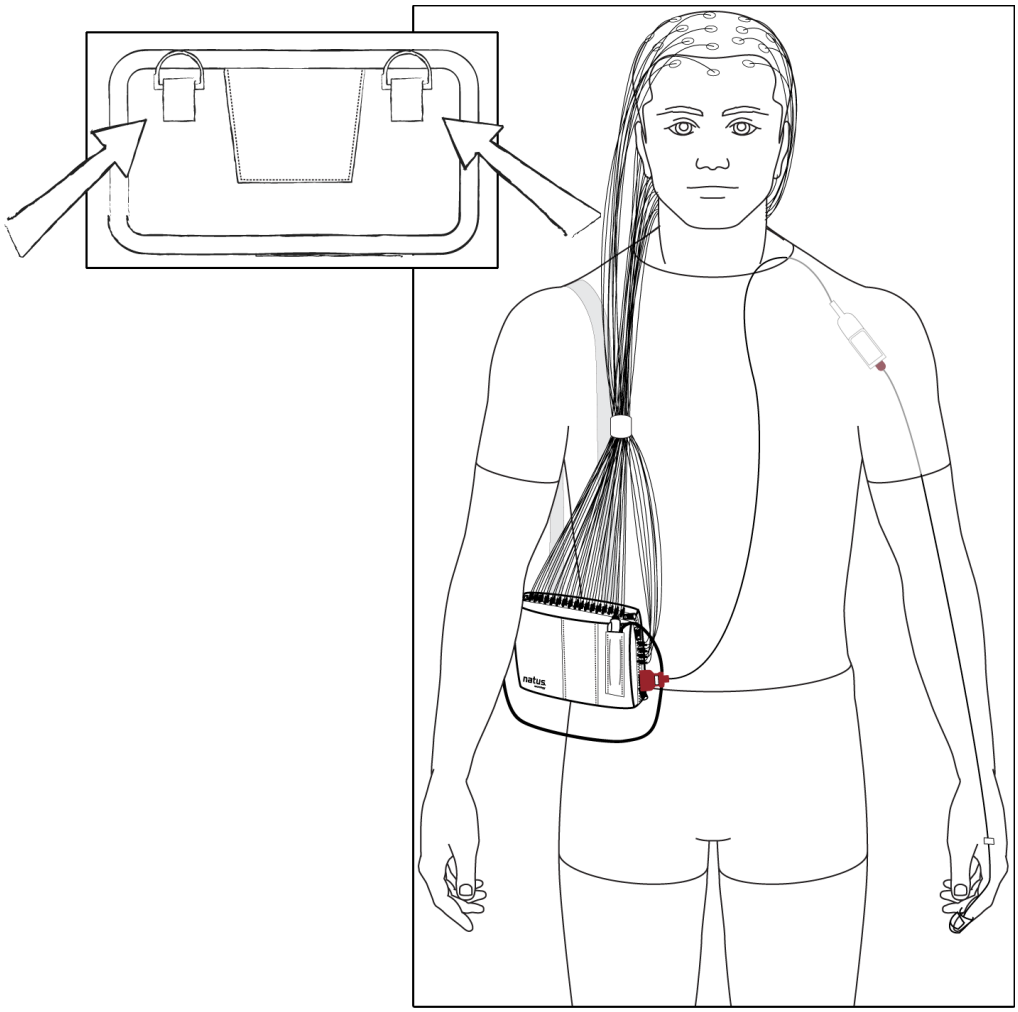
1. Attach the pouch to the belt by threading the belt through the back of the pouch.
2. After attaching the electrodes to the patient, place the Breakout Box into the pouch with the electrode wires exiting at the top or on the sides, as required. If an external battery pack is used, insert it into the pouch beside the Breakout Box.
3. Close the zippers as much as possible so that the Breakout Box is secured.
4. Once the Breakout Box is enclosed in the pouch, fit the belt snugly around the patient's mid-section. Ensure the belt is neither too tight, nor too loose and the patient is comfortable.
5. Insert the patient event switch into the holder on the front of the pouch and the gather the electrodes into a ponytail.



Lanyard Setup

To use the lanyard setup:

1. Attach the lanyard to the two (2) rings on the back of the pouch.
2. After attaching the electrodes to the patient, place the Breakout Box into the pouch with the electrode wires exiting at the top or on the sides, as required. If an external battery pack is used, insert it into the pouch beside the Breakout Box.
3. Close the zippers as much as possible so that the Breakout Box is secured in the pouch.
4. Once the Breakout Box is enclosed in the pouch, place the lanyard around the patient's neck or shoulder, or hang it on the bedside post.
5. Insert the patient event switch into the holder on the front of the pouch and the gather the electrodes into a ponytail.



Potential Equalization Conductor

The Base unit provides a potential equalization conductor for optional use. To install, connect a bus cable from the potential equalization conductor to the potential equalization busbar of the electrical insulation in the room where the EMU40EX system is used.

EMU40EX Amplifier System Description

This section presents a description of the **EMU40EX** amplifier system and its modes of operation,

The **EMU40EX** EEG amplifier system consists of a Patient Electrode Set, Breakout Box, and Base Unit. The **EMU40EX** Amplifier System is designed to work with an XLTEK host computer system running the **Natus Database** and **NeuroWorks** data review and analysis software.

The **EMU40EX** Breakout Box is a 40-channel EEG amplifier with touch-proof jacks for the EEG electrode lead-wires. It converts the electrical activity of the patient's brain into a digital data stream. It also integrates SpO2 and Pulse Rate channels from its built-in Masimo SET® Pulse Oximeter, as well as Patient Event Markers from a pendant-style, pushbutton switch at the bedside.

The digital EEG waveform data is transmitted to the Base Unit for further signal processing and storage. The Base Unit makes this data available over Ethernet or USB to an XLTEK **NeuroWorks** workstation for live waveform display, later review and clinical interpretation of the waveforms. The Base Unit also provides four DC inputs, photic stimulator control, another event marker input, and controls for EEG electrode impedance testing in the patient room.

The **EMU40EX** Breakout Box can be connected to the Base Unit with a cable, or can connect wirelessly through a secure BlueTooth link. Using the **EMU40EX** amplifier system in its various operational modes is described in detail below.

EMU40EX Breakout Box to Base Unit Data Link

The **EMU40EX** breakout box communicates with the Base Unit through a bi-directional 4 Mbit/s wired connection. This connection is used to send the real-time, full-resolution digitized EEG waveforms and associated signals to the Base Unit.

In addition, the Breakout Box and Base Unit can connect wirelessly using an optional unidirectional 230.4 Kbit/s wireless connection. With this option, the Breakout Box stores the data into its flash memory and sends down-sampled EEG wafeform data to the Base Unit, which in turn forwards the data to the NeuroWork computer for real-time display of the EEG waveforms.

Note that the Base Unit can send data/commands to configure and control the **EMU40EX** Breakout Box only through the cable connection.

The optional wireless feature is available at the customer's request. There are two steps required in order to use this option. First, at the customer's request, this feature is enabled at the factory. Secondly, the user must enable this feature in the NeuroWorks software prior to using the BlueTooth wireless mode.

The following two sections describe how to use the **EMU40EX** when the the wireless option is disabled, and when the wireless option is enabled.

Feature Description of EMU40EX with Wireless Option Disabled

When the Base Unit is physically connected to the Breakout Box, i.e. with the Breakout Box Data Cable, the **EMU40EX** is referred to as being in **Physical Connection Mode**. In this mode, the data is transmitted over the wired connection to the Base Unit, which then transmits the data to the computer.

The computer software will display and store this data (see Figure 8).

