Technical Specifications

ErgoJust Cart Configuration
Height .... 198.1 cm (78 in)
Width at Widest Point .... 55.9 cm (22 in)
Depth at Widest Point .... 81.9 cm (32.25 in)
Weight (Cart Only) .... 44.4 kg (98 lb)
Height with Video Assembly .... 198 cm (78 in)
Footprint Dimensions .... 50.8 x 66 cm (20 x 26 in)

Work Surface
Work Surface Dimensions (WxD) .... 55.9 x 43 cm (22 x 17 in)
Work Surface Material .... plastic
Keyboard Tray Dimensions (WxD) .... 47 x 20.3 cm (18.5 x 8 in)
Keyboard Tray Material .... plastic

Work Surface Range of Motion Dimensions
Fully Raised .... 114.3 cm (45 in)
Fully Lowered .... 78.74 cm (31 in)
Fully Lowered Clearance .... 68.6 cm (27 in)

Accessories
Basket Dimensions (HxWxD) .... 15.2 x 33.6 x 8.2 cm (6 x 13.25 x 3.25 in)
Basket Materials .... plastic
Handle Height (from Ground) .... 109.2 cm (43 in)
Handle Width .... 40.6 cm (16 in)
Compatible Display(s)
.... VESA MIS-D, 100/75, C (100 x 100 mm and 75 x 75 mm)

Compatible Natus ErgoJust EEG Cart Equipment
– Brain Monitor Base Unit
– EMU40EX Base Unit
– Natus Quantum Base Unit
– Supplies Basket
– EEG/Sleep Acquisition Desktop 110V (Small-form factor only)
– 24" FP Monitor (or equivalent monitor that meets size and weight
   requirements)
– LED Photic Stimulator
– IP PTZ ErgoJust Video Extension
– IP PTZ HD ErgoJust Video Extension
– EMU40EX / Brain Monitor / Quantum Headbox Side Quick Disconnect Kit
– EMU40EX / Brain Monitor / Quantum Wall/Pole Side Quick Disconnect Kit
– Comet-PLUS Headbox Side Quick Disconnect Kit
– Isolation Transformer
– Medical Grade UPS with Isolation

Regulatory Compliance
The Natus ErgoJust cart meets the following safety standards set by domestic
and international regulatory agencies for Medical Electrical Equipment.
UL 60601-1
CSA 22.2 No. 601.1-M90
IEC/EN 60601-1

Healthcare solutions with one thing in mind. You.

natus®

Natus Medical Incorporated

natus.com

Xltek® Trex™ HD

Capture high quality video/EEG data without confining your patients

Optimize your clinical workflow with the next generation of advanced Video EEG ambulatory monitoring, featuring unsurpassed video quality and simple setup.

Compact patient carrying case

HD video

Trex **HD**
Small & lightweight Xltek Trex HD amplifier, featuring exceptional EEG signal quality

Flexible camcorder setup options

- Up to 96 hours of best in class HD video, wirelessly synchronized with EEG

- No cables or computer to set up at home – avoid costly patient home visits

- Start and stop video without affecting synchronization

- Lightest ambulatory amplifier in the industry

- Enhanced patient comfort & mobility

- Perfect for both EEG & full featured sleep studies

- Compatible with Natus® NeuroWorks®/SleepWorks 7.1 or later software
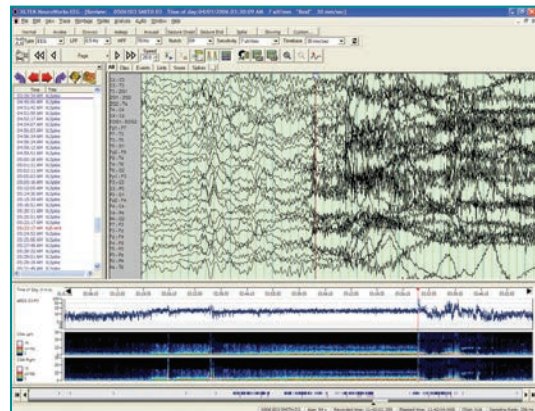
Call your Natus Neurology sales representative today at 1-800-303-0306 for additional information and pricing.

natus neurology

natus
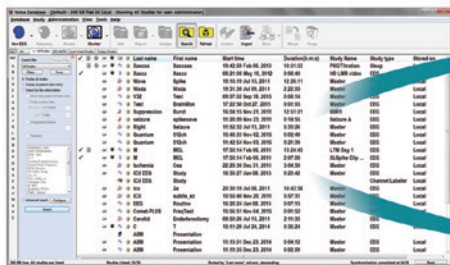### neurology

Database Migration

Simplifying Migration to Natus EEG/PSG

Some of our most popular legacy EEG and Sleep monitoring devices are now compatible with Natus NeuroWorks and SleepWorks software. The Database Migration tool imports studies recorded with legacy Natus devices into the NeuroWorks/SleepWorks database, providing convenient review of all studies from a single database platform. Now there are even more reasons for our customers to adopt Natus NeuroWorks and SleepWorks.
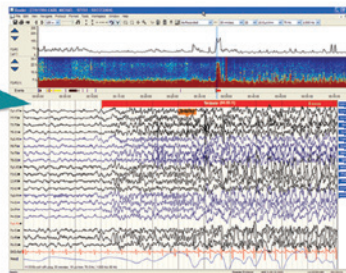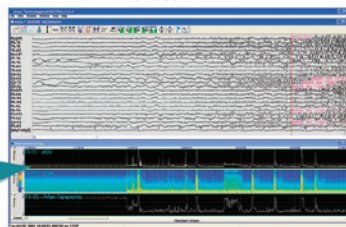
Product Features:

