

neuro

Natus[®] Quantum[™]

Natus[®] Quantum[™] 64

User and Service Manual



Publisher's Notice



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Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)

2568 Bristol Circle Oakville, Ontario, L6H 5S1 Canada Tel: 905-829-5300 or Fax: 905-829-5304 Toll Free (US & Canada): 800-303-0306 Technical Support Email: OTS@natus.com Website: www.natus.com



EUROPEAN AUTHORIZED REPRESENTATIVE

Natus Manufacturing Limited IDA Business Park, Gort, Co.Galway, Ireland Tel: +353 (0)91 647400 Fax: +353 (0)91 630050

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1. Getting Started

1.1. Quantum System Features

The Natus[®] Quantum[™] amplifier system is designed for the acquisition of EEG data from both scalp and intracranial contacts. The Quantum system's modular design consists of of a Natus base unit and Portable Breakout Boxe(s).

- Quantum breakouts have 128 channels and can be cascaded up to 256 AC channels
- Quantum 64 breakout with maximum 64 AC channels

Additionally, there is an integrated software controlled Digital Switch Matrix (DSM), control of Nicolet Cortical Stimulator, integrated Nonin® pulse oximeter, event button connection, 16 DC inputs, and integrated memory allowing ambulatory recording with automatic backfill to main unit. 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.

Quantum Breakout features include:

- Up to 128 referential channels per breakout, 2 breakouts cascade-able up to 256 channels.
- Up to 8 configurable differential channels per 128 channel breakout (2 inputs per channel)
- Breakouts storing data in internal memory while disconnected from the Natus base unit, and automatic upload to the main unit when re-connected to the natus base unit

Quantum 64 Breakout features include

- Up to 64 referential channels per breakout.
- Up to 4 configurable differential channels (2 inputs per channel)

Features common to systems with Quantum and Quantum 64 breakouts include

- 16 DC channels (12 base unit + 4 first breakout)
- Integrated Pulse Oximeter including SpO2, Pulse Rate and Plethysmogram signals
- Ability to initiate an impedance test, change the threshold, and view the results on an LCD screen
- Digital Switch Matrix (DSM)
- Nicolet Cortical stimulator interface allowing full software controlled Cortical Stimulation in combination with DSM control.
- Digital Trigger Input
- A small and lightweight wearable breakout box
- TCP/IP and USB connectivity
- Patient-event switch interface on both the breakout box and base units
- Photic stimulator interface for EEG applications
- Input for Nicolet Cortical Stimulator
- Modular pouch





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

1.2. Intended Use

The Natus Quantum Amplifier is intended to be used as an electroencephalograph: to acquire, display, store and archive electrophysiological signals. The amplifier should be used in conjunction with *Natus* NeuroWorks[®]/SleepWorks[™] software to acquire scalp and intracranial electroencephalographic (EEG) signals as well as polysomnographic (PSG) signals. The amplifier is designed to facilitate functional mapping using a Digital Switch Matrix. The Digital Switch Matrix portion of the headbox is a combination of hardware relays and software controls allowing the user (physician or technologist) to switch electrode pairs between the EEG recording amplifier and the external cortical stimulator for stimulus delivery.

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

1.3. System Components

The Quantum Amplifier system is provided with optional system components. Computers are intended to run the NeuroWorks/SleepWorks 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 Quantum amplifier while keeping the system mobile.

1.4. Essential Performance 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.

1.5. Operating Principle of the Quantum Amplifier

The Natus Quantum amplifier system is comprised of a base unit and several breakout boxes. It is part of a system that is made up of a personal computer, a photic stimulator, an isolation transformer, video and audio equipment, networking equipment, and mechanical supports. The amplifier also contains an internal switch matrix to allow for a connection to an external cortical stimulator.

EEG and other physiological signals, from scalp electrodes, grid or needle electrodes, and other accessories such as pulse oximeters can be acquired by the Natus Quantum amplifier. These signals are



digitized and transmitted to the personal computer running the *Natus* NeuroWorks/SleepWorks software. The signals are displayed on the personal computer and can be recorded to the computer's local storage or to remote networked storage for later review.

The following diagram illustrates the components and the workflow in a typical setup with NeuroWorks/SleepWorks main unit:



Quantum Breakout (amplifier): Neurophysiological signals like EEG, EMG, EOG, ECG are measured using commonly available electrodes and sensors connecting to the amplifier through standard DIN42802 touch-proof connectors. Low voltage EEG, EMG EOG or ECG signals are amplified, low pass filtered and converted from analog to digital.

- 2 The Natus Base Unit, connected to the computer through a standard Ethernet or USB cable, allows for connection of the breakout box and a photic stimulator.
- 3 Video is captured and synchronized with EEG

4

- A **Photic stimulator** may be connected to the Natus base unit and controlled from the NeuroWorks/SleepWorks acquisition software.
- 5 NeuroWorks/SleepWorks software controls the amplifier and records data to the hard disk. The data is displayed with a user configurable referential or bipolar montage.
- 6 Computer running Windows OS and NeuroWorks/SleepWorks software. Data from Quantum amplifier system and camera are stored locally or on a server.

7 Isolation transformer



1.6. Using the Manual

This manual describes the theory, features, set up, operation and maintenance of the **Quantum** amplifier. It also provides information on specifications, troubleshooting and getting help.

When reviewing the procedures, we recommend you read the entire section first, before beginning a sequence. Please follow the instructions carefully.

1.6.1. 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
\bigwedge	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.



2. Safety & Standards Conformity

2.1. Standards of Compliance and Normative References

Multichannel Sleep/EEG Headbox System, Model Quantum Amplifier, detachable cord connected, portable 100-230Vac, 50/60Hz, 80VA.

- 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 anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- 5. Mode of operation: Continuous
- 6. Environmental Conditions: Normal: 10-30°C, 30-75% rH, 700-1060hPa

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

Table 1 – Safet	v 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	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
CENELEC EN 60601-1:2006 + A1:2013	
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, Edition 4.0, February 1, 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– 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



2.2. Declaration of Compliance for IEC 60601-1-2

Table 1 - Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions

The Quantum is intended for use in the electromagnetic environment specified below. The customer or the user of the Quantum should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Quantum 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 Quantum is suitable for use in all establishments other than domestic and those directly connected to
Harmonic emissions IEC 61000-3-2	Class A	supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	



Table 2 - Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity

The Quantum is intended for use in the electromagnetic environment specified below. The customer or the user of the Quantum should assure that it is used in such an environment.

Immunity Test	IEC 60601	Compliance	Electromagnetic Environment - Guidance	
	Test Level	Level		
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 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, 100Khz for power supply lines ±1 kV, 100Khz 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	<100% drop, 0/5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods 40% dip for 5 cycles	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Quantum requires continued operation during power mains interruption, it is recommended that the Quantum be powered from an uninterruptible power supply or a battery.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 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 Quantum is intended for use in the electromagnetic environment specified below. The customer or the user of the Quantum should assure that it is used in such an environment							
Immunity test	IEC 60601 Test Level	60601 Compliance Electromagnetic Environment - Guidance Level Level					
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 2.7 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Quantum, 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:				
NUTE 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 Quantum is used exceeds the applicable RF compliance level above, the Quantum should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the Quantum.

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

Table 4 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency	Band ^{a)}	Service ^{a)}	Modulation ^{b)}	Maximum Power	Distance	IMMUNITY TEST LEVEL		
(MHz)	(MHz)			(W)	(m)	(V/m)		
385	380 –390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27		
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28		
710			Pulse					
745	704 – 787	LTE Band 13, 17	modulation ^{b)}	0,2	0,3	9		
780			217 Hz					
810		CCM 000/000						
870	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA	Pulse modulation ^{b)} 18 Hz	2	0,3	28		
930		850,LTE Ballu 5						
1,720		GSM 1800; CDMA 1900;						
1,845	1,700 – 1,990	1,700 – 1,990	1,700 – 1,990	GSM 1900; DECT; LTE Band	Pulse modulation ^{b)} 217 Hz	2	0,3	28
1,970		1, 3, 4, 25; UMTS						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28		
5,240			Pulse					
5,500	5,100 - 5,800	WLAN 802.11	modulation ^{b)}	0,2	0,3	9		
5,785]	a/11	217 Hz					
NOTE: If nece	essary to achieve	the IMMUNITY TEST	LEVEL, the distance betw	ween the transmi	tting antenna and	the ME		
EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.								

^{a)} For some services, only the uplink frequencies are included. ^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal.

^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.



2.3. 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.
- <u>Warning:</u> Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.



3. Contraindications and Warnings

3.1. Contraindications

Natus Quantum systems shall NOT be used in the following conditions:

\bigwedge	Do NOT operate the system in the presence of flammable anesthetics.
\bigwedge	Check areas of use to avoid using the system in the presence of flammable gases.
\bigwedge	To ensure the validity of signals, do not operate the device near any sources of electromagnetic interference.
$\mathbf{\mathbf{\hat{N}}}$	<i>Natus</i> systems are not AP or APG rated. DO NOT USE a <i>Natus</i> system in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
	The Quantum amplifier system is NOT designed to work with defibrillators. The system could be damaged when used with this device.
\bigwedge	Operation of this equipment with input signals in excess of a range of +/-10mV may cause incorrect results.