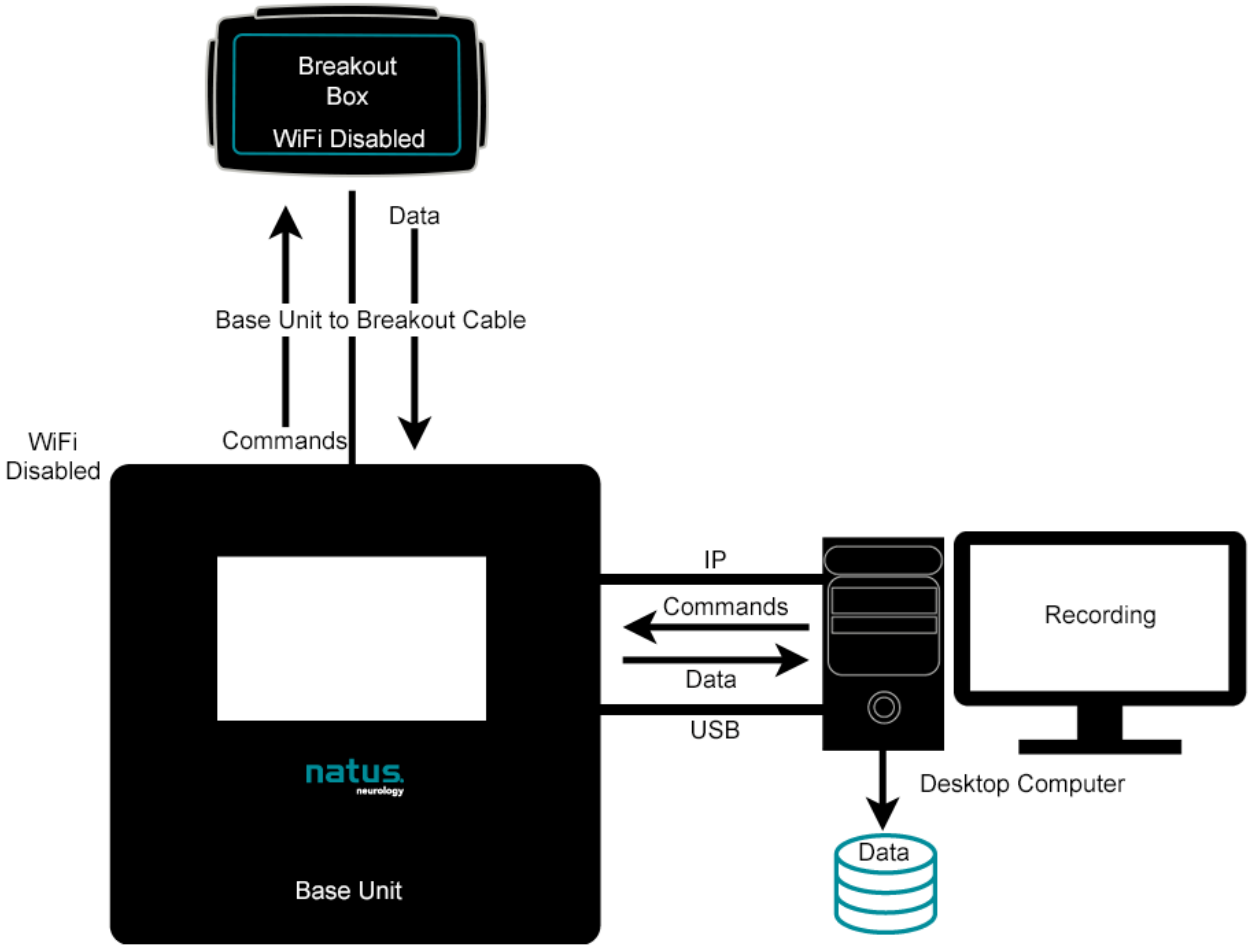


Figure 8: Physical Connection Mode without Wireless Option

When the Base Unit is physically disconnected from the Breakout Box, the **EMU40EX** is referred to as being in **Physical Disconnection Mode**. In this mode, the Breakout Box uses compact flash memory to store the study data (see Figure 9).

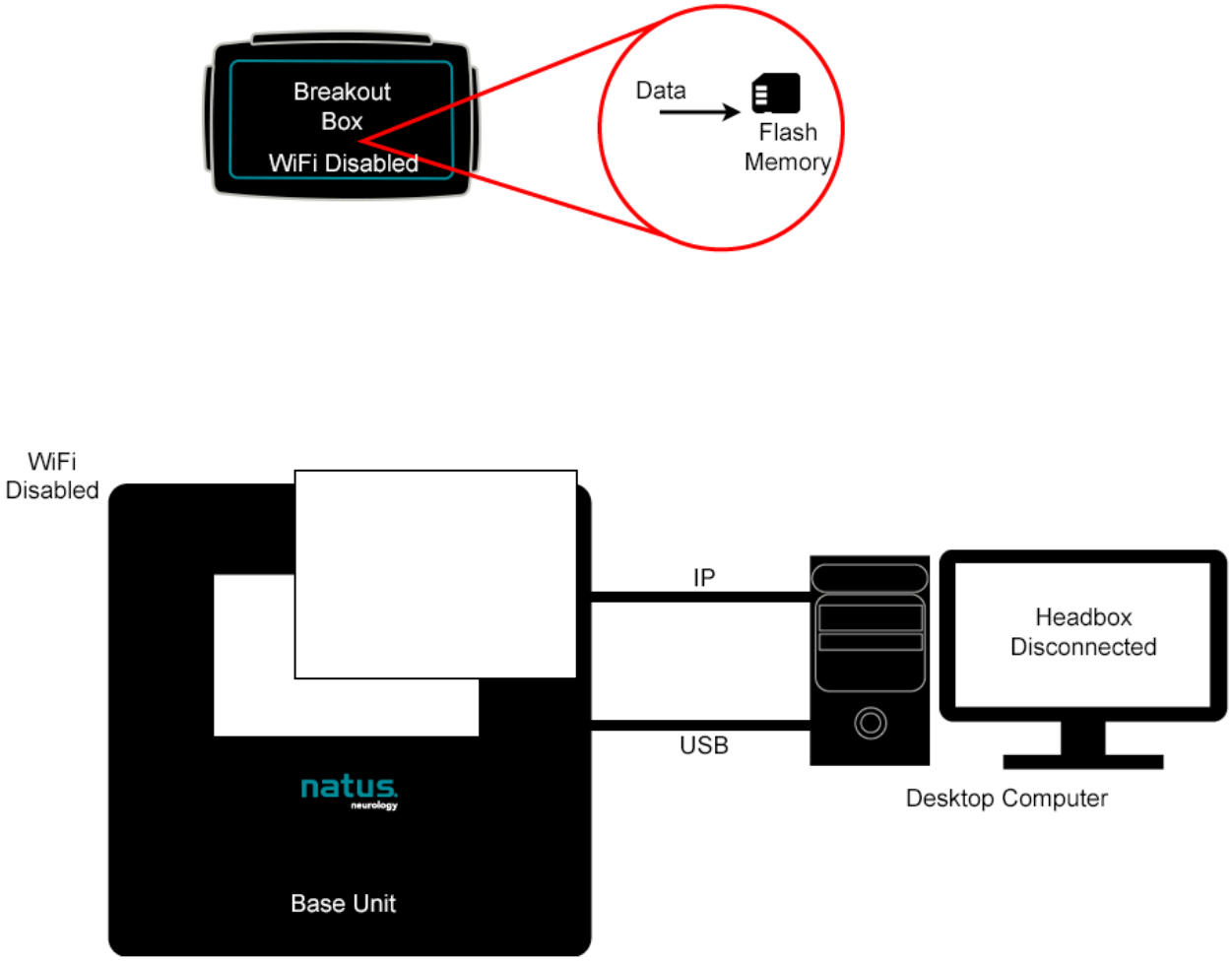


Figure 9 - Physical Disconnection Mode without Wireless Option

When the Breakout Box is reconnected to the Base Unit, the **EMU40EX** is referred to as being in Physical Reconnection Mode. In this mode, any data stored in the Breakout Box is transferred to the computer via the Base Unit and merged with the recorded study (see Figure 10).