- Unified database allowing review of studies recorded with legacy Natus devices
- Preserves legacy data, including patient demographics, study information and EEG/PSG reports
- Currently available for studies recorded with Nicolet® NicVue, Nicolet® StudyRoom and Grass® TWin

Natus Database triggers the native review application to activate and open the selected study

Grass TWin

Call your Natus Neurology sales representative today at **1-800-356-0007** for additional information.

Nicolet NicVue/StudyRoom

natus
neurology

Natus Neurology Incorporated
3150 Pleasant View Road
Middleton, WI 53562 USA
Tel: 1-800-356-0007
1-608-829-8500
Fax: 1-608-829-8709
www.natus.com

Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario, L6H 5S1 Canada
Tel: 1-800-387-7516
1-905-829-5300

P/N 017684B

Lab-quality EEG recordings from home testing

natus®

Extend your reach with ambulatory services

Ambulatory EEG has become an integral part of seizure detection with accurate testing and data recorded from the comfort of the patient's own home. With Trex HD's exceptional signal quality in a compact hardware device, patients are free to move without constraint while valuable EEG data is recorded for clinical review.

Available in two amplifier systems, Trex HD and Trex HD Monitoring, both of which are multi-modality, full-channel ambulatory recorders, deliver reliability, flexibility and performance. Both systems allow for EEG and Type II Sleep recording and wireless Bluetooth® connectivity options.

Trex HD and Trex HD Monitoring amplifiers easily connect to a portable computer via a high-speed USB cable and can upload 24 hours of EEG data in less than five minutes. Combined with Natus NeuroWorks® and SleepWorks™ software, the system enhances workflow with easy, intuitive functions to help you efficiently and effectively review data.

Natus NeuroWorks software

Industry leading software with an extensive and flexible feature set for a variety of environments

Leading-edge software that provides an intuitive clinical experience

- Windows® 10 compatible
- Multiple spike and event analysis options, plus many additional Advanced Trending options
- Fully synchronized, easy to set up, full HD (1080p), onboard and wireless cameras

Security and peace of mind for IT professionals and clinicians working together

- XLSecurity Layer with role-based security package and drive encryption
- Searchable and powerful enterprise level SQL server distributed database
- Bi-directional HL7 integration with HIS/EMR

Trex HD hardware option features and benefits

- Start and stop video without affecting synchronization
- Lightweight wearable amplifier for enhanced patient comfort and mobility
- Flexible for both EEG & full-featured sleep studies performed ambulatory and in-lab
- Optional power pack for 72 hours battery life
- Internal SD card storage space to record up to 96 hours of ambulatory EEG data

Natus NeuroWorks ambulatory EEG hardware

Durable, reliable, high-quality amplifiers for dependable data acquisition

Trex HD Monitoring video ambulatory system

Provide continuous EEG monitoring in real-time with a complete uniform solution for observing, recording and annotating all types of EEG testing in both pediatric and adult patients
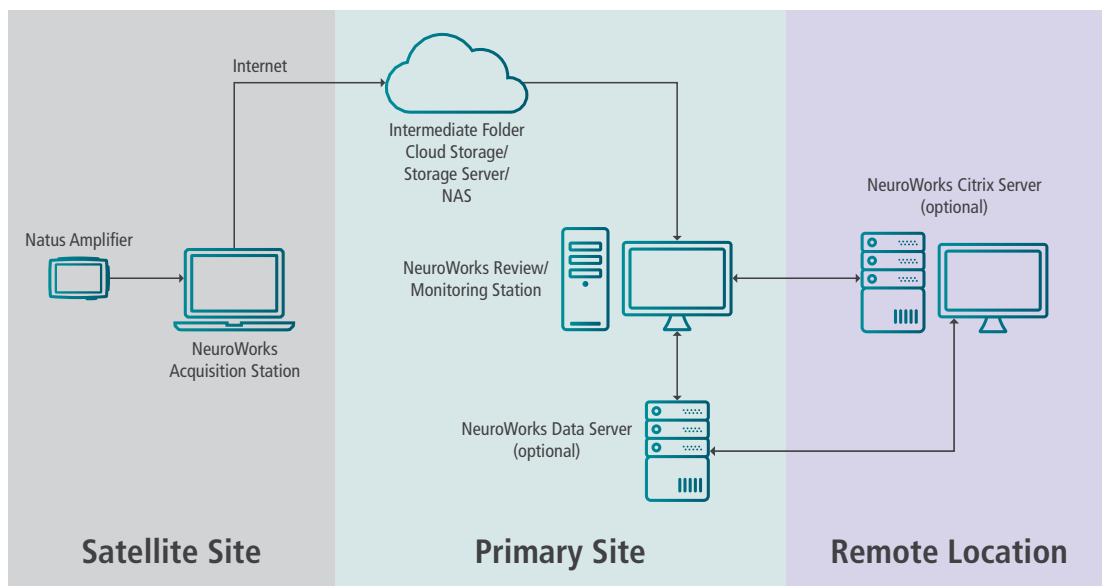
- Features high-definition USB and integrated camera options
- Automated export of study data from the patient's home setting to clinic servers
- Bluetooth pairing for synchronized video recording