3.2. Warnings and Cautions

3.2.1. 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.

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 Quantum amplifier 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.	



	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 section for further details.
Λ	Do not immerse the amplifier or any of its components in water or other fluid.
	This equipment/system is intended for use by Healthcare professionals ONLY. Please read this section before installing any of the hardware. Refer to this section when you operate, transport, store, or re-install the system.
	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.
	When replacing the fuse for the Quantum amplifier system, it must be replaced by a fuse with the same type and rating as the original fuse. Replacement fuses should be <u>purchased</u> from Natus directly.
\bigwedge	The Quantum Amplifier system is compatible with NeuroWorks/SleepWorks v9.0 and newer.
$\underline{\land}$	The Natus base unit is classified as an IPX0 – ordinary degree of protection against ingress of water according to IEC 60529.
	The Quantum 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.
$\underline{\land}$	The Quantum amplifier system is classified as a class I device according to IEC 60601-1.
	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.
$\underline{\wedge}$	WARNING: No modification of this equipment is allowed.
	For systems used in the Operating Room with a Cautery device, the use of Ethernet type connection is mandatory to ensure continuous recording.



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	For cortical mapping procedures with software controlled Nicolet cortical stimulator, make sure that the Nicolet cortical stimulator device is accessible for manual operation. It is required to stop stimulation manually on the device in case the connection with the stimulator is lost.
\bigwedge	Operation of this equipment with input signals in excess of a range of +/-10mV may cause incorrect results.
	Quantum Breakout Main contains internal Lithium ion (Li-ion) battery with 2260 mAh (8.4Wh) capacity. The cell is approved according UL1642 and UN 38.3 certified. This battery is UL 2054 listed and certified according to IEC 62133 Edition 2. Upon initial use, the battery requires a full charge before use. Use only Quantum Breakout Main for charging. Using an incorrect charger can damage the battery.
	For long term storage of main breakouts, the internal battery will deplete. It is recommended to insert fresh internal battery when the breakout is used after a long term storage. Keep Breakout away from fire or other sources of extreme heat. Exposure of the Quantum to extreme heat may result in an explosion.

3.2.2. Electrostatic Discharge (ESD) Precautions:

\land	Electrostatic Discharge (ESD) Precaution: Be sure to take the appropriate Electrostatic Discharge (ESD) precautions. Disconnect the cables before moving, cabling, or performing any set up procedures. Connectors marked with the ESD protection symbol should not be touched. For detailed handling procedures, refer to the Electrostatic Discharge (ESD) Handling Procedures and Warnings section.	
\wedge	Turn off all system power and disconnect the power cord from the system and the wall before attempting to clean the unit. The Quantum unit can be wiped clean with a soft, damp cloth using non-conductive distilled water, electrically non-conductive inert surfactants or a Natus approved cold sterilizing agent. It is important to dry off the unit quickly. Avoid letting liquid seep into any of the internal electronics of the system. Do not use any abrasive cleaner on the system.	
\wedge	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.	
\land	The Quantum amplifier system needs special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and operated according to EMC guidelines. Refer to the EMC Standard of Compliance and Normative References table in the Safety & Standards Conformity section.	



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\bigwedge	Using the Quantum amplifier system with cables and accessories not approved by Natus may negatively affect EMC performance, including electromagnetic immunity. Refer to the <u>Electromagnetic Immunity</u> table in the <u>Safety & Standards Conformity</u> section.
	External equipment may interfere with the performance of the Quantum amplifier system, even if other equipment complies with CISPR Emission requirements. Refer to the <u>EMC</u> <u>Standard of Compliance and Normative References</u> table in the <u>Safety & Standards</u> <u>Conformity</u> section.
	The Quantum amplifier system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the amplifier should be observed to verify normal operation in the configuration in which it will be used. Refer to the <u>Recommended Separation Distances</u> table in the <u>Safety & Standards Conformity</u> section for minimum recommended separation distances.
\land	Do not connect items which are not specified as part of the Quantum amplifier system to the system.

3.2.3. Electrical Warnings and Cautions

\bigwedge	<i>Natus</i> systems are intended for connection to a properly grounded electrical outlet only.
\bigwedge	Conductive parts of electrodes and their connectors are not to contact other conductive parts and earth.
\bigwedge	Do not place MULTIPLE PORTABLE SOCKET-OUTLETS (MPSOs) on the floor.
\bigwedge	Do not connect additional MPSOs or extension cords to the Quantum Amplifier system.
\bigwedge	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.
\bigwedge	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 Quantum Amplifier system for supplying power to any equipment that is not part of the system.



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	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 Quantum 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.
\bigwedge	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.
	Do NOT connect electrical equipment which has not been supplied as a part of the system to the MPSO.
\land	Ensure that the Quantum Amplifier system is solely connected to a three-wire, grounded, hospital-grade receptacle.

3.2.4. Patient Environment Warnings and Cautions

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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.

\bigwedge	Connect all patient electrodes to fully electrically isolated physiological devices only. Connecting patient electrodes to any other device or external outlet may result in personal injury.	
	If a computer is located in the patient environment and is connected to a network, the computer and other hardware connected to it MUST be powered using an isolation transformer, and a network isolator MUST be used to isolate the computer from the site's LAN.	
\bigwedge	The patient event button attached to the Quantum Amplifier system is NOT intended for critical patient-safety-related incidents.	
	Patient connections are NOT intended for direct cardiac contact.	
\bigwedge	As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.	
\bigwedge	Do NOT touch any Quantum system accessible metal parts and the patient simultaneously.	



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\wedge	Do NOT touch any earth-grounded components of the Quantum system and the patient simultaneously.	
\bigwedge	Do NOT allow loose electrodes to contact metal parts.	
\bigwedge	Do not use the Quantum system in the vicinity of MRI or CT systems.	
	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 harness/belt and pouch(es) are used without ensuring they are secured to the patient properly. Refer to the <u>Adding the</u> <u>Quantum or Quantum 64 breakout box(es) to the Modular Pouch</u> section for details.	
$\mathbf{\mathbf{k}}$	REPETITIVE STRESS INJURY HAZARD: Sustained use of this product without ergonomic consideration may result in repetitive stress injury.	
\bigwedge	User is not to position ME equipment in such a way as to make it difficult to operate the disconnection device.	
\bigwedge	The Quantum Amplifier system does NOT include SpO2 or Pulse Rate alarms.	
$\mathbf{\mathbf{k}}$	If a video camera is present in the patient environment, the network as well as the power supply must be isolated.	
	Each Breakout box should be placed separately in an individual Quantum Modular Pouch. Neither the Quantum pouch(es) nor the breakout box(es) should be covered by blankets or any other material. Failure to follow these instructions could raise the temperature of the Quantum Breakout(s) above normal operational levels.	
\bigwedge	The Quantum breakout box(es) should only be used in conjunction with the <u>Quantum</u> Modular Pouch.	
	If a computer is located in the patient environment, it must be 60601-1 approved or 60950-1 approved and powered by a 60601-1 approved isolation transformer.	
	No parts of the ME equipment shall be serviced or maintained while in use with a patient.	



3.2.5. 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.
\land	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.
$\underline{\land}$	Only Trolleys and Carts validated by Natus for use with the Quantum amplifier system may be used.

3.2.6. Pulse Oximeter Sensor Warnings



Refer to the pulse oximeter sensor user manual for associated precautions, warnings, and instructions for use.

3.2.7. Wireless Option Warnings and Cautions



Refer to the pulse oximeter sensor user manual for associated precautions, warnings, and instructions for use.

3.2.8. Conducted Immunity Warnings



In environments where parasitic electrical noise interferes with the electrical biologic signal, there is no risk of misinterpretation of EEG waveforms or ancillary data . Any abnormal pattern or out of range value is confirmed by trained medical professionals performing the test. In addition to ancillary data (e.g. SpO2), the accompanying EEG (Electroencephalograph) amplifier's signals will also be contaminated past the point where any clinical signal interpretation is possible. Trained electroencephalographers and technologists are well equipped to identify and disregard signals that are obscured by environmental noise.



3.3. Procedures and Warnings

3.3.1. Electrostatic Discharge (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 poweron.

3.3.2. 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, which are coupled 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:

- Verify the power supply and all portable multiple socket-outlets are off the floor 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.



4. Description of Symbols

Symbol	Description
\triangle	ATTENTION: Consult Accompanying Documents
ĺ	Consult Accompanying Documents
E	Consult Operating Instructions
	Pushing Prohibited
	Protective Earth (Ground)
★	Type BF Equipment
<u>/</u>	Dangerous Voltage
\bigcirc	Alternating Current
===	Direct Current
	Power On
0	Power Off
	EU only: Do Not Dispose as Unsorted Municipal Waste



Symbol	Description
C E 0086	CE Mark
	Class II Equipment (non-grounded enclosure)
	ESD Sensitive or Static Sensitive
\bigcirc	Base to Breakout Cable
←	Breakout to Breakout Cable Connector (not available on Quantum 64)
	Cortical Stimulator Adapter Connector
\checkmark	Breakout Box Status LED
DC13 I DC16	DC Inputs 13 to 16 Breakout Cable Connector
Ô	Patient Event Button Connector
SpO ₂	Nonin Pulse Oximeter Sensor SpO2 Connector
品	LAN Connection
•	USB Connection
	Manufacturer Information



Symbol	Description
Ť	Non-Waterproof Device
	Equipotential stud
Ţ	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.