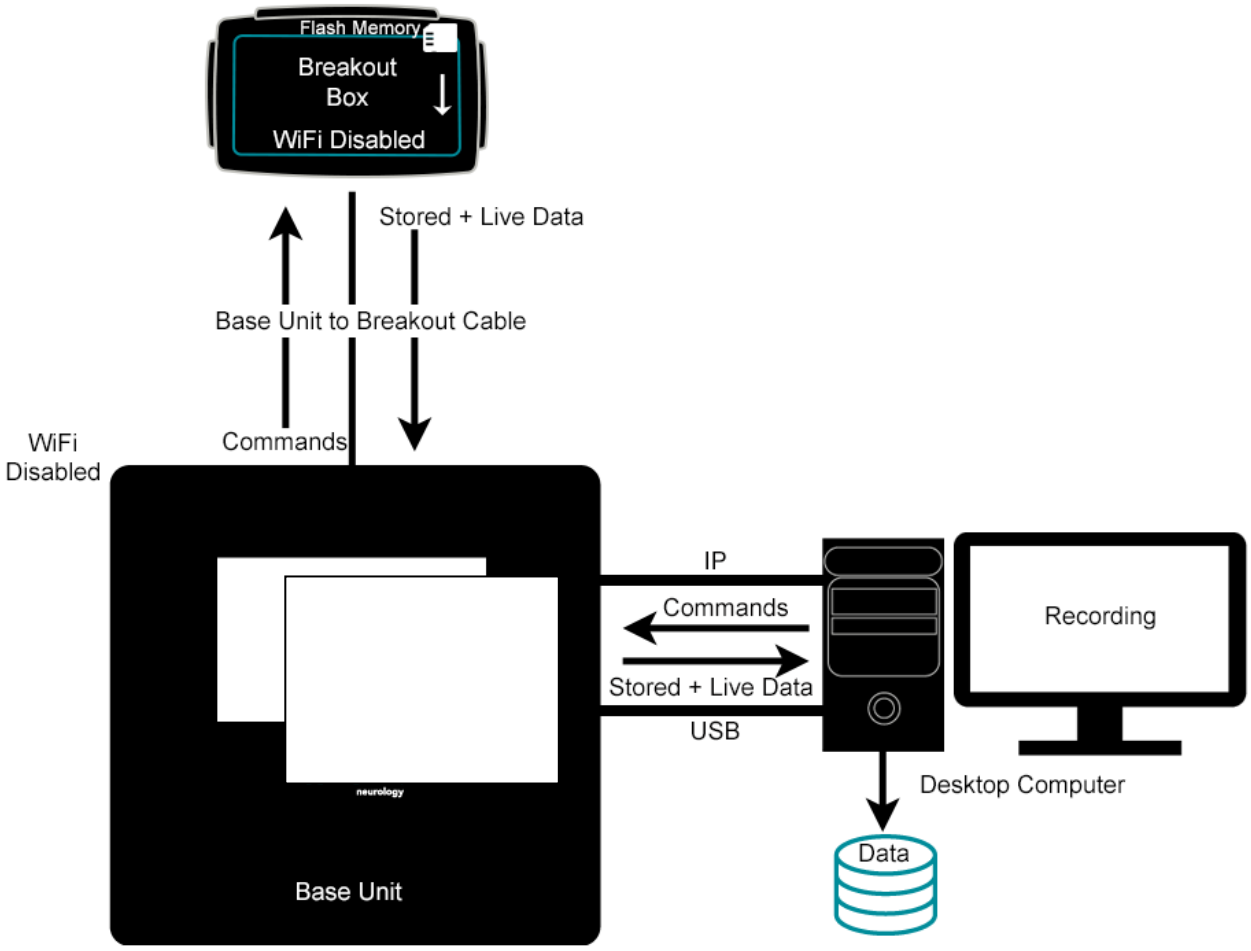


Figure 10 - Physical Reconnection Mode without Wireless Option

After all the data stored in the flash memory of the Breakout Box is transferred to the computer, the Breakout returns to Physical Connection Mode.

Feature Description of EMU40EX with Wireless Option

The wireless option has no effect on wired operation.

During **Physically Connected Mode**, data is transmitted over the wired connection to the Base Unit and then transmitted to the computer. The computer software displays and stores this data (see Figure 11).

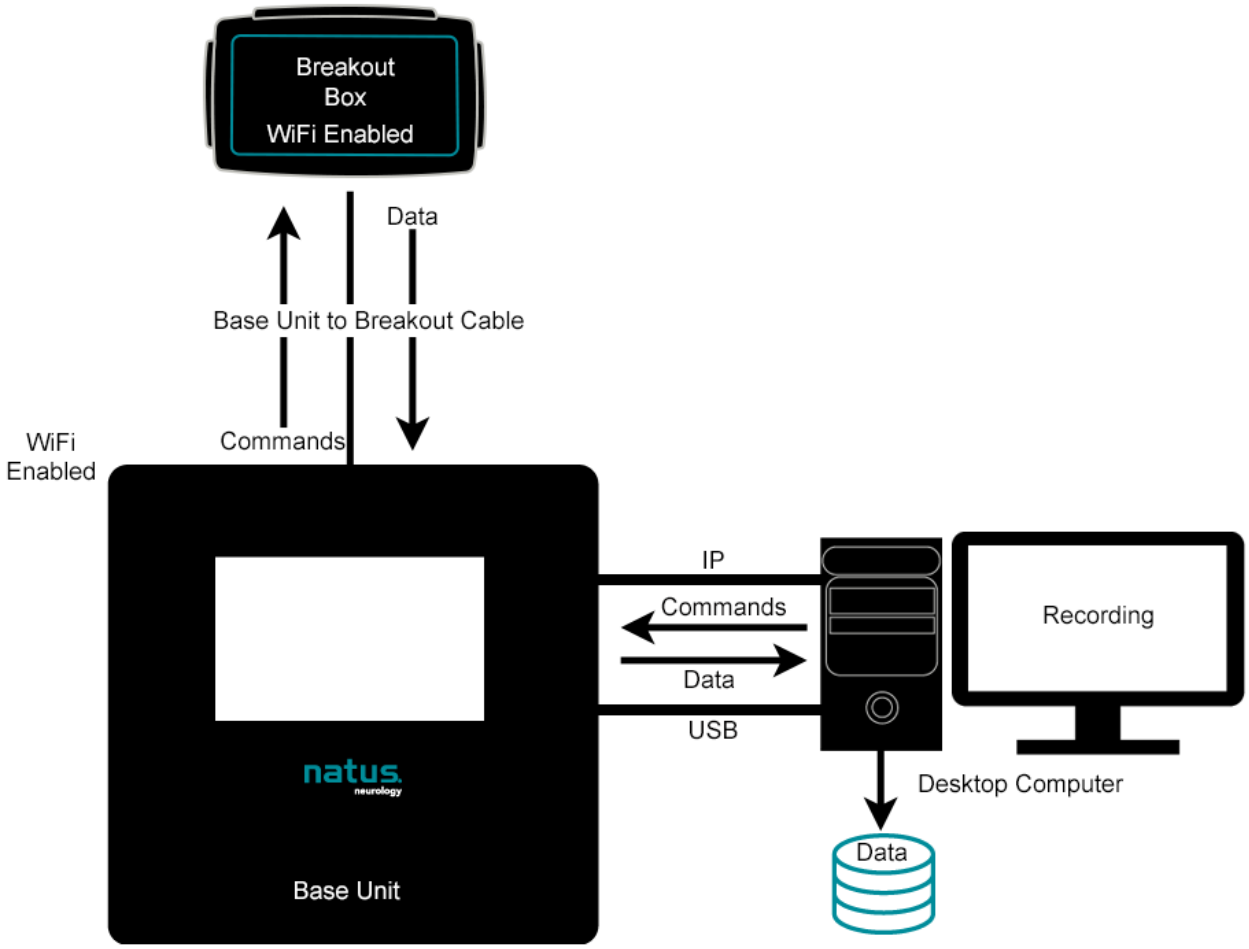


Figure 11 - Physical Connection Mode with Wireless Option

When the Base Unit is physically disconnected from the Breakout Box, the Breakout Box uses compact flash memory to store the study data and simultaneously transmits a down-sampled version of this data over the wireless connection (see Figure 12).