Trex HD video ambulatory system

Provide a reliable, simple solution for monitoring in the patient's home environment with HD video recording directly on a camcorder memory card, eliminating all cabling. Record high-quality video around the clock utilizing IR for night recording

- Up to 96 hours of best-in-class HD video, wirelessly synchronized with EEG
- No cables or computer to set up at home – avoid costly patient home visits

Eliminates the need for Citrix infrastructure at each satellite site

Internet

Intermediate Folder Cloud Storage/ Storage Server/ NAS

Natus Amplifier

NeuroWorks Acquisition Station

NeuroWorks Review/ Monitoring Station

NeuroWorks Data Server (optional)

NeuroWorks Citrix Server (optional)

Satellite Site

Primary Site

Remote Location

Data security

Set up individual user or group access and permissions for the system and within the application. Assign separate lock-down rules for different computers on the same network. Access Audit Logs to review user activity on the system. Security is integrated with Microsoft® Active Directory and peace of mind is enhanced with system encryption.

EEG supplies solutions

Convenient, complete, trusted

Natus supports the full spectrum of EEG care, providing a complete portfolio of EEG supplies for a seamless solution.

- Dedicated and knowledgeable customer support
- Streamlined order processing
- Convenient online ordering (US Customers only)
  Natus Medical Store – natusmedicalstore.com

Service

At Natus, we strive for excellence in customer and technical service.

Here's how we can help:

- Accessible and effective Technical Support
- Definitive technical documentation and knowledgeable installation teams
- Optional extended warranty and service coverage programs
- Comprehensive, flexible customer training courses

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Technical Specifications

Part Number PK1170, PK1171
Use Cases .... High Channel LTM, Intracranial

Analog Specifications - AC Channels

Referential Channels 256
Differential Channels.. Up to 8 per 128 Breakout (112 Ref.)
Common Mode Rejection Ratio ....≥110 dB @ 60 Hz
Common Mode Input Impedance.. >1 GΩ
Differential Input Range .... 20 mVpp
Input Noise (peak to peak) .... ≤1.5 μV (256 Hz), ≤40 nV/rtHz wideband
Input Signal Range (peak to peak) ....20 mV, ±0.66 VDC
Input Bias Current ....<1 nA
Channel Crosstalk ....< -67 dB

Analog Specifications – DC Channels

DC Channels (patient side) ....4 non-isolated
DC Channels (computer side)..12 isolated
DC Input Range.. ±5 V

User Interface

Base Unit

Additional Connections .... Photic Stimulator, Digital Trigger, EMU40EX Breakout
Event Switch Connection 1
Display.. Touchscreen LCD

Breakout Box

Additional Connections
   Event Switch, Nonin Xpod® Pulse Oximeter SpO$_2$, Cortical Stimulator

Digital Specifications

Sampling Frequency ....256 Hz, 512 Hz, 1024 Hz, 2048 Hz, 4096 Hz, 8192 Hz, 16384 Hz
Bandwidth ....0.01 Hz to ~$^1/_3$ sample rate selected or 4 KHz max
Digital Trigger... 8 bit TTL
Pulse Oximetry ....SpO$_2$, Plethysmography, Pulse Rate
Sampling Resolution... 24 bits
Sampling Quantization ....305 nV
Storage Resolution .... 16 bits

Modes of Operation

Power ....70 VA
Input...100 – 230 V, 50/60 Hz
Impedance Check..< 2.5, < 5, < 10, < 25, <50 kΩ
Channel Test Signal ....Software Controllable (0.25, 0.5 and 1 Hz; 10 – 2000 μVpp)

PC Interface

Network... Gigabit Ethernet, DHCP
Direct... USB 2.0 Hi-Speed, Ethernet

Amplifier Mechanical

Base Unit to Breakout Box Cable Maximum Length..10 m (32 ft)
Base Unit Size .... 29.0 x 26.5 x 5.0 cm / 11.4 x 10.4 x 2.0 in
Breakout Size (each)... 13.8 x 13.2 x 5.4 cm / 5.4 x 5.2 x 2.1 in
Breakout Weight (each) ....650 g

Environmental Conditions for Use

Operating Environmental Limits Temperature .... 10° C – 30° C
Relative Humidity ....30% – 75%
Atmospheric Pressure ....700 hPa – 1060 hPa
Transport and Storage Temperature Range ....-25° C – 60° C
Transport and Storage Humidity Range .... 10 % – 95 %
Transport and Storage Atmospheric Pressure Range ....500 hPa – 1060 hPa