5. Specifications

Specifications specific to Quantum breakout(s)		
AC Channels	128 per breakout, cascade-able up to 256	
AC Channels, Referential	128 per breakout	
AC Channels, Differential	Programmable up to 8 per bank (112 ref)	
Specifications specific to Quantum 64 break	out	
AC Channels	64	
AC Channels, Referential	64	
AC Channels, Differential	Programmable up to 4	
Specifications common to all Quantum configurations		
DC Channels	16	
Digital Trigger Channel	8-bit TTL	
Pulse Oximetry Channels	SpO2, Pulse Rate	
Input Impedance	Common Mode/DC Input Impedance: ≥ 1 Gohm Differential Mode: 44 Mohm // 280pF +/- 20%	
Input Noise ³	≤ 2 uV pk-to-pk (0.1Hz to 100 Hz)	
Common Mode Rejection ratio	≥ 106 dB min	
Sampling Rates	256, 512, 1024, 2048, 4096, 8192, 16384Hz	
Bandwidth	DC to 4288Hz (default HFF is 0.08Hz)	
Input Signal Range	20mV pk-to-pk, +/-0.3VDC	
Channel Crosstalk	< -67dB	
Host Interface		
Network Connection	Gigabit Ethernet DHCP	
Direct Connection	USB 2.0 Hi-Speed, Gigabit Ethernet	
Modes of Operation		
Recording Mode	Tethered / Ambulatory	
Ambulatory Mode	64GB Internal memory, Autonomy: at least 2h (with new fully charged External battery pack)	

³ 1.8uV pk-to-pk noise is typical, 2uV pk-to-pk is guaranteed.



Base Unit Fuse Type and rating	T 1.6A / 250V	
Power	80VA	
Base unit power supply	100 – 230V, 50/60Hz	
Breakout power supply	Breakout connected to base unit: Powered by base unit Breakout disconnected from base unit (ambulatory	
	mode): Powered by external battery pack.	
Environmental Conditions for Use		
Operating Environmental Limits	Temperature: 10°C to 30°C	
	Relative Humidity: 30%–75%	
	Atmospheric Pressure	: 700 hPa to 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	e 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")
	Natus Quantum Breakout Main	137.0mm x 133.3mm x 53.6mm (5.39" x 5.25" x 2.11")
	Natus Quantum	137.0mm x 133.3mm x 53.6mm
	Breakout B	(5.39" x 5.25" x 2.11")
	Natus Quantum 64 breakout	(5.39" x 5.25" x 2.11") 137.0mm x 133.3mm x 53.6mm (5.39" x 5.25" x 2.11")
Weight	Natus Quantum 64 breakout Natus Base Unit	(5.39" x 5.25" x 2.11") 137.0mm x 133.3mm x 53.6mm (5.39" x 5.25" x 2.11") 2.298kg (5.067 lb)
Weight	Natus Quantum 64 breakout Natus Base Unit Natus Quantum Breakout Main	(5.39" x 5.25" x 2.11") 137.0mm x 133.3mm x 53.6mm (5.39" x 5.25" x 2.11") 2.298kg (5.067 lb) 0.708kg (1.56lb)
Weight	Breakout B Natus Quantum 64 breakout Natus Base Unit Natus Quantum Breakout Main Natus Quantum Breakout B	(5.39" x 5.25" x 2.11") 137.0mm x 133.3mm x 53.6mm (5.39" x 5.25" x 2.11") 2.298kg (5.067 lb) 0.708kg (1.56lb) 0.610kg (1.35lb)



Li-Polymer Battery Specifications (Inside Quantum Main Breakout) - Internal Rechargeable		
Battery Type	Lithium Polymer	
Rated Capacity	2260 mAh	
Voltage	3.7V	
Watt-hour Rating	8.4Wh	
Charging Method	Constant Current + Constar	nt Voltage
Maximum Charge Voltage	4.2V (±50mV)	
Maximum Continuous Charge Current	1080 mA	
Maximum Continuous Discharge Current	2000mA	
Operating Conditions	Charging Temperature	0°C to +45°C
	Discharging Temperature	-20°C to +60°C
	Humidity	65 ± 20%RH
Approvals	UL 1642	

Sample rates and corresponding -3dB (+/-5%) bandwidths supported by the amplifier include:

Fs(Hz)	BW (Hz)	Connection Mode
256	109	USB / LAN
512	219	USB / LAN
1024	439	USB / LAN
2048	878	USB / LAN
4096	1757	LAN
8192	3514	LAN
16384	4288	LAN



6. Product Images and Description

6.1. Quantum Amplifier System with 128 to 256 channels





6.2. Quantum 64 Amplifier System





6.3. Natus Base Unit

1	Power Button. Labeled with 🕛.
2	Connects to Nicolet Cortical Stimilator. Labeled with IOIO.
3	Can be used to connect the Natus Base Unit directly to a PC and/or Laptop. Labeled with
4	Can be used to connect the Natus Base Unit to a system network. Labeled with
5	Ground equipotential terminal.
6	Connects to the Natus Base Unit to the mains power supply.
7	Fuse Compartment. Labeled with: ~ Fuse: T1.6A/250V~80VA; 100-230VAC.
8	Labeled with .
9	Can be used to connect DC signals from external devices. Labeled with DC1-DC12.
10	Photic Stimulator Connector. Labeled with
11	Patient Event Button Connector. Labeled with $\hat{\mathbb{Q}}$.
12	Base to Breakout Main Cable Connector. Used to connect the base unit to the Quantum patient breakout box. Labeled with Quantum .
13	Used to connect the EMU40EX breakout box (p/n 006562). 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 a Quantum breakout box.



6.4. Quantum Breakout Boxes MAIN and B



Quantum breakout MAIN, channels 1 to 128

Quantum breakout B, channels 129 to 256

1	Natus Base to Breakout Main Cable Connection. Labeled with 🕙.
2	Cortical Stimulator Adapter Connection. Labeled with 🥄
3	DC Inputs 13 to 16 Breakout Cable Connection. Labeled with DC16.
4	Nonin Oximeter Connection. Labeled with 🙀.
5	Patient Event Button Connection. Labeled with $\widehat{\Box}$.
6	Breakout Main to Breakout B Cable Connection. Labeled with 4
7	Breakout Box Status LED. Labeled with ✓.
8	Reserved for future use. Labeled with
9	Reserved for future use. Labeled with .
10	Labeled with ⊙A. Green Indicates Power On.
11	LED Indicator based on breakout boxes attached. Labeled with B, C, or D.
12	Standard EEG Channel Inputs. Labeled numerically.
13	Breakout B to Breakout Main Cable Connection. Labeled with 🕙.
14	Reserved for future use. Labeled with ◄⊖.


6.4.1. Quantum Breakout MAIN, Bottom View



6.5. Quantum Pin Box Options

6.5.1. Standard Numerical Pin Boxes



Standard Numeric Channel Inputs, 1 – 256 channels



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6.5.2. 10-10/10-20 Pin Box



1 Standard 10-10/10-20 Channel Inputs. See <u>Connecting the 10-10/10-20 Pin box to the Quantum</u> <u>Breakout</u> for additional information.



NOTE: The 10-10/10-20 pinbox is unavailable with the Quantum 64 breakout.

6.5.2.1. 10-10/10-20 Pin Box (Side View)



1 Additional Channel Inputs.



6.5.3. Bulk Connector Pin Boxes

Bulk connector Pin Boxes feature a single multi-pin connector for all 64 channels per bin box, and are designed for convenient connection of head caps with up to 256 electrodes. Other electrodes such as Subdermal grids may be connected too. Connector Pin layout is available in Appendix B.

The last 16 inputs of each 64 channel pin box are also available as individual touch proof inputs. These may be used for connecting additional electrodes and sensors with head caps with less than 64 channels connected to the bulk connector.



1 Bulk Connectors. Used to connect pre-wired headsets or assemblies for EEG acquisition from the patient. See <u>Appendix B</u> for additional wiring details.



NOTE: Only one pinbox can be used with the Quantum 64 breakout..



6.6. Quantum 64 Breakout Box



Quantum 64 breakout (64 channels max.)

1	Base to Breakout Main Cable Connection. Labeled with 🕙.
2	Cortical Stimulator Adapter Connection. Labeled with 🥄
3	DC Inputs 13 to 16 Breakout Cable Connection. Labeled with DC16.
4	Nonin Oximeter Connection. Labeled with 🙀.
5	Patient Event Button Connection. Labeled with $\hat{\mathbb{Q}}$.
6	This functionality is unavailable Labeled with ${}^{\bullet}\!$
7	Breakout Box Status LED. Labeled with ✓.
8	Reserved for future use. Labeled with
9	Reserved for future use. Labeled with .
10	Labeled with ⊙A. Green Indicates Power On.
11	Standard EEG Channel Inputs. Labeled numerically.