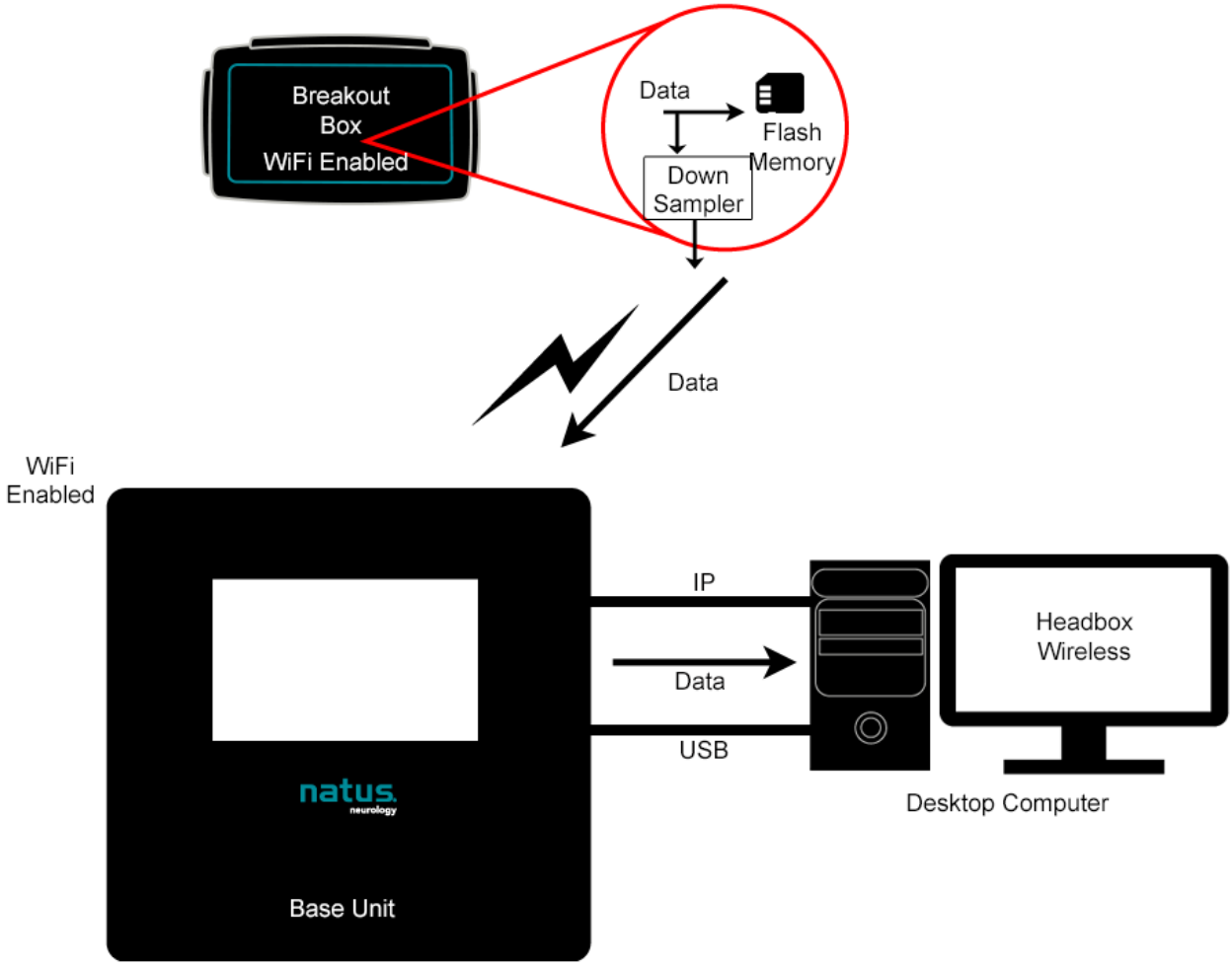


Figure 12 - Physical Disconnection Mode with Wireless Option

The data transmitted through the wireless connection is used by the **NeuroWorks** software to present a passive visualization of the EEG signals. It is not possible to perform any action on the signals presented by the software (passive signal representation). The data sent over the wireless connection is not stored.

Upon reconnection, any data stored in the Breakout Box is transferred to the computer via the Base Unit and merged into the recorded study (see Figure 13).