Regulatory Compliance

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, 3rd Edition
IEC 60601-1-6:2010, Edition 3.0, IEC 62366:2007, Edition 1.0
IEC 60601-2-26:2012, Edition 3
EN ISO 80601-2-61:2011, Edition 1
IEC 60601-1-2:2007, Edition 3.0
CISPR11, Edition 5.0 (with A1:2010)

Our most advanced LTM system
in a user friendly package

natus®

Long-term monitoring solutions

Enhanced patient mobility and comfort
Continuous monitoring, even when the patient disconnects

Maximum comfort and convenience for clinicians
Sit-to-stand height adjustable, ergonomic cart that provides effortless access to software, devices and supplies

High-quality data
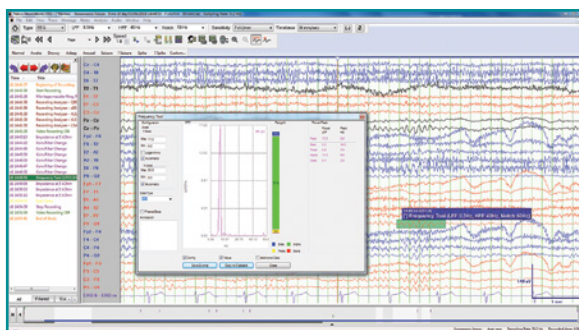Record up to 256 channels at 16 kHz with the Natus Quantum amplifier

Functional brain mapping
Software integrated Cortical Stimulator compatible with the Natus Quantum amplifier

Built-in backup features for unattended operation
On-board amplifier memory serves as backup in case of an emergency with built-in self-monitoring to rectify problems encountered in unattended operation

Natus NeuroWorks software
The Natus NeuroWorks platform simplifies the collection, monitoring and management of data for epilepsy studies

Leading-edge software that provides an intuitive clinical experience
- Windows® 10 compatible
- Multiple spike and event analysis plus many additional Advanced Trending options
- Physiological Monitoring Integration options
- Fully synchronized, easy to set up, Full HD (1080p) TCP/IP PTZ network cameras
- Powerful qEEG trending
- Data sharing in multi-site environments

Time-saving administrator functions
- Automated discovery of amplifiers and cameras using DHCP
- Automated settings synchronization across networked NeuroWorks stations

Security and peace of mind for IT professionals and clinicians working together
- XLSecurity Layer with role-based security package and drive encryption
- Searchable and powerful enterprise level SQL server distributed database
- Bi-directional HL7 integration with HIS/EMR
- Automated software installation for large sites with Cerebrum Enterprise Solution
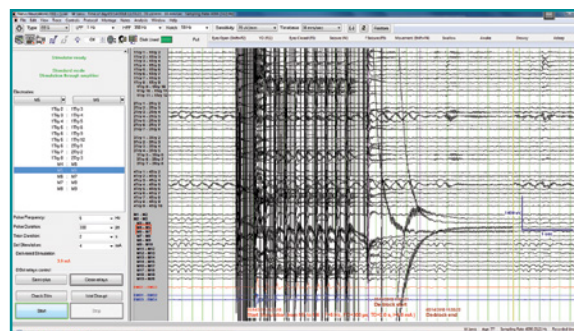
Software controlled Cortical Stimulator in NeuroWorks

Cortical stimulator integration into NeuroWorks software
- Control all parameters through the software
- Stimulation parameters as well as delivered current automatically captured into events
- Capture and classify patient response to stimulation
- Creation of reports for Cortical Stimulation procedures

Frequency analysis tool in NeuroWorks

Frequency analysis tool
- Drag the area of interest
- Quickly identify frequency, amplitude and power for selected data
- Display percent for each frequency range

Natus NeuroWorks LTM hardware

A full line of durable, reliable, high-quality amplifiers for dependable data acquisition

Natus Quantum

Ideal for advanced epilepsy diagnostic procedures

- 64-, 128- or 256-channel configurations available with up to 16 differential channels
- Excellent signal quality with up to 16 kHz sampling rate
- On-board memory and battery operation with automated backfill of data
- Data Stream Wizard to speed up clinical workflow when reviewing high sampling data
- Integrated Digital Switch Matrix to facilitate functional brain mapping

Natus EMU40EX

Ideal for scalp and diagnostic studies with wireless capabilities

- 40 AC channels, 4 DC channels, SpO_2
- 1 kHz sampling rate
- Bluetooth wireless technology with on-board memory for live monitoring
- Lightweight, patient wearable breakout box

Natus Brain Monitor*

Ideal for scalp and diagnostic studies

- Up to 64 referential, up to 12 differential, 16 DC channels
- 4 kHz sampling rate
- On-board impedance check

*requires NeuroWorks 9.0 or higher

Cortical Stimulator

Functional brain mapping for brain tumor and epilepsy surgery

- Use as standalone or software controlled
- Provides direct, constant current stimulation to the brain
- User configurable frequency, duration and current levels
- Displays selected and actual current delivered

Natus Base Unit

Universally compatible with Quantum, EMU40EX and Natus Brain Monitor amplifiers

- Touchscreen display with real time interaction with ongoing studies
- Visual impedance checking and adding notes
- Perform bio-calibrations from the patient bedside
- Trigger input for research
- Includes 12 DC Inputs

Data security

Set up individual user or group access and permissions for the system and within the application. Assign separate lock-down rules for different computers on the same network. Access Audit Logs to review user activity on the system. Security is integrated with Microsoft® Active Directory and peace of mind is enhanced with system encryption.