6.7. Quantum 64 Pin Box Options

6.7.1. Standard Numerical Pin Boxes





NOTE: Only one pinbox can be used with the Quantum 64 breakout..

6.7.2. Bulk Connector Pin Box

Bulk connector Pin Boxes feature a single multi-pin connector for all 64 channel, and are designed for convenient connection of head caps with up to 64 electrodes. Other electrodes such as Subdermal grids may be connected too. Connector Pin layout is available in <u>Appendix B</u>.

The last 16 inputs of each 64 channel pin box are also available as individual touch proof inputs. These may be used for connecting additional electrodes and sensors with head caps with less than 64 channels connected to the bulk connector.





7. Setup

7.1. Connecting the Natus Base Unit

The Quantum amplifier system is designed to work with a *Natus* computer system running Natus NeuroWorks/SleepWorks software.

- 1. Confirm 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 cable or via USB. The base unit can be connected to a standard switched gigabit network jack or to a secondary gigabit network interface card (recommended) on the acquisition computer.
- 3. Connect the power cable, base to breakout cable, patient event button, and any additional accessories (DC input cables, Stimulator adapter cable etc.) as required.

7.2. Potential Equalization Conductor

The Natus 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 Quantum system is used.

7.3. Connecting the Breakout Boxes to the Natus Base Unit

The Natus Base unit and Breakout Boxes can be interfaced with a quick and easy connection of the patient tether cable. The connection on the Breakout and the Natus Base unit are light gray for easy identification.





To Connect the Natus base unit to the Quantum Main Breakout box:

- Locate the Quantum Patient Cable from Breakout to Base (p/n 013348) which was included with your purchase and connect it to the Natus Base unit at the connection labeled with Quantum (#1 on the image above).
- 2. Connect the other end of the tether cable to the Quantum Main Breakout at the connection labeled with (#2 on the image above).

7.3.1. Connecting to the Secondary Breakout Box

Once the Natus Base unit and the Main Breakout box #1 are connected, you can connect an additional breakout box which provides additional channels for use with the Quantum Amplifier.

To Connect to the Secondary Breakout box:

- Connect the black marked connector on the Quantum Breakout to Breakout Cable (p/n 013415) to the black marked connector on the Quantum Main Breakout unit. The connection is labeled with [▲] (#3 on the image above).
- 2. Connect the other end of the cable to the secondary breakout box. This connector on both units are marked in blue and the breakout box is labeled with () (#4 on the image above).

7.3.2. Removing the Connections

To remove the Cable Connections:

• Grasp the connector, slide outwards to unlatch, and then remove the cable with a gentle pull.





7.4. Connecting the Standard or Bulk Connector Pin Boxes to the Breakout Box

Quantum provides multiple Pin Box options for input connections. The Standard Pin boxes, Quantum 10-10/10-20 Pin box, and Bulk Connector Pin boxes are easily connected to the Quantum Breakouts by following the steps described in this section.

To Connect the Standard or Bulk Connector Pin Boxes:

- 1. Connect the Standard (#1 in the image below) or Bulk Connector (Not Shown) Pin box to the Breakout box by seating the pin box module into place.
- Once the pin box module has been seated into position, lock the module onto the breakout box (#2 in the image below) by sliding the lock towards the back of the breakout box.
- 3. Seat and lock additional pin boxes into the breakouts as required.





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NOTE: Prior to removing the Standard or Bulk Connector pin boxes from the breakout, ensure you have unlocked the unit by sliding the locks toward the front of the breakout box.

7.5. Quantum 10-10/10-20 Pin box

The Quantum 10-10/10-20 Pin box option can be connected directly to the Quantum's main Breakout to facilitate EEG recordings while using the 10-10 and 10-20 electrode placement systems. The Quantum 10-10/10-20 Pin box can be used for routine EEG recordings, extended EEG recordings, PSG recordings, and more, by providing the following:

- 75 10-10 EEG inputs
- 6 additional EEG inputs Sp1, Sp2, T1, T2, Cb1, and Cb2
- 2 dedicated EOG inputs LOC and ROC
- 2 dedicated ECG inputs ECG+ and ECG-
- 38 additional universal EEG inputs



- Dedicated REF and GND inputs
- Uniquely colored 10-20 inputs to facilitate Routine EEG recordings

A secondary Breakout (129-256) may be connected to the system for additional channels.

To connect the 10-10/10-20 Pin box to the Quantum Main Breakout:

- 1. Connect the 10-10/10-20 Pin box (#2 in the image below) to the Quantum Main Breakout (#1 in the image below) by seating and locking (#3 in the image below) the larger pin box module into place.
- 2. Once the larger pin box module has been connected, seat (#4 in the image below) and lock (#5 in the image below) the smaller input module into position.



- 3. Create or select a Quantum montage which uses the 10-10 or 10-20 labels. Please refer to the NeuroWorks or SleepWorks user manuals for additional information on how to create or select the montage.
- Ensure the 10-10/10-20 Pin box is enabled in the NeuroWorks/SleepWorks software by selecting Edit | Settings | Acquisition (tab).



NOTE: Additional Breakout boxes can be added for additional channels. See <u>Connecting the Natus Base Unit and Breakout Boxes</u> for additional information.



dit Settings	×
Protocol Montage Channel Labels Timebase Acquisition	Review Analysis Alarms
Quantum Headbox	Electrode Detection
Reference Electrode	Channel Status
External(Ref)	All channels on Set manually
Comment:	Fp1 ON Channel Off Fp2 ON E F3 ON E
Sampling Frequency 256 512 1024 2048 4096 8192 12304	F4 ON C3 ON C4 ON P3 ON P4 ON O1 ON P7 ON F7 ON F8 ON T3 ON T4 ON
Automatic Actions Image: Start data recording when study starts Image: Record video when data recording starts Image: Start ambulatory study when HB disconnected Image: Restart study at: 07:30 AM	T5 ON ID-10 MODULE T6 ON 1 A1 ON 1 A2 ON Cz ON Oz ON 5 6 Fpz ON C24 OFF
Restart study every: 24 Nours Run protocol when data recording starts: Impedance Check Default montage used when study starts: Quantum 10-10 Average Reference	Pg1 ON Image: Constraint of the second sec
Named Profile Quantum 10-10 Pinbox	
	OK Cancel Apply

5. Activate the 10-10 module for the Quantum by selecting the checkbox next to **10-10 MODULE** under the **Pinboard Usage** section.



7.6. Quantum Amplifier System Connection Diagram



NOTE: Setup and Installation of the Quantum Amplifier System should be performed by Natus qualified personnel only.



NOTE: When the Base Unit is connected to an acquisition computer via USB, the maximum sample rate is 2048Hz. When the Base Unit is connected to an acquisition computer via gigabit Ethernet, sample rates up to 16KHz may be used for 128 and 256 channel configurations.



For systems used in the Operating Room with a Cautery device, the use of Ethernet type connection is mandatory to ensure continuous recording.



7.7. Quantum 64 Amplifier System Connection Diagram



NOTE: Setup and Installation of the Quantum 64 amplifier System should be performed by Natus qualified personnel only.



NOTE: When the natus base unit is connected to an acquisition computer via USB, the maximum sample rates are 4096Hz. When the Base Unit is connected to an acquisition computer via gigabit Ethernet, sample rates up to 16KHz may be used.



For systems used in the Operating Room with a Cautery device, the use of Ethernet type connection is mandatory to ensure continuous recording.



8. Configuring the Natus Base Unit

8.1. Setting the IP Address

1. Once the base unit has been powered up, press and hold power button \bigcirc 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 **Use the following IP address**; otherwise, the DNS server will enable manual entry of the **IP** address and **DNS server** for the base unit.



- 4. Press **Save** to finalize changes to the IP configuration.
- 5. Press **Close** to return to the main screen.
- 6. From the Main Screen, confirm system setup by pressing the **Info** button to view the information screen.



7. On the information screen, ensure that the **IP address** is set as intended, and that the connection information related to the breakout and pin-boxes show that all components are recognized by the system.

Serial number.	QUANTUM-0000	Breakout A	Connected		
Breakout model:	Quantum	Breakout B	Connected		
Connection status:	Connected (ETH)				
Machine name:					
IP DHCP/STATIC:	DHCP	Pinb 1 (001-064)	Connected		
IP address:	192.168.2.68	Pinb 2 (065-128)	Connected		
Subnet mask:	255.255.255.0	Pinb 3 (129-192)	Connected		
Default gateway:		Pinb 4 (193-256)	Connected		
MAC address:	00:E0:4C:15:0A:6A				
Net. speed (Mb/s):					
Network cable:					
Digital trigger mode:					
Brkb. status:	Idle	Oximeter:			
Brkb. total storage:	32 GB	Oximeter sensor.			
Brkb. free storage:	100%	SpO2 (%):			
Brkb. battery level:	Normal (Full)	Pulse rate (bpm):			
		More	Close		
●●●● 舌舌 〔					



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

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

The amplifier is now setup and ready to use.