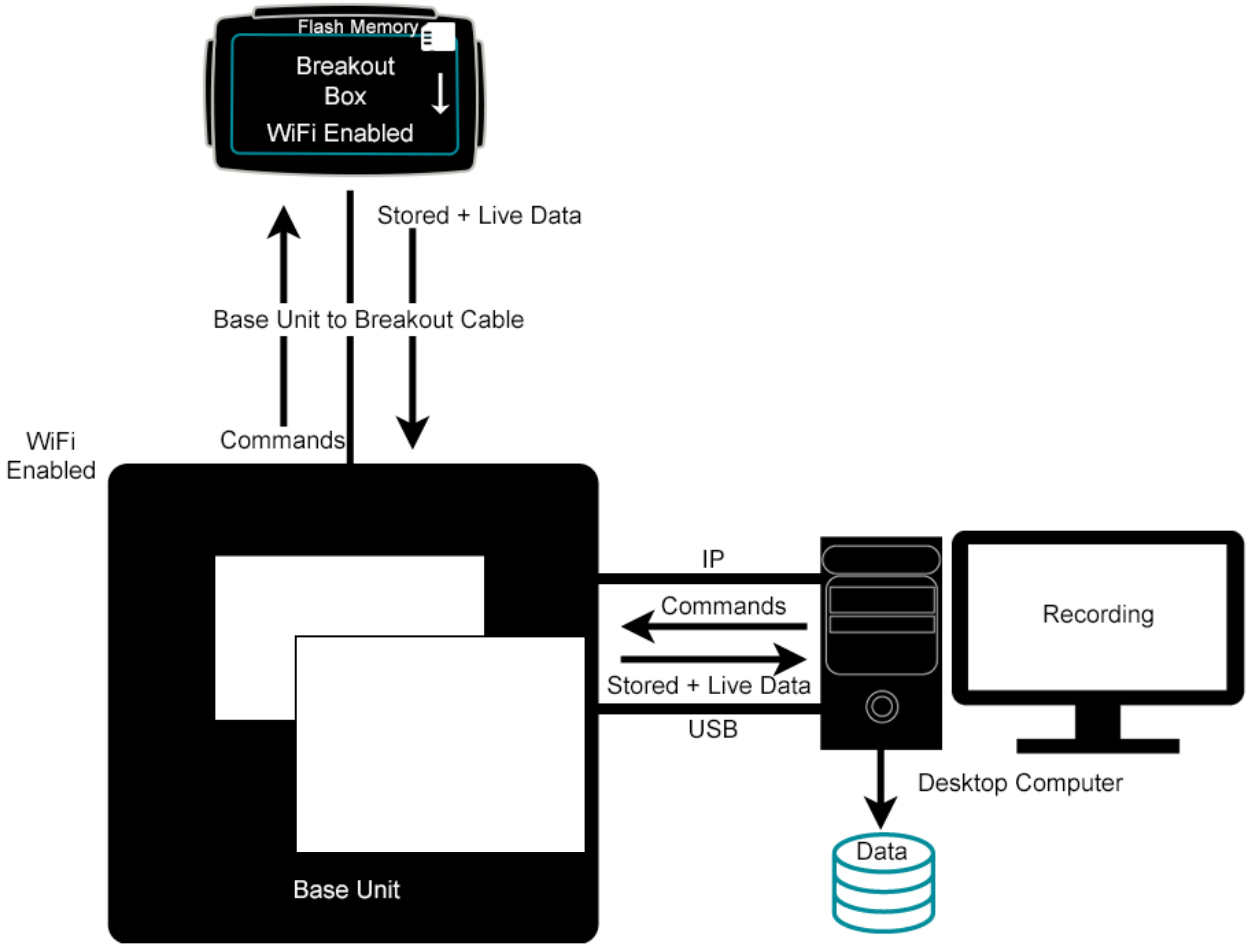


Figure 13 - Physical Reconnection Mode with Wireless Option

Setting the Wireless Power Limit

The Bluetooth radio module in the **EMU40EX** features adjustable power levels. It can be configured to allow Standard or Extended wireless range, or it can be disabled entirely. Each **EMU40EX** headbox can be configured individually using the utility from a **NeuroWorks** CD. The selected configuration will be retained in non-volatile memory until explicitly changed.

In order to adjust the wireless power, run the **EMU40EX.exe** application from a NeuroWorks CD. The following window appears:

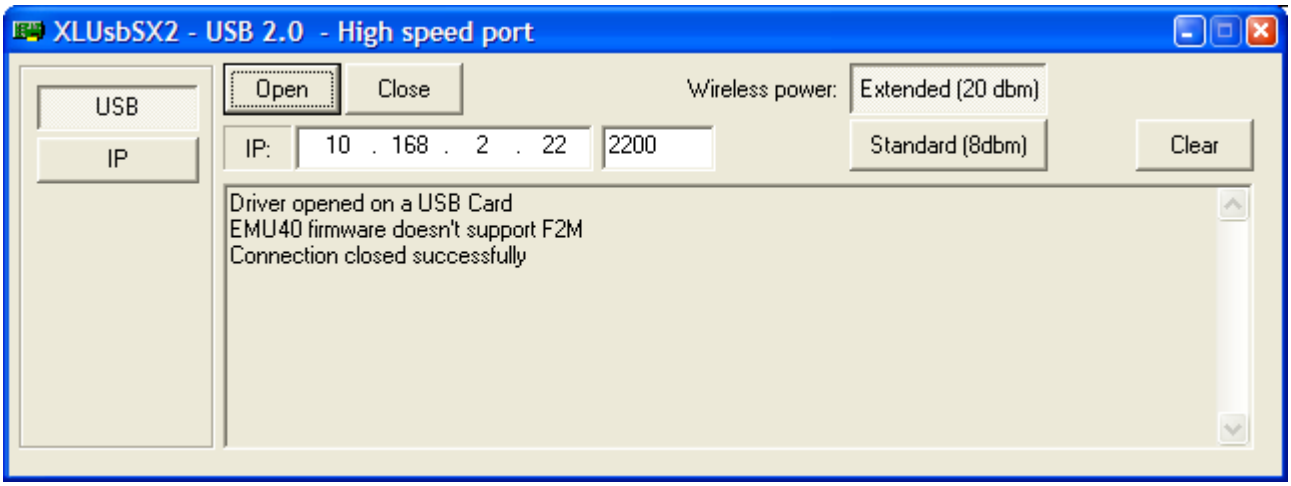


*Figure 14: Using **EMU40Ex**.exe Utility to adjust the Wireless Power*

Click [**Open**] to establish a connection to the amplifier. If the **EMU40EX** amplifier is connected over Ethernet (IP), enter the IP address of the amplifier (the same address that is shown in NeuroWorks amplifier setup). When **EMU40EX** connects, the log will indicate successful connection and the user will be able to adjust the wireless power by clicking [**Extended**] or [**Standard**].

Testing the EMU40EX Amplifier

The **EMU40EX** amplifier is fully assembled, tested, and calibrated before being shipped to you. However, the following sections describe some tests you can perform to verify the performance of the **EMU40EX** amplifier.

Calibration and Verification

There is no need to calibrate the software or the **EMU40EX** amplifier. All calibration is done at the factory before the system is shipped. To verify that the **EMU40EX** amplifier is correctly calibrated, perform the following procedure:

1. Connect the Base Unit to an ***XLTEK*** computer and turn on the system.
2. Start **Natus Database**.
3. To start a new study, click **New EEG** or **Sleep**.
4. Choose **Edit > Settings > Acquisition**.
5. On the Acquisition tab, set the **Reference Electrode** to **Common**.
6. Design four bipolar montages that take the difference of adjacent channels; for example, C3 CZ, C4 T4, T5 P3, etc.
7. Apply a sine wave of 50 microvolts, peak-to-peak amplitude, 10 Hz to all channels of the group using a signal generator. Ensure there is a 50 Ohm load on the generator output if the generator is designed to deliver the specified level into this load.

8. Set the LFF filter to 0.1, the HFF filter to OFF, and the Notch filter to OFF.
9. Verify that no sine wave is greater than 50 microvolts peak-to-peak. 50 microvolts represents gain match to 1%.

NOTE: For more information on setting up a montage, consult the online **Help**.

Channel Test

While in **Acquisition** mode, a channel test may be performed to check whether a signal is being properly processed from the amplifier to the display. A channel test applies a **test signal** to all channels. This allows you to examine the waveforms on the screen to see if all channels are working.

NOTE: A channel test does not validate the connection from the patient electrode to the amplifier input.

To Run a Channel Test

1. Choose **Controls > Channel Test Signal**. The **Channel Test** toolbar appears above the waveform window.
2. Use the Channel Test toolbar to select the desired wave **shape**, **amplitude**, and **frequency**.
3. To stop the channel test and save the current settings, click **Done**.

Channel Test Signal Control

The Channel Test Signal control turns on the channel test signal according to the last settings saved and displays a Channel Test Signal toolbar. The **Channel Test Signal** toolbar is located above the trace display. The toolbar has controls for shape, amplitude and frequency of the test signal.

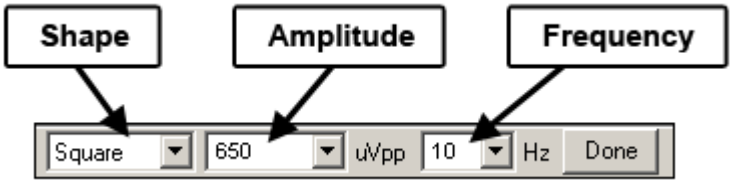


Figure 15 - Channel Test Toolbar

Impedance Check

An impedance check is performed to ensure that the electrode contact with the patient is satisfactory. You can perform an impedance check at any time during a study.

Running an Impedance Check from the Software

When an impedance check is initiated, the software scans all channels (in auto scan mode).