Natus cybersecurity program

Proactively addressing cybersecurity as an integral part of our design process

- Secure handling of confidential information generated or maintained by our hardware and software
- Continuous evaluation of our products against identified threats and vulnerabilities in medical technology
- Monitoring of feedback channels to manage security events in the field

Supplies

Convenient, complete, trusted

Natus supports the full spectrum of EEG care, providing a complete portfolio of EEG supplies for a seamless solution.

- Dedicated and knowledgeable customer support
- Streamlined order processing
- Convenient online ordering (US Customers only)
  Natus Medical Store – natusmedicalstore.com

Natus support

At Natus, we strive for excellence in customer and technical service.

Here's how we can help:
- Accessible and effective Technical Support
- Definitive technical documentation and knowledgeable installation teams
- Optional extended warranty and service coverage programs
- Comprehensive, flexible customer training courses

To learn more about Natus products,
contact your local distributor or sales representative.

US Customers Call: **1-800-356-0007**

International Customers Call: **+1-608-829-8500**

Making sense of the body's signals

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Natus® NeuroWorks® Software

A common software platform for EEG, Sleep and research studies

The Natus NeuroWorks platform simplifies the process of collecting, monitoring and managing data for routine EEG testing, long-term monitoring (LTM), ICU monitoring, ambulatory and Sleep studies. NeuroWorks systems are scalable to meet the needs of private practice clinics, hospitals and large teaching facilities.

What's new in NeuroWorks

- Advanced Trending
- Physiological Monitoring Integration
- Support for new LTM data management
- Improved display of annotations and navigation to regions of interest across a set of studies
- Windows® 10 compatibility
- Support for Quantum on-board memory and Nicolet Cortical Stimulator integrations
- Support for new cutting-edge Brain Monitor
- Frequency Analysis Tool
- Addition of Full HD (1080p) video

Intuitive clinical experience

- Multiple Spike & Event analyzer options
- Fully synchronized HD video
- Monitoring options for home ambulatory studies
- Scalable remote access with Citrix provisioning
- Powerful qEEG trending

Time-saving administrator functions

- Ease of setup using IP streaming cameras and amplifiers
- Powerful enterprise level SQL database
- Automated discovery of amplifiers and cameras using DHCP

Streamlined workflow

- Easy data searching with a variety of customizable parameters
- Automated settings synchronization across networked NeuroWorks stations
- Convenient import and export with EDF/EDF+
- Data sharing in multi-site environments

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NeuroWorks configures to your network and security needs

Robust Security Features

- HIPAA requirements via dedicated XLSecurity layer
- Role-based security access to features and studies
- Automated power recovery
- Microsoft® BitLocker™ drive encryption support

Advanced IT Capabilities

- Bi-directional HL7 integration with HIS/EMR
- Citrix® and VMWare® Ready partner – the most powerful infrastructure to facilitate collaboration

CITRIX READY

vmware READY APPLICATION SOFTWARE

A cutting-edge, single solution for EEG and Sleep Studies

Advanced software for clinical excellence

- EEG/Sleep combo software package
- User customizable personal workspaces
- Software Development Kit for direct data access for research
- Data-Stream Wizard with two data streams for efficient clinical and research workflow*

Reliable and flexible hardware options

- Patient wearable compact and lightweight amplifiers
- Range of EEG amplifiers with 32- to 256- channels, plus differential and DC channel options
- Wireless amplifier options for long-term monitoring
- Range of sampling rates from 200 Hz to 16 kHz
- Perform EEG recordings in DC mode**
- Advanced Digital Trigger Input (up to 256 trigger values)**

A family of amplifiers to meet your needs

| *NEW!* Natus Quantum | EMU40EX | *NEW!* Natus Brain Monitor | Trex HD Monitoring |

| Nicolet® v32 | Nicolet® v44 | EEG32U | Trex HD |

To learn more about Natus products contact your local distributor or sales representative.

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International Customers Call: **+1-608-829-8500**

*Only available with Quantum
**Only available with Quantum and Natus Brain Monitor

Healthcare solutions with one thing in mind. You.

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Natus® NeuroWorks® ICU Solutions

Continuous brain monitoring wherever and whenever you need it – changing the standard of care in the ICU

Powerful neurological monitoring for clinical confidence

- Assist in diagnosis of patient's cerebral function
- Many Advanced Trending options to assist with quick identification of pathological signals for immediate intervention
- Physiological Monitoring Integration options
- Online observation can help the physician identify irreversible brain damage

Security and peace of mind for IT professionals and clinicians

- XLSecurity Layer with role-based security package and drive encryption
- Searchable and powerful enterprise level SQL server distributed database
- Bi-directional HL7 integration with HIS/EMR
- Automated software installation for large sites with Cerebrum Enterprise Solution