8.2. Touchscreen Icons

When properly installed and connected to the PC, the Quantum Amplifier 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.

lcon	Description				
0000	Shows the number of breakout boxes (1 to 2) that are connected to the base unit.				
¢.	Indicates that th connection with	e headbox is connected t the software.	to the PC via USB and has estal	blished a	
	Indicates that the	e headbox is connected to	the PC via an Ethernet cable.		
	If the co box and	lor is BLUE, the PC softv I is typically running a stu	vare is connected to the head dy.		
	 If the consoletation 	olor is BLACK, the Ethern has not established a co	et cable is connected but the onnection with the headbox.		
1	• If it is T	RANSPARENT, then no r	network cable is plugged in.	22	
	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				
	This symbol indicates that status of the SD card. It is representative of the amount of Disk space available on the breakout box. The color changes with the available space remaining on the card				
	lcon	Color	Approximate Space Remaining		
	í	Gray	< 5%		
		Red	< 25%		
	1	Orange	< 50%		
	1	Yellow	< 75%		
	Green <100%				
	Note: The Battery symbol will also be disabled if there is no card in the unit.				
	This symbol shows the number of pin boxes attached to the breakout boxes (1 through 4).				
**	Turns the LCD Screen off.				
Info	Displays the info Address for add	ormation about the Break itional information on this	out connected. See 8.1 Setting screen.	the IP	



lcon	Description
۲	Indicates that the breakout is recording in Ambulatory Mode. This means that the breakout is recording data to the internal memory. If the breakout is disconnected from the base, this icon shows briefly when the breakout is reconnected, but switches to the stored icon while the study backfills and uploads the data to the NeuroWorks/SleepWorks software.
t -	Indicates that there is stored data on the internal SD card. This icon shows when the Natus base unit is backfilling the data from the internal SD card to the NeuroWorks/SleepWorks software. Once the backfill is finished the icon disappears.



9. Amplifier Usage and Features

9.1. 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.

9.2. 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 <u>Adding the Quantum breakout box(es) to a harness</u> or <u>belt</u> for details on the placement of the Quantum breakout boxes on the patient.

At no point should the system be leaned against or rested upon. Refer to the <u>Transport System</u> <u>Specifications and Maintenance</u> 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.

9.3. Creating acquisition profiles for Studies with Quantum or Quantum 64 Breakouts

The acquisition profile defines which channels are recoreded and and at which sampling frequency. The settings from the the acquisition can be configured from the "Edit" menu in the acquisition/review program, provided that no study is open.



Note: When using the Quantum 64 breakout, it is required to activate the second pin-board in the Software (Edit > Settings > Acquisition (tab)), and switch channels 65 to 128 OFF.

The acquisition profile to be used for the study can be selected in the Study Information window.

The acquisition profile to be used for the study can be selected in the Study Information window.





9.4. Beginning a study

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



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 Quantum breakout boxes via the patient cable.



NOTE: Make sure to select the the correct amplifier hardware as well as the acquisition profile in the New Study window in NeuroWorks.

The Running study screen displays.



Refer to the section 8.2 Touchscreen Icons for icons available both in Idle mode and recording mode.



Icons related to ongoing acquisition:

Button	Description			
*	Turns the LCD Screen off.			
Allows for the signals to recover from saturation.				
	Note: De-Block is automatically applied when opening relays after cortical stimulation.			
	Inserts an EEG or Sleep Acquisition Note or Bio-Calibration.			
Impedance	 Keeping this button pressed allows the impedance test screen to display. With the Cycle feature set to ON in the NeuroWorks/SleepWorks User interface, the system will automatically measure and display impedances for each 64-channel bank. Pressing on one of the buttons for each of the 64-channel banks will interrupt cycling and will continuously measure the selected 64 channels. Pressing "Unlock" will resume cycling between the 64-channel banks. Pressing "Unlock" will resume cycling between the 64-channel banks. If 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 13 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 19 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 17 20 кΩ If 2 3 4 5 6 7 8 9 10 11 2 3 4 45 46 47 48 19 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 17 20 κΩ If 2 3 4 5 6 7 8 9 10 11 2 3 4 45 46 47 48 19 51 2 13 13 2 13 13 2 13 2 13 2 13 2 13			
Info	Displays the information about the Breakout connected. See 8.1 Setting the IP Address for additional information on this screen.			



9.5. Recording in Ambulatory Mode

The Ambulatory feature is available with Quantum (128/256 channels) as well as with Quantum 64.

Whenever the connection between the Quantum Breakout(s) and NeuroWorks / SleepWorks software is lost, the Quantum Breakouts will start recording in Ambulatory mode. This is the case in the following situations:

- Breakout unit is disconnected from the Natus Base Unit
- Base unit is losing power
- LAN or USB connection is lost between the acquisition computer and the Natus Base
- Acquisition computer is powered down

The following message is displayed in the NeuroWorks/SleepWorks acquisition application:

Breakout Disconnected



NOTE: While in Ambulatory Mode, the data is stored to the internal memory at a maximum sampling rate of 512 Hz even if no decimated stream is activated in the acquisition profile.



NOTE: In ambulatory mode, an external battery pack with sufficient charge level must be connected to the Breakout MAIN instead of the cable to the Base unit to provide power during ambulatory recording.

The Quantum External Battery Pack is considered as the main battery with the internal battery being used only during swapping to avoid data loss.

Place the external battery in the following location in the pouch, and connect the cable to Breakout MAIN:





The charge level of the external battery pack is shown on the battery:



Provided that the internal temperature of the breakout is not too high, the internal battery is automatically recharged when the external battery is connected or when the breakout is reconnected to the Base unit.

Because the Natus Base unit and NeuroWorks do not provide the exact charge level and autonomy of the internal battery, the user will be only notified of the following battery status indications via LCD Base and NeuroWorks:

Internal battery charge indications	Internal battery charge status
[+]	Normal
[CH]	Charging
[]	Battery charge not available

- Refer to the NeuroWorks User manual for details on how to display indications on internal battery charge and available memory in the NeuroWorks status bar or in the Heads-Up window.
- If the main sampling rate is set to 256Hz, ambulatory data will also be stored in 256Hz.
- A new fully charged extremal battery pack allows for an approximately 6 hours ambulatory recording with 256 channels (2 breakout boxes).
- If the battery level of external and internal battery is critical, the Quantum breakouts will automatically stop recording and power down. Reconnecting a charged battery pack will resume the recording.



NOTE: Natus does not recommend replacing the internal battery during a study. If for any reason the internal battery is replaced while the breakout is connected to the Base unit, the recording will continue without data loss. Replacing the internal battery in ambulatory mode will cause the breakouts to shut down.

Wile recording in ambulatory mode, the LED's on both breakouts will be blinking. Refer to section *9.10 Breakout Box LED Indicators* in this manual for more information.





When the Breakout box is reconnected to the base, live recording will automatically resume after a few seconds. While recording real time data, ambulatory data upload will start.

Uploading	
Total Blocks: 2391	
Completed Blocks: 452 (19%)	

- Ambulatory data uploaded during recording is automatically deleted in the internal memory.
- If the breakout box is disconnected while backfill is being completed, reconnecting the breakout to the base unit will cause backfill to resume.

If the NeuroWorks recording is stopped while the breakout is in ambulatory mode or while backfill is ongoing, the remaining ambulatory data must be downloaded using the Ambulatory Manager.



NOTE: The Quantum internal memory must be cleared before starting a new study. Use the Ambulatory Manager in the NeuroWorks/SleepWorks software to upload the remaining ambulatory data. The Ambulatory Manager will add the data to the original study.

Ambulatory Headbox Manager	Ambulatory Headbox Manager		Ambulatory Headbox Manager	
Headox BASE A Correct	Headbox BASE A	Connect	Headbox BASE A	Connect
Storage Management Refresh	Sonage Management Skudes:	Refresh	Storage Management Studies:	Refresh
Soldy Field State Reg Party Field State Reg Party Field To State Reg Party Field State R	Suby Tie ID Construction (Geodesic) (Sub 14) is the excitated of	Size (ki) Purring 160000 NO	Soly Te D Overtrageneert, George 2005 (2011 46%) Store on Pohlad Clart	Ster (k8) Running 160000 NO
End Study Undeles Study Clear Menoy Memory Used 1%	End Study Memory Lined Ts.	Clear Memory	C End Study Undelete Study Undelete Study Uploading	Clear Memory
Power Level [*]	Power Level [*]		Total Blocks 1718 Completed Blocks 788	
O Close		Close		Cose

Select the study, and press End Study.

Select Upload Study

Ambulatory data Uploading

Refer to the NeuroWorks/SleepWorks User Manual for more information on how to use the Ambulatory Manager.



9.6. Connecting the Nicolet Cortical Stimulator

The Quantum Breakout Boxes can be connected directly to the Nicolet Cortical Stimulator.