To…	Do this…
Start the impedance check	Choose **Controls > Impedance Check**
Lock onto a channel	Click **Lock Channel**. Then make adjustments to the electrode connection until satisfactory levels are achieved
Proceed to a full impedance check	Click **Release Lock**
End the impedance check	Click **End**
Save the impedance check as part of the study	Click **End and Start Recording**

An impedance check displays bar graphs that show the impedance of each electrode connection. A **green** bar indicates that the reading is below the set threshold. A **red** bar indicates the reading is above the threshold. To set the impedance threshold, click one of the **Threshold** buttons in the **Threshold Group** box on the right side of the **Check Impedance** box.

Pulse Oximeter

The following topics list the specifications cleared by the FDA under K990966 for Masimo SET® board that is built into the **EMU40EX**. The board connects to sensors and provides oxygen saturation, pulse rate, pulse waveform, and other output information via the NeuroWorks software. The **EMU40EX** provides power and isolates the board from the main power and ground. The *NeuroWorks/SleepWorks* software currently provides two types of SpO2 data: a 4 beat averaged pulse rate based on the previous four continuous acceptable pulse rates, and a beat to beat pulse rate value which is calculated based on the previous beat.

Masimo Patents

This device is covered under one or more of the following U.S.A. Patents: 5,758,644; 5,823,950; 6,011,986; 6,157,850; 6,263,222; 6,501,975, international equivalents, or one or more of the patents referenced at www.masimo.com/patents. Other U.S.A and international patents pending.

No Implied License

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in any combination with this device, fall within the scope of one or more of the patents relating to this device.

Indications for Use

The pulse oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® pulse oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Instruction for Use

The indication of a signal inadequacy and/or probe faults for the SP02 sensor is alarmed through the Neuroworks 9.0 software and is displayed on the computer monitor. Software will indicate the following if an anomaly, signal degradation or probe fault is noted during monitoring:

1. Oximeter Event, notes the time of the event and is recorded
2. Pulse rate Event, notes the time of the event and is recorded
3. "Channel Off" indication
4. Low Quality
5. "-----" indication if the probe is misaligned or is not receiving a signal

How the Pulse Oximeter Works

The Masimo SET® pulse oximeter is based on three principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
2. The volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethsymography).
3. The arterio-venous shunting is highly variable, and that fluctuating absorbance by venous blood is a major component of noise during pulse.

The Masimo SET® pulse oximeter as well as traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle.

Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 905 nm:

S(660) = AC(660)/DC(660)

S(905) = AC(905)/DC(905)

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

R = S(660)/S(905)

This value of R is used to find the saturation SpO_2 in a ook-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The Masimo SET® pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. The Masimo SET® pulse oximeter decomposes S(660) and S(905) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

S(660) = S1 + N1

S(905) = S2 + N2

R = S1/S2

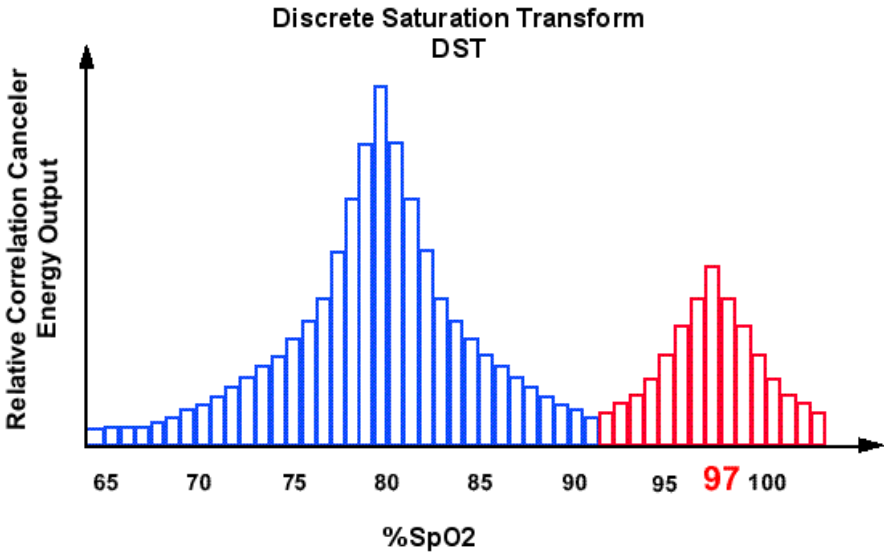
Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation into the pulse oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The above equations are combined and a noise reference (N') is determined:

N' = S(660) - S(905) x R

If there is no noise N' = 0: then S(660) = S(905) x R which is the same relationship for the traditional pulse oximeter.

The equation for the noise reference is based on the value of R, the value being sought to determine the SpO_2. The pulse oximeter's software sweeps through possible values of R that correspond to SpO_2 values between 1% and 100% and generates an N' value for each of these R-values. The S(660) and S(905) signals are processed with each possible N' noise reference through an adaptive correlation canceler (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possible SpO_2 value as shown in the following figure where R corresponds to SpO_2 = 97%:



Discrete Saturation Transform (DST™) plot

The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO_2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The Masimo SET® pulse oximeter SpO_2 therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

Pulse Oximeter Accessories

PC Series Cable: Connects the pulse oximeter module to the oximetry sensors. Transfers LED drive power to the oximetry sensors from the pulse oximeter. The pulse oximeter receives the detector signal from the oximetry sensor through the PC series cable.

LNCS® Series Oximetry Sensors: Low Noise Cabled Sensors (LNCS) and integrated cables are designed to provide optimal pulse oximetry performance. Offering additional protection from liquids and improved moisture resistance, these sensors perform accurately with motion, low perfusion, and intense ambient light. LNCS® sensors can be used with all Masimo SET® pulse oximeters.

Available Oximeter Sensors

Model Number	Description
008775	EMU40EX Masimo LNCS Oximetry Kit
1006 (PC-12)	MASIMO PATIENT CABLE 12' - CONNECTS TO ALL MASIMO PULSE OXIMETER SENSORS
2013	Masimo LNCS Reusable 14ft Patient Cable
2653	Masimo LNCS DBI Reusable Adult Soft with 3ft Cable
1859	Masimo LNCS Disposable Adult Sensor with 18" Cable
1863	Masimo LNCS DCI Reusable Adult Finger Clip Sensor with 3ft Cable
1864	Masimo LNCS DCIP Reusable Pediatric Finger Clip Sensor with 3ft Cable
2258	Masimo LNCS Y1 Reusable Multisite Sensor Requires disposable wraps, standard and petite sizes available

Measurements

If the accuracy of any measurement does not seem reasonable, check the patient's vital signs by alternative means. Then, check the pulse oximeter for proper functioning.

Causes of Inaccurate Measurements

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins (e.g. carboxyhemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight. Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.
- Excessive patient movement.
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