Natus NeuroWorks software

- Simple and intuitive interface designed specifically for intensive care workflow
- Cart-mounted for portability or mounted directly on a column or wall
- Leading-edge software with powerful trending options including qEEG
- True TCP/IP amplifiers and cameras with DHCP support plug and play anywhere on the network
- Data sharing in multi-site environments

Brain monitoring using Natus' renowned NeuroWorks system provides critical and immediate patient cerebral function to ICU staff and remote monitors for physician review.

natus®

Natus Brain Monitor*

- Up to 64 referential, up to 12 differential, 16 DC channels
- 4 kHz sampling rate
- On-board impedance check
- Touchscreen display on base unit with real time interaction with ongoing studies
- Visual impedance checking and adding notes
- Perform bio-calibrations from the patient bedside

*requires NeuroWorks 9.0 or higher

Natus EMU40EX

- 40 AC channels, 4 DC channels, SpO_2
- 1 kHz sampling rate
- Bluetooth wireless technology with on-board memory for live monitoring
- Lightweight, patient wearable breakout box

Natus cybersecurity program

Proactively addressing cybersecurity as an integral part of our design process

- Secure handling of confidential information generated or maintained by our hardware and software
- Continuous evaluation of our products against identified threats and vulnerabilities in medical technology
- Monitoring of feedback channels to manage security events in the field

Natus support

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- Definitive technical documentation and knowledgeable installation teams
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- Comprehensive, flexible customer training courses

EEG and ICU supplies solutions

Convenient, complete, trusted

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Healthcare soluWons with one thing in mind. You.

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Natus Medical Incorporated

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Natus® Quantum™ Amplifier

A quantum leap in amplifier technology in an ultra-small package

Natus Quantum is our most innovative amplifier for epilepsy monitoring and research. Designed specifically to meet the versatile needs of today's modern Epilepsy Units and research centers, the Quantum enables clinical EEG, long-term scalp and intracranial epilepsy monitoring and research.

A compact, patient wearable amplifier with the most advanced technology

- Clinical EEG, long-term scalp and intracranial epilepsy monitoring and research
- 256 referential channels, up to 16 differential channels
- Excellent signal quality with up to 16 kHz sampling
- On-board memory with automated backfill of data for improved mobility
- Data-Stream Wizard (DSW) for efficient clinical and research workflow
- Software integrated cortical stimulator
- Integrated Digital Switch Matrix (DSM) to facilitate functional brain mapping

CITRIX® READY

vmware READY
APPLICATION SOFTWARE

natus®

Natus NeuroWorks® Software

A common software platform for EEG, LTM, ICU, Sleep and Research studies

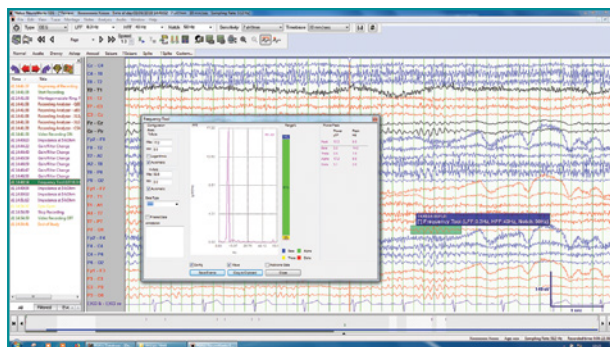### Leading-edge software that provides an intuitive clinical experience

- Windows 10 compatible
- Multiple Spike & Event analyzer options
- Powerful trending options including qEEG
- Fully synchronized, easy to set up, Full HD (1080p) TCP/IP PTZ network cameras

Security and peace of mind with IT focused features

- XLSecurity Layer with drive encryption
- Searchable and powerful enterprise level SQL server distributed database
- Bi-directional HL7 integration with HIS/EMR

Frequency Analysis Tool

- Drag the area of interest
- Quickly identify frequency, amplitude and power for selected data
- Displays percent for each frequency range

Cortical Stimulator integration into NeuroWorks software

- Control all parameters through the software
- Stimulation parameters as well as delivered current automatically captured into events
- Capture and classify patient response to stimulation
- Creation of reports for Cortical Stimulation procedures

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Making sense of the body's signals

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.   **CE 592232**

Issued To: **Natus Neurology Incorporated**
                                     3150 Pleasant View Road
                                     Middleton
                                     Wisconsin
                                     53562
                                     USA

In respect of:

Design and manufacture of Electro-Neurophysiologic Diagnostic and Monitoring Devices and Sterile and Non-Sterile Invasive Electrodes.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-02-12**   Date: **2020-03-25**   Expiry Date: **2023-07-01**

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Page 1 of 1

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 592232**
Date:	**2020-03-25**
Issued To:	**Natus Neurology Incorporated**
	3150 Pleasant View Road
	Middleton
	Wisconsin
	53562
	USA