- 1. Connect the Natus Base unit to the computer via USB or LAN cable.
- Connect the Quantum Main Breakout box to the Natus Base unit. See <u>Connecting the Natus</u> <u>Base Unit and Breakout Boxes</u> for additional information.
- 3. Connect the Secondary Breakout box to the Main Breakout box. See <u>Connecting Secondary</u> <u>Breakout Boxes</u> for information.
- 4. Connect the stimulator control cable 016728 to the connectors labeled ^{ICCI} on the Natus Base unit and on the Nicolet Cortical stimulator.
- 5. If there is a single Quantum Breakout in-use, connect the Nicolet Cortical Stimulator to Breakout Main directly using the 013833 stim input cable. The stim input cable should be connected to the input labeled with **X**.



Natus Base Unit connected to the Nicolet Cortical Stimulator when one breakout box is used.



6. If there are two Quantum Breakouts in-use, first connect the 013833 stim input cable to the Nicolet Cortical Stimulator. Next, attach the 013769 stim daisy chain cable to the 013833 stim input cable on one side and to the connections on the Quantum Main and Secondary Breakout Boxes. Please refer to the diagram below for reference.



Natus Base Unit connected to the Nicolet Cortical Stimulator when two breakout boxes are used.

9.7. 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.



9.8. Adding the Quantum or Quantum 64 breakout box(es) to the Modular Pouch

Placing the Quantum breakout box(es) on the patient, can be accomplished by using adding it to the modular pouch.



The Quantum breakout box(es) should only be used in conjunction with the <u>Quantum</u> <u>Modular Pouch</u>. The use of other pouches is not allowed.



Each Breakout box should be placed separately in an individual Quantum Modular Pouch. Neither the Quantum pouch(es) nor the breakout box(es) should be covered by blankets or any other material. Failure to follow these instructions could raise the temperature of the Quantum Breakout(s) above normal operational levels.

To use the Quantum Modular Pouch:

- 1. Place the Quantum breakout box(es) into the pouch.
 - Both pin-boxes should be accessible on either side of the inner harness
 - The Natus logo should be on the front
 - Connectors to the base unit and 2nd Breakout, as well as status LED's, should be on the upper side.
- 2. Secure the inner harness around the breakout by snapping it to the main pouch.

3. The electrodes wires can then be routed to exit on the left and right sides.





- 4. The wired connections, such as the breakout to breakout or breakout to Main cable(s), and secured through the loops provided. The pouch should then be closed by snapping the outside snaps together to enclose the breakout box(es) completely.
- 5. The top of the pouch can be secured by snapping the top to the main part of the pouch.



6. If more than one breakout box is being used, connect multiple pouches by zipping them together at the sides.



7. Once connected, the pouches can be hung beside the bed, or over the patient's shoulder.





NOTE: The modular pouch system must be worn over top of the patient's clothes or hospital garment.



9.9. Quantum Amplifier System Communication Mode

The following section describes how the Quantum amplifier system is connected.

When the base unit is physically connected to the breakout box with the patient tether cable, the **Quantum** 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 1).



Figure 1: Physical Connection of the Quantum System

When the Base unit is physically disconnected from the Breakout box(es), the **Quantum breakouts** are referred to as being in **Physical Disconnection Mode** or in **Ambulatory Mode**. In this mode, the Breakout box(es) store the study data in the internal memory and power is provided by a battery.





Figure 2: Physical Disconnection of the Quantum System – Ambulatory Mode

Ambulatory recording status is indicated on the Breakout box LED's. Refer to section *9.10 Breakout Box LED Indicators* for more details.



9.10.1.

9.10. Breakout Box LED Indicators

Breakout MAIN indicators are shown below:

LE	ED	۰A			\checkmark
Color	Status	Position A	Battery	Disk	Status (check mark)
Green	Solid	Ready	Normal Level Not Charging/ Not Discharging	Normal Capacity Not Writing	Power ON and Idle
Green	Flash	Ambulatory	Normal Level Charging/Discharging	Normal Capacity Writing	Running Study
Yellow	Solid	DSM Armed	Critical Level Not Charging/Not Discharging	Critical Capacity Not Writing	Reserved
Yellow	Flash	DSM Active	Critical Level Charging/Discharging	Critical Capacity Writing or Error	Breakout upgrade or Error
None	None	Not Ready	No Battery Present	No Disk Present	Power OFF

9.10.2. Breakout B indicators are shown below:



LE	ED	В	С	D	\checkmark
Color	Status	Position B	Position C	Position D	Status (check mark)
Green	Solid	Ready	Reserved	Reserved	Power ON and Idle
Green	Flash	Ambulatory	Reserved	Reserved	Running Study
Yellow	Solid	DSM Armed	Reserved	Reserved	Reserved
Yellow	Flash	DSM Active	Reserved	Reserved	Breakout upgrade or Error
None	None	Not Ready	Reserved	Reserved	Power OFF



10. Animal Research

10.1. Independent References Mode Versus Common Reference Mode

In the default clinical operating mode, a single "common" reference is used for amplification of all channels.

Activation of the optional "Independent Reference licence" (PN 019893) enables an individual reference for each group of 8 inputs. This allows connection and recording of multiple subjects without interference between each subject which is a typical workflow for Pharmaceutical Companies and Research centers doing research on animals.

Up to seven (7) channels can be recorded with one (1) reference channel per subject. All subjects should be connected to a linked ground channel using the 011224 Ground Jumper Cable. By using an individual reference for each subject, data can be recorded without any interference from the other connected subjects. If additional referential channels are required per subject, references can be linked, and fewer subjects can be recorded.



Note: The last 8 inputs on the pinboard cannot be used.

Breakout	Common Reference Mode (Clinical)	Independe (Anin	ent Reference Mode mal Research)	
	max # active inputs	max. # subjects	max # active inputs	
Quantum 64	64	7	49 (7 banks of 7 inputs)	
Quantum MAIN	128	14	98 (14 banks of 7 inputs)	
Quantum MAIN + B	256	28	196 (28 banks of 7 inputs)	

10.2. Connecting Multiple Subjects to the Quantum or Quantum 64

- 1. Connect the subject leads as required. Channels are marked with a * in the image below showing that up to seven (7) subjects can be connected at one time to the pinbox.
- 2. Ground leads for all subjects should then be linked together using the 011224 Gound Jumper Cable and plugged into the **GND** input on the pinbox.
- 3. Ensure each subject has an independent reference electrode in addition to the referential electrodes and the Ground leads attached in the previous steps. In the image below, ports marked with ∞ are the reference channels for each channel set.
- Once all leads are connected to the subjects, ensure the pinbox is attached to the breakout box, and the study begun in the NeuroWorks software. Refer to the <u>Connecting the Quantum Base</u> <u>Unit and Breakout Box</u> section for additional details.





Multiple subjects connected to the pinbox

10.2.1. Setting up Neuroworks for Multiple Subject Connections

When connecting multiple subjects to the Quantum or Quantum 64 amplifier breakouts, the Acquisition Profile should be setup with the Independent reference box checked. This is found in the **Acquisition Tab** of the **Edit Settings Dialog**. When selected, this ensures that each subject has an independent reference dictated in the software.

To Setup the Acquisition Profile for Connecting Multiple Subjects:

- 1. Open the NeuroWorks software, and choose Edit > Settings > Acquisition (tab).
- 2. Choose the **Quantum headbox** from the drop-down menu.
- 3. Ensure that the Independent checkbox is selected under the Reference Electrode section.

Settings	
otocol Montage Channel Labels Timebase Acquisiti	n Review Analysis Alarms
Augustum Headbox Reference Electrode External(Ref) Comment:	Channel Status All channels on Set manually C1 C2 C0 C3 C0 C4 C5 C0 C5 C C C C C C C C C C C C C C C
256 512 512 2043 2045 204	C/ ON C8 EF C3 ON C10 ON C11 ON C12 ON C13 ON C14 ON C15 ON C16 REF C17 ON C18 ON C19 ON C20 ON C21 ON C22 ON C23 ON C24 GFF C25 ON C26 ON C27 ON C28 ON C31 ON C32 ON C31 ON C32 ON C31 ON C32 ON C32 ON C33 ON C34 ON C35 ON C36 ON C37 ON <
Quantum Independent Reference	OK Cancel Apply



- 4. Adjust the required settings for acquisition.
- 5. Click on the **New Profile** button . This automatically generates a new profile name based on the current selected profile, appending a numeric sequence to ensure that the named profile is unique. If the drop-down list is empty, the profile name **Default** will appear.



NOTE: As a best practice, ensure to rename profiles so that they have meaningful names. These should not include the numeric sequence that is generated automatically each time the profile list is loaded.

- Use only alpha-numeric characters, underscores, and dashes.
- Do not use other characters including but not limited to:~!@#\$%^&*()+{}[]"'<>/,.



NOTE: If an attribute or setting on the current, named profile is changed, an asterisk is placed to the left of the profile name next to the drop-down list.



Named Profile - Change to profile made

To undo these changes to the profile, select the current profile name again or select another saved profile from the drop-down list. The changes will be reverted to the saved copy. Alternately, clicking **Cancel** on the **Edit Settings** dialog will prevent these changes from being saved.