Causes of Loss of Pulse Signal

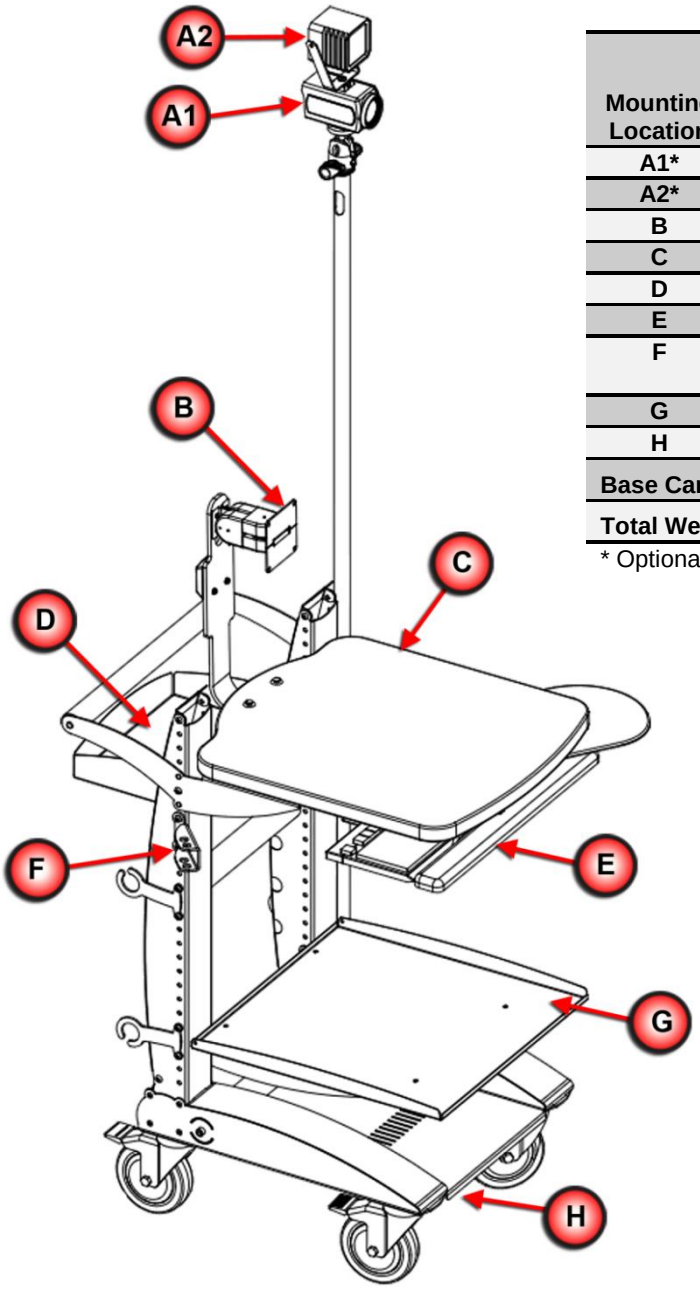
- Sensor is too tight.
- Excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.
- Blood pressure cuff is inflated on the same extremity as the one with a SpO_2 sensor attached.
- Patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- Arterial occlusion is proximal to the sensor.
- Patient is in cardiac arrest or is in shock.

Transport System Specifications and Maintenance

Refer to the corresponding *Instructions for Use* for all system components prior to use. This should include, but is not limited to: cameras, computers, stimulators, and software.

NOTE: Transportation System setup and installation should be performed by Natus qualified personnel only.

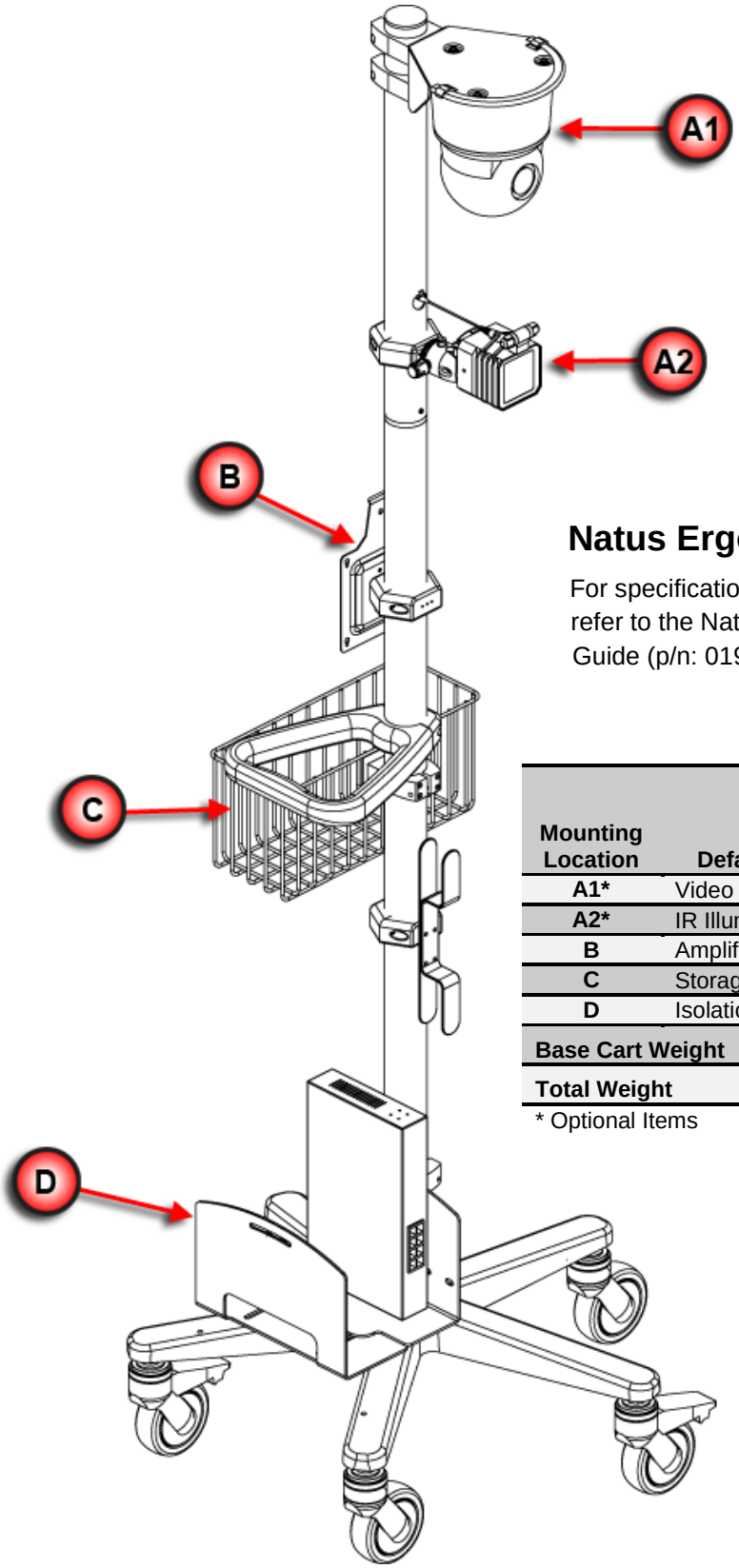
XLTEK Trolley Specifications



Mounting Location	Default Equipment	Equipment Weight [lbs]	Maximum Load [lbs] (including equipment)
A1*	Video Camera	1	3
A2*	IR Illuminator	2	2
B	Monitor Mount	10	10
C	Work Surface	0	10
D	Storage Bin	0	10
E	Keyboard Tray	3	5
F	Natus Photic Stimulator Mount	5	5
G	Tray for Acquisition DT	20	50
H	Isolation Transformer	22	60
Base Cart Weight		**100**	
Total Weight		**163**	**255**

* Optional Items

Neurowand Cart (No PC) Specifications



Natus ErgoJust Cart Specifications

For specifications and details on the ErgoJust cart, please refer to the Natus ErgoJust Installation & Functionality Guide (p/n: 019667).

Mounting Location	Default Equipment	Equipment Weight [lbs]	Maximum Load [lbs] (including equipment)
A1*	Video Camera	4	4
A2*	IR Illuminator	2	2
B	Amplifier Mount	5	5
C	Storage Bin	0	10
D	Isolation Transformer	23	40
Base Cart Weight		**48**	
Total Weight		**82**	**109**

* Optional Items

Maintenance

1. Regularly inspect the trolley to ensure that casters, bolts, equipment mounting and shelf fasteners are secured tight at all times.
2. Regularly inspect all wires and cables for cuts and damages.
3. Regularly inspect all electrical plugs to ensure they are securely inserted into their mating receptacles.

Warnings and Cautions

WARNING: Only use XLTEK approved equipment on the trolley/cart. Non-approved equipment may compromise the function and safety of the system.

Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the system and its components is adequate, sturdy, and safe. Natus is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces. Natus is not responsible for any injury or damage that may result from improper cable storage during transport.

WARNING: Do not tilt the trolley/cart more than 10° incline as this will compromise the stability of the trolley/cart.

TIPPING HAZARD: During transport, the user should guide the cart using both hands, ensuring the wheel base is aligned so that a single caster leads in the direction of motion. Failure to lead the cart with one wheel could result in a tipping hazard when ascending or descending steps or thresholds.

Electrical Input and Isolation Transformer Details

EU	
Electrical Input	200-240V AC, 2.24A @ 50 Hz
Isolation Transformer	Powervar ABC500-22MED
North America	
Electrical Input	120V AC, 3.10A @ 60 Hz
Isolation Transformer	Powervar ABC300-11MED
Japan	
Electrical input	100V-120V AC, 8.0A, 50/60Hz
Isolation Transformer	Powertronix D1CSWFCNOE2

Maintenance, Cleaning, & Disposal

To keep the **EMU40EX** amplifier in good working condition, follow a regular schedule of preventive maintenance. Regular preventive maintenance does not involve access to the interior of the **EMU40EX** amplifier and components. For servicing problems that require corrective maintenance and/or internal component service, call ***Natus Technical Support*** at **1-800-303-0306**, or contact your local ***XLTEK*** representative.

Periodically check cable connections and electrodes for damage and wear. Inspect cables for bent pins. Replace frayed or worn cables. Also, regularly inspect and clean all system components, including:

- Connectors and jack ports
- Base Unit, Breakout Box and USB 2.0 cable
- Electrodes and accessories

Like any piece of equipment, the **EMU40EX** is subject to increased daily wear and tear. Taking basic care of the system, and avoiding extreme physical abuse, helps prolong the lifespan of the **EMU40EX**.

Recommendations

	Disconnect all cables from the **EMU40EX** before wiping. Use a lint-free cloth. Do not use cleaners on any system component.
	Be careful not to allow any fluid to seep into the internal electronic components of the system.
	Do NOT leave the amplifier attached to the computer when transporting the unit.
	Do NOT autoclave, pressure sterilize or gas sterilize this amplifier. It is not possible to clean bio-contaminate from the amplifier.
	Do NOT soak or immerse the amplifier in any liquid.
	A cleaning solution of 70% isopropyl alcohol is recommended.
	Use cleaning solution sparingly. Excessive solution can flow into the amplifier and cause damage to internal components.
	Do NOT touch, press or rub the LCD with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the panel.
	Do NOT use petroleum-based or acetone solutions, or other harsh solvents, to clean the amplifier. These substances attack the device's materials and device failure can result.

Disposal

At the end of the expected service life, when disposing of the **EMU40EX** amplifier and its components, it is recommended that federal, state, and local laws be followed for proper disposal of printed circuit boards, plastics, and metal parts. For disposal of non-Natus accessories, please follow the instructions provided with these items.

Troubleshooting

If you are experiencing problems, try the solutions listed below.

Troubleshooting Checklist

☑	Ask the patient to relax.
☑	Inspect your cables.
☑	Make sure all cables are connected properly between the **EMU40EX** and the computer. If using a LAN, make sure the hardware and software are configured correctly.
☑	Make sure the patient electrodes are connected to the correct channels in the Breakout Box.
☑	Make sure the patient electrodes fit properly into the Breakout Box (not loosely).
☑	Make sure there are no apparent breaks in the patient electrode cables.
☑	Are any of the electrodes touching? If so, they are causing a short circuit and will develop an artifact.
☑	Install a medical grade ground to make sure that your clinic has a properly grounded electrical system.
☑	Check the impedance.
☑	Unplug any other devices on the same circuit such as printers, mechanical beds, vacuum cleaners or other potential sources of interference.
☑	Check the gain and timebase settings to ensure that they are appropriate for the current test. You may also want to check the LFF, HFF, and Notch Filter settings. Choose **Edit > Settings > Montage**. Right-click a cell in the appropriate column and select a value.
☑	Turn the Base Unit off and on. This will reset the system.
☑	Shut down for at least 10 seconds. Then set up the test again from the beginning. Shutting down the computer and restarting sometimes solves the problem.

Getting Help

Natus is committed to providing you with support so you can operate the **EMU40EX** amplifier with ease and confidence. If you need help, follow these steps to find a solution:

Step 1: Document the Incident

Carefully document the incident. If possible, note error messages, dialog box names and what you did before the problem occurred.

Step 2: Search NeuroWorks Online Documentation

To access the help file, choose either the **Help > NeuroWorks Database Help** or the **Help > NeuroWorks EEG Help** (depending on the application).

Alternately, the help documentation can be located using the **Windows Start Menu**:

1. Click the **Start** button on the Windows taskbar.
2. Navigate to the **Excel Tech | Documentation** folder

Step 3: Restart the Computer

Often restarting the computer will solve a problem.

1. Close all applications.
2. Click the **Start** button on the Windows taskbar.
3. Choose **Shut Down…** from the Start menu.
4. Select **Restart the computer** and click **Yes**.

Step 4: Shut Down the Computer

Sometimes you need to shut down the computer completely in order to solve a problem.

3. Click the **Start** button on the Windows taskbar.
4. Choose **Shut Down…** from the Start menu.
5. Select **Shut Down** and click **Yes**.
6. Turn the power off to the unit. Wait for 10 seconds. Turn the power back on.

Step 5: Contact Technical Support

First, write down the serial number of your computer (located on the back) and the serial number of your **EMU40EX** amplifier. Then contact your local XLTEK distributor or Natus Technical Support at **1-800-303-0306** or OTS@Natus.com.

We welcome your feedback and suggestions regarding the **EMU40EX** amplifier and any aspect of our SleepWorks or NeuroWorks systems and software, online Help, line of accessories, and support services.

Accessories & Replacement Parts List

The following are compatible accessories:

Part Number	Description
013926	Natus Base Unit
006562	EMU40EX Breakout Box
See Natus Neurology Accessories Catalog	EEG Accessory Kit
W6438H	EMU40EX Patient Cable from Breakout Box to Base Unit, 10m
002874	EMU40EX Battery Pack
W6232H	EMU40EX Patient Event Switch, 8'
10440	Natus Photic Stimulator
008775	EMU40EX Masimo LNCS Oximetry Kit – For additional Oximetry Accessories, refer to the Available Oximetry Sensors section of this manual.
105295	EMU40EX Cyclops Mounting Kit
10368	EMU40EX Wall Mount Kit
A1011X	Power Cord, 6’
W8194X	USB 2.0 6ft Cable (Hi Speed Gold)
W8128F	Network Cable, 15ft
004893	EMU40EX Modular Pouch
103664	Breakout Box Lanyard, 36”
010863	Network Medical Isolator
015162	Isolation Transformer (EU)
015163	Isolation Transformer (NA)
PSM-22318	Isolation Transformer (JA)
015170	Replacement Fuse, Natus Base Unit
015170	Fuse, Glass 1.5A 250VAC 5X20mm Slow

EEG accessories which can be used with the **EMU40EX** Amplifier System are available for you to browse in the Natus Neuro Accessories Catalog online at *www.natus.com* or via Natus Sales and Support at 1-800-303-0306.

Index

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A Total Service Solution

Standing behind every XLTEK product is Natus Medical Incorporated, an internationally respected innovator of medical products and services.

Our Neurology systems are backed up by an in-house support team staffed with technical and clinical experts, 24/7 support, remote support via WebEx or VPN, the largest clinical and technical field support network in Neuro/Sleep and customized service contracts that include preventative maintenance visits and computer upgrades.

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