Subcontractor:	Service(s) supplied
Ad-Tech Medical Instrument Corp. 400 West Oakview Parkway Oak Creek Wisconsin 53154 USA	**Manufacture**
Chalgren Enterprises, Inc 380 Tomkins Court Gilroy California 95020 USA	**Manufacture**
Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive Appleton Wisconsin 54911 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Date:	**2020-03-25**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Subcontractor:	Service(s) supplied
Natus Manufacturing Limited IDA Business Park Gort Co. Galway Ireland	**EU Representative** **Manufacture**
Paul E. Danchell A/S Lyngvej 8 Jyderup 4450 Denmark	**Manufacture**
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit Rechain Avenue Andre Ernst 21 Verviers B-4800 Belgium	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No:	**CE 592232**
Date:	**2020-03-25**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 2311 Lincoln Avenue Hayward California 94545 USA	**Gamma Sterilization**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**
Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No:	**CE 592232**
Date:	**2020-03-25**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Date	Reference Number	Action
12 February 2013	7909188	Transfer from another Notified Body. The legal manufacturer, Natus Neurology Incorporated, is also known as Natus Medical Incorporated, CareFusion 209, Inc., VIASYS NeuroCare, VIA SYS Healthcare, Nicolet Biomedical, Nicolet Vascular.
18 June 2013	7999455	Certificate renewal, and removal of Jabil Circuit Inc as significant subcontractor.
17 December 2013	8030396	Reissue due to change of company address from '1850 Deming Way, Middleton, WI 53562, USA' to '3150 Pleasant View Road, Middleton, WI 53562, USA' Addition of, 'Natus Neurology Incorporated, 1850 Deming Way, Middleton, Wisconsin, 53562, USA', for services of Design, Manufacture, Control of Sterilization and Regulatory Compliance. Change of subcontractor name from 'Natus Nicolet Ireland Ltd also trading as CareFusion Manufacturing Ireland 241 Limited' to 'Natus Manufacturing Limited'.

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Date	Reference Number	Action
06 February 2015	8270322	Removal of the following significant subcontractors Transpack Medical Ltd for Packaging, Synergy Health Sterilisation UK Ltd for Gamma Irradiation, Medline Industries Inc for ETO Sterilization and SGM d.o.o for Manufacture, Natus Neurology Incorporated for Control of Sterilization, Design, Manufacture and Regulatory Compliance . Addition of significant subcontractor Paul E. Danchell A/S for Manufacture.
08 November 2016	8603325	Change of EU Representative from Natus Europe GmbH, Robert-Koch-Str 1, 82152 Planegg, Germany to Natus Manufacturing Limited, IDA Business Park, Gort, Co. Galway, Ireland. Removal of the following significant subcontractors Medisize Ireland Ldt for Packaging and Synergy Health Westport Ltd for Gamma Sterilization.
29 June 2018	8907455	Certificate renewal. Rewording of scope to remove "Non-Imaging Ultrasound Devices for Diagnosis and Monitoring of Vascular Flow." Change in address of subcontractor Ad-Tech. Removal of subcontractor Medizintechnik Basler AG.
08 February 2019	8862799	Traceable to NB 0086.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No:	**CE 592232**
Date:	**2020-03-25**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Date	Reference Number	Action
Current	3111135	Change in ETO sterilization subcontractor location from Sterigenics US, LLC, 7775 South Quincy Street, Willowbrook, Illinois, 60527, USA to Sterigenics US, LLC, 84 Park Road, Queensbury, New York, 12804, USA.

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Natus Medical Incorporated
5900 First Avenue South
Seattle
Washington
98108
USA

Holds Certificate No: **FM 702798**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, distribution, installation and service of Medical Devices, including: Phototherapy lights (fluorescent, fiberoptic, LED), support - patient position, holder infant position, infant scales, pasteurizers washers, cerebral function monitor (electroencephalograph), pad neonatal eye, spectroradiometers, temperature probes, hearing protectors, protective restraint cooling caps for infants, products for the quantitative assessment and rehabilitation of balance disorders, and electroencephalograph systems, evoked response systems, otoacoustic emissions systems, hearing screeners and audiometers. Distributor of oral care kits, blood lancets and electrodes (ECG and CFM/EEG).

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2008-11-11   Effective Date: 2019-01-18
Latest Revision Date: 2019-02-28   Expiry Date: 2022-01-17

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SCC Accredited
CB-MS

OCSM
Accrédité CCN

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Natus Neurology Incorporated
3150 Pleasant View Road
Middleton, Wisconsin 53562 USA

European Declaration of Conformity
to the Medical Device Directive, 93/42/EEC
as Amended by 2007/47/EC

$$CE$$ 2797

Declaration Number: QMS-002131
Product Name: Natus Neurology Diagnostic and Monitoring Devices - Class IIb
Product Model Number: see Annex: Product List
Description: Electroencephalography (EEG), Electromyography (EMG) and Evoked Potential (EP) Diagnostic and Monitoring Devices

Natus Medical Incorporated hereby declares that the above medical devices which bear the CE Mark are in conformity with the applicable requirements of EC Directive 93/42/EEC with amendments up to 2007/47/EC as enforced in the national laws of the European Union member states.

Classification/Rule: Class IIb, by Annex IX, Rule 10
Conformity Assessment Route: Annex II (excluding section 4)

This declaration is based on Certification of a full Quality Assurance System and compliance to the Medical Device Directive.

Certificate No.: CE 592232
Issued by: BSI Group The Netherlands B.V. (No 2797),
Say Building, John M. Keynesplein 9,
1066 EP Amsterdam,
Netherlands
Expiry Date: 01 Jul 2023

Additionally: Natus hereby declares, under its sole responsibility as Legal Manufacturer and not evaluated by the Notified Body listed above, that the product specified on this Declaration of Conformity is in conformity with Commission Delegated Directive 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. It has been demonstrated that the requirements specified in Annex II of Directive 2015/863 have been met.

This declaration of conformity is valid from August 31, 2021.

EU Authorized Representative:
Natus Manufacturing Limited
IDA Business Park, Gort,
Co. Galway, Ireland

Signature: _____ date **August 31, 2021**
Sanjay Mehta (Director Global Regulatory Affairs, QARA)

Annex to the Declaration of Conformity

PRODUCT LIST

ELECTROENCEPHALOGRAPHY, ELECTROMYOGRAPHY and EVOKED POTENTIAL DIAGNOSTIC, MONITORING DEVICES
PRODUCT FAMILY - Class IIb

This product list belongs to the Declaration of Conformity identified by Electroencephalography, Electromyography and Evoked Potential Diagnostic and Monitoring Devices Product Family - Class IIb and specifies the CE marked products concerned that Natus Neurology Incorporated intends to distribute in conformity with the provisions of the Council Directives 93/42/EEC and 2011/65/EU as amended by (EU) 2015/863. The following list identifies the products by name and type and by serial number or beginning shipping date.

VikingQuest

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
982A0474	VikingQuest International	21-Jul-2014	11474	Z121004
842-127600	VikingQuest Windows 10 Laptop PC	21-Jul-2014	11474	Z121004

Nicolet EDX

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
515-012700	EDX HB7 Head Box 0127	21-Jul-2014	11474	Z121004
515-015100	EDX 2 channel Amplifier	21-Jul-2014	11474	Z121004
515-015300	EDX Base Unit	21-Jul-2014	11474	Z121004
515-016100	EDX 8 channel Amplifier	21-Jul-2014	11474	Z121004
515-016200	EDX 8 channel Amplifier 0162	21-Jul-2014	11474	Z121004
515-016600	EDX HB7 Head Box	21-Jul-2014	11474	Z121004
515-016700	EMG USB Control Panel	21-Jul-2014	11474	Z121004
515-020400	Stimulus Switching Pod SP1	21-Jul-2014	11474	Z121004
515-020500	Stimulus Switching Pod SP2	21-Jul-2014	11474	Z121004
842-689700	EDX Windows 10 Desktop PC	21-Jul-2014	11474	Z121004
842-689900	EDX Windows 10 Laptop PC	21-Jul-2014	11474	Z121004
842-689900DE	EDX Windows 10 Laptop PC, German	21-Jul-2014	11474	Z121004
842-691800	EDX 3 channel Amplifier	21-Jul-2014	11474	Z121004
842-691900	EDX 4 channel Amplifier	21-Jul-2014	11474	Z121004
842-692000	EDX 5 channel Amplifier	21-Jul-2014	11474	Z121004
842-692100	EDX 6 channel Amplifier	21-Jul-2014	11474	Z121004
842-692200	EDX 7 channel Amplifier	21-Jul-2014	11474	Z121004
842-692300	EDX 8 channel Amplifier	21-Jul-2014	11474	Z121004
982A0568	Viking EDX International	21-Jul-2014	11474	Z121004
982A0569	Synergy EDX International	21-Jul-2014	11474	Z121004

UltraPro S100

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
033100	UltraPro S100 Windows 10 Desktop PC	05-Nov-2020	11474	Z121004
025904	UltraPro Desktop PC - MFF	05-Nov-2020	11474	Z121004
842-695400DE	UltraPro S100 Laptop Win-10PC, German	05-Nov-2020	11474	Z121004
842-695400	UltraPro S100 Windows 10 Laptop PC	05-Nov-2020	11474	Z121004
9031UP742	UltraPro S100 4 Channel Amplifier	05-Nov-2020	11474	Z121004
9033UP731	UltraPro S100 3 Channel Amplifier	05-Nov-2020	11474	Z121004

Nicolet Cortical Stimulator (Nicolet CS)

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
982A0558	CORTICAL STIMULATOR UNIT	21-Jul-2014	32545	N0101020101
515-009000	Cortical Stimulator Control Unit with Power Supply and Cables	21-Jul-2014	32545	N0101020101
515-005500	Nicolet Cortical Stimulator	21-Jul-2014	32545	N0101020101

Nicolet EEG (NicoletOne)

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
022777	Nicolet EEG Desktop Computer Windows 10	21-Jul-2021	11467	Z121003
023035	SOFT/NICOLETONE v5.95.1 b.17	21-Jul-2014	11467	Z121003
023240	Win10 Computer Upgrade (Desktop w/out DigVideo)	21-Jul-2021	11467	Z121003
023241	Win10 Computer Upgrade (Desktop w/ DigVideo)	21-Jul-2021	11467	Z121003
023623	NicoletOne v5.9 Software Upgrade	21-Jul-2014	11467	Z121003
023627	NicoletOne Reader Licence - WIN 10	21-Jul-2014	11467	Z121003
023648	Nicolet EEG - LTM Computerless