6. Once the profile has been configured, click the **Apply** button or **OK** to save the changes.

For additional details on profile setup and information, refer to the **Acquisition Profiles** section of the **NeuroWorks User Manual**.



11. 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.

11.1. XLTEK Trolley Specifications





11.2. Neurowand Cart (No PC) Specifications





11.3. Roll Stand Specifications

	Mounting Location	Default Equipment	Equipment Weight [lbs]	Maximum Load [lbs] (including equipment)
	Α	Natus Photic Stimulator Mount	5	5
	В	Breakout Stations (x4)	2*	2*
	С	Storage Bin	0	10
	D	Cable Management	0	0
2 2	Base Cart V	Veight	21	
	Total Weigh	nt	34	44
	*Per Breako	ut station		

11.4. Natus ErgoJust Cart Specifications

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



11.5. Maintenance

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

11.6. Warnings and Cautions



WARNING: Only use Natus 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.


12. 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. 0A @ 60 Hz					
Isolation Transformer	Powervar ABC300-11MED					
Japan						
Electrical input	100V-120V AC, 8.0A, 50/60Hz					
Isolation Transformer	Powertronix D1CSWFCNOE2					



13. Pulse Oximeter

¥

NOTE: Refer to the Instructions for Use for any pulse oximeter sensors prior to use.

The following topic lists the specifications for the Nonin Oximeter sensor that is used with the Quantum or Quantum 64 breakouts. The Quantum Amplifier provides power and isolates the oximeter from the main power and ground.

The user of this medical equipment can verify the operation of the pulse oximeter by appropriately applying the proper sensor, and viewing the displayed SpO2 signal and pulse rate display using the *NeuroWorks/SleepWorks* software. 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.



NOTE: The SpO2 and pulse rate waveforms are not normalized.

13.1. Pulse Oximeter Specifications

Pulse Oximetry Specification	
Displayed Oxygen Saturation Range (SpO2)	0 to 100%
Displayed Pulse Rate Range	18 to 321 beats per minute (BPM)

13.2. Pulse Oximeter 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.

13.3. Pulse Oximeter Accessories

Oximetry Sensors: Measure the light absorption of blood from two light emitting diodes (LED's). Oxygen saturated blood absorbs light differently compared to unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood.

The Nonin Xpod pulse oximeter may be connected to the Quantum or Quantum 64 breakouts, providing oxygen saturation (SpO2) and pulse rate information via the NeuroWorks/SleepWorks software. Reusable and disposable Nonin pulse oximeter sensors may be used with the Nonin Xpod device. A list of commonly used sensors is shown below.



Model Number	Description
8000SS	Sensor, Reusable, Soft, Small, 1 m (3 ft) cable
8000SS-3	Sensor, Reusable, Soft, Small, 3m (9.8ft) cable
8000SM	Sensor, Reusable, Soft, Medium, 1 m (3 ft) cable
8000SM-3	Sensor, Reusable, Soft, Medium, 3 m (9.8 ft) cable
8000SL	Sensor, Reusable, Soft, Large, 1 m (3 ft) cable
8000SL-3	Sensor, Reusable, Soft, Large, 1 m (3 ft) cable
8000Q2	Sensor, Reusable, Ear Clip
8000R	Sensor, Reusable, Reflectance
6000C	Sensor, Disposable, Cloth Series
6500	Sensor, Disposable, Durafoam Series
7000	Sensor, Disposable, Flexi-Form III Series

13.3.1. Available Nonin Oximetry Sensors

13.4. Pulse Oximeter Precautions and Warnings

The user must refer to "Instructions for Use" provided with the Nonin Oximeter Sensor, prior to using the device.

Please consult the instructions for use provided with each Nonin oximeter sensor for display ranges, specifications, precautions and warnings.



14. Maintenance, Cleaning, & Disposal

To keep the Quantum amplifier system in good working condition, follow a regular schedule of user performed maintenance. Regular maintenance performed by the user does not involve access to the interior of the Quantum and components. For service problems that require corrective maintenance and/or internal component service, call Natus Technical Support at 1-800-303-0306 or <u>OTS@natus.com</u>, or contact your local Natus 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(es), and Ethernet cables
- Electrodes and accessories

The Quantum amplifier and its components should not be immersed in water or any other fluid. To clean, use a damp cloth to wipe all surfaces including the LCD panel.

14.1. Quantum Amplifier Pouch

The modular pouch(es), belt, and harness, can be cleaned as follows:

- 1. Hand wash with warm water or machine wash on "Gentle" cycle with mild detergent.
- 2. Do not bleach.
- 3. Tumble dry on low or air dry.

14.2. Recommendations

\wedge	Disconnect all cables from the amplifier before cleaning. Use a lint-free cloth. Do not use cleaners on any system component.
\bigwedge	Take care not to allow any fluid to seep into the internal electronic components of the system.
\bigwedge	Do NOT autoclave, pressure sterilize, or gas sterilize this amplifier.
\bigwedge	Do NOT soak or immerse the amplifier in any liquid.
\bigwedge	A cleaning solution of 70% isopropyl alcohol is recommended.
\land	Use cleaning solution sparingly. Excessive solution can flow into the amplifier and cause damage to internal components.





Do **NOT** use petroleum-based or acetone solutions, or other harsh solvents, to clean the amplifier.

14.3. Disposal

At the end of the useful service life, when disposing of the Quantum 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.



15. Troubleshooting

If the acquired waveforms are flat, do not appear, or do not appear correctly (or as expected), try shutting down the computer for at least 10 seconds, and then set up the test again from the beginning. Shutting down and starting over resets the headbox and sometimes solves the problem. If you are still experiencing problems, here are some more solutions to try:

Troubleshooting Checklist

	Ask the patient to relax.
•	Inspect your cables.
	Make sure that there is a tight connection between the headbox, the breakout box and the computer.
	Make sure that the patient electrodes are connected to the correct channel in the headbox.
	Make sure that the patient electrodes fit properly into the headbox (not loosely).
	Make sure that 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.
•	Unplug any other devices on the same circuit such as printers, mechanical beds, vacuum cleaners, or other potential sources of interference.
•	Install a medical grade ground to make sure that your clinic has a properly grounded electrical system.
	Change the acquisition cable. You should always have a backup acquisition cable.
√	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 .)
	LFF – Filters out low-frequency interference.
	HFF – Filters out high-frequency interference.
	Notch filter – Minimizes electrical interference.
	Gain – Increasing gain makes traces appear larger.



15.1. Problems with Signal Quality

If there is a missing or bad signal, first try swapping cables to the Breakout Box. If you are still experiencing problems, try running a channel test.

Run a Channel Test

- 1. On the montage settings toolbar, set LFF to 0.1 Hz.
- 2. Choose **Controls->Channel Test**. The Channel Test control bar appears above the waveform display.
- 3. Point to the first menu on the Channel Test control bar and click **Sine** or **Square**. The Sine wave setting is good for general use. A low-frequency Square wave setting can reveal problems in the integrator of the DC removal stages on the Analog Board.
- 4. Adjust the waveform frequency and amplitude on the Channel Test control bar as required.

The Channel Test signal is applied to the first amplifier stage; therefore, it tests the amplifiers and ADCs but cannot check the connection to the front panel connector.



16. Accessories & Replacement Parts List

The following are compatible accessories:

Part Number	Description	System with Quantum breakouts	System with Quantum 64 breakout
016862	Base Unit	~	~
016867	Quantum Main Breakout Box (no Pin Boxes included)	~	
016868	Quantum Secondary Breakout Box ("B") (no Pin Boxes included)	~	
024229	Quantum 64 Breakout Box (no Pin Boxes included)		✓
013348	Natus Quantum Breakout to Base Cable, 33ft (10m)	\checkmark	\checkmark
013414	Natus Quantum Breakout to Base Cable, 16ft (5m)	~	✓
013415	Natus Quantum Breakout to Breakout Cable, 32in (81cm)	√	
014162	Natus Quantum Pin Box 1-64	✓	✓
014163	Natus Quantum Pin Box 64-128	✓	
014164	Natus Quantum Pin Box 129-192	~	
014165	Natus Quantum Pin Box 193-256	~	
021332	Natus Quantum Pin Box 0 (cover for 2 nd 64 channel bank on Quantum 64)		~
013891	Quantum Patient Event Button, 30ft (9.1m)	~	✓
013762	Quantum Patient Event Button, 5ft (1.5m)	~	~
013931	Quantum Nonin Oximeter Adapter Cable	~	~
105592	Nonin Reusable Soft Sensor, Medium, model 8000SM	~	✓
013930	Quantum Breakout DC Input Cable	~	
013790	Quantum Base DC Input Y Cable	~	~
A1011X	Power Cord, Unshielded 10ft (3m)	~	✓
W8194X	USB 2.0 Hi-Speed Gold Cable, 6ft (1.8m)	~	~
W8128F	CAT5e Network Cable, 15ft (4.6m)	✓	✓



Part Number	Description	System with Quantum breakouts	System with Quantum 64 breakout
007310	USB-to-Ethernet Adaptor	~	~
022588	Natus Quantum Modular Pouch	✓	~
014808	Quantum Electrode Sleeve, 35in (89cm)	~	✓
014883	Quantum Reference (REF) Jumper Cable, 3ft (0.9m)	~	
010893	Medical Network Isolator with 10in (25cm) Patch Cable	√	✓
015162	Isolation Transformer (EU)	~	\checkmark
015163	Isolation Transformer (NA)	✓	~
PSM-22318	Isolation Transformer (JA)	✓	✓
015170	Replacement Fuse, Natus Base Unit	✓	~
982A0558	Nicolet Cortical Stimulator	✓	\checkmark
016728	Natus Base Unit to Nicolet Cortical Stim Cable	✓	✓
013833	Natus Quantum Stim Input Cable, 8ft (2.4m)	~	~
013769	Natus Quantum Stim Daisy Chain Cable, 1 to 2, 41in (104cm)	√	
017048	Natus Quantum 10-10/10-20 Pin Box	~	
018980	Quantum 10-10/10-20 Pin Box Pouch	~	
016269	Quantum Bulk Connector Pin Box 1 (1 – 64)	~	~
016270	Quantum Bulk Connector Pin Box 2 (65 – 128)	~	
016271	Quantum Bulk Connector Pin Box 3 (129 – 192)	~	
016278	Quantum Bulk Connector Pin Box 4 (193 – 256)	✓	
021255	External Battery Pack with packaging	~	\checkmark
019756	Quantum Ext Battery Cable	~	\checkmark
019755	External Battery Pack Power Supply	~	√



EEG accessories which can be used with the Quantum amplifier are available for you to browse in the Natus Neurology Accessories Catalog online at <u>www.natus.com</u> or call Natus Sales and Support 1-800-303-0306.



17. Getting Help

Natus is committed to providing you with support so you can operate the Quantum System 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

Choose the following in NeuroWorks/SleepWorks EEG or the Natus Database software:

• Help > Natus Database Help

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.

- 1. Click the **Start** button on the Windows taskbar.
- 2. Choose Shut Down... from the Start menu.
- 3. Select Shut Down and click Yes.
- 4. 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 Quantum amplifier. Then contact your local XLTEK distributor or *Natus* Technical Support at **1-800-303-0306** or <u>OTS@natus.com</u>.



18. Appendix A

18.1. Digital Trigger Input Port Wiring Diagram

TTL Trigger pulses from external stimulator devices and push buttons may be connected to the trigger inputs on the Natus Base unit in order to record the events in the study.

The trigger input is available with Natus Quantum and natus Brain Monitor. The trigger inputs are not available when using EMU40EX breakout with Natus Base.

Trigger signals applied on the 8-bit trigger input port creates a pulse with value 0 to 255 on the TRIG channel in NeuroWorks.



Pin#	Definition	Note
1	TRG1	Digital Trigger in (0~5V)
2	TRG2	a
3	TRG3	ι,
4	TRG4	σ
5	TRG5	σ
6	TRG6	ι,
7	TRG7	ι, μ
8	TRG8	σ
9	LT	Digital Trigger Latch (0~5V)
10~15	GND	Ground



NeuroWorks can also insert annotations during recording for each trigger.

Configuration of the trigger inputs is available in EDIT – SETTINGS – ACQUISITION – ADVANCED:

Advanced Settings	and instant America Street Ameri	
Manage Trigge	er Events	Hardware Filters
✓ Enable •	digital trigger	HPF-N: 0,01 v Hz
Trigger	Free Running Catched	HPE-D: 0.64 THZ
Auto-mark	trigger events Rising edge Ealling edg	ne
Minimum a	uration for trigger 2 msec (Min: 2)	
Trigger	Default	Other Options
		Use Nicolet cortical stimulator
Trigger Val	u Annotation	A
000	RARE	
001	FREQUENT	
002	Patient response button	
003	out of the box	
004	out of the box	
005	out of the box	
006	out of the box	
007	out of the box	
008	out of the box	
009	out of the box	
010	out of the box	
011	out of the box	
012	out of the box	
013	out of the box	
014	out of the box	
015	out of the box	
016	out of the box	
017	out of the box	
018	out of the box	
019	out of the box	
020	out of the box	
021	out of the box	
000		*
		OK Cancel

In Free Running mode, every change on the 8 inputs generates an event in the NeuroWorks study. This mode is typically used when trigger pulses arrive at different timing on each of the 8 input ports. Resulting in the following trigger values:

- Trigger on TRIG 1 input \rightarrow generates a square wave and annotation with value 1
- Trigger on TRIG 2 input \rightarrow generates a square wave and annotation with value 2
- Trigger on TRIG 3 input \rightarrow generates a square wave and annotation with value 4
- Trigger on TRIG 4 input \rightarrow generates a square wave and annotation with value 8
- Trigger on TRIG 5 input \rightarrow generates a square wave and annotation with value 16
- Trigger on TRIG 6 input \rightarrow generates a square wave and annotation with value 32
- Trigger on TRIG 7 input \rightarrow generates a square wave and annotation with value 64
- Trigger on TRIG 8 input \rightarrow generates a square wave and annotation with value 128

In Latch mode, the status of all 8 inputs is recorded as an 8-bit value, but only when a trigger pulse is applied to the Latch input. An event is also inserted in the NeuroWorks study. For example:

- Simultanuous triggers on TRIG 1 and TRIG 2 inputs (and LATCH) □ generates a square wave and annotation with value 3 (= 1 + 2)
- Simultanuous trigger on TRIG 2, TRIG 3 and TRIG 8 inputs (and LATCH) □ generates a square wave and annotation with value 134 (= 2 + 4 + 128)



19. Appendix B

19.1. Bulk Connector Pin Box Input

To connect a pre-wired headset or assembly to the bulk connector pin boxes, a Mini D Ribbon 68-pin female type latch connector is required. This should come from the manufacturer of the pre-wired headset or assembly or a 3rd party vendor. The following shows the layout of the bulk connector pin box inputs.



19.2. Bulk Connector Pin Box Input Wiring Diagram

		1st Cor	nductor				2nd Conductor			
Pair	Cond	Solid	Band	Pin	Channel	Cond	Solid	Band	Pin	Channel
1	1	Black	Red	N/C	N/C	2	Red	Black	3	TP5
2	3	Black	White	66	GND	4	White	Black	7	C1
3	5	Black	Green	9	C2	6	Green	Black	28	C3
4	7	Black	Blue	27	C4	8	Blue	Black	57	C5
5	9	Black	Yellow	24	C6	10	Yellow	Black	22	C7
6	11	Black	Brown	20	C8	12	Brown	Black	21	C9
7	13	Black	Orange	51	C10	14	Orange	Black	48	C11
8	15	Red	White	14	C12	16	White	Red	47	C13
9	17	Red	Green	11	C14	18	Green	Red	41	C15
10	19	Red	Blue	10	C16	20	Blue	Red	42	C17
11	21	Red	Yellow	8	C18	22	Yellow	Red	60	C19
12	23	Red	Brown	61	C20	24	Brown	Red	59	C21
13	25	Red	Orange	56	C22	26	Orange	Red	25	C23
14	27	Green	White	55	C24	28	White	Green	53	C25
15	29	Green	Blue	50	C26	30	Blue	Green	19	C27



		1st Cor	ductor				2nd Conductor			
Pair	Cond	Solid	Band	Pin	Channel	Cond	Solid	Band	Pin	Channel
16	31	Green	Yellow	16	C28	32	Yellow	Green	15	C29
17	33	Green	Brown	45	C30	34	Brown	Green	13	C31
18	35	Green	Orange	43	C32	36	Orange	Green	64	C33
19	37	White	Blue	62	C34	38	Blue	White	63	C35
20	39	White	Yellow	30	C36	40	Yellow	White	58	C37
21	41	White	Brown	26	C38	42	Brown	White	29	C39
22	43	White	Orange	54	C40	44	Orange	White	40	REF
23	45	Blue	Yellow	23	C41	46	Yellow	Blue	52	C42
24	47	Blue	Brown	18	C43	48	Brown	Blue	49	C44
25	49	Blue	Orange	17	C45	50	Orange	Blue	46	C46
26	51	Brown	Yellow	44	C47	52	Yellow	Brown	12	C48
27	53	Brown	Orange	31	C49	54	Orange	Brown	33	C50
28	55	Orange	Yellow	34	C51	56	Yellow	Orange	32	C52
29	57	Violet	Orange	68	C53	58	Orange	Violet	67	C54
30	59	Violet	Red	65	C55	60	Red	Violet	5	C56
31	61	Violet	White	6	C57+	62	White	Violet	39	C58-
32	63	Violet	Green	38	C59+	64	Green	Violet	4	C60-
33	65	Violet	Blue	36	C61+	66	Blue	Violet	37	C62-
34	67	Violet	Yellow	35	C63+	68	Yellow	Violet	2	C64-
SHIELD				1	DGND					



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Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) 2568 Bristol Circle Oakville, Ontario L6H 5S1 Canada T: +1 905.829.5300 F: +1 905.829.5304 www.natus.com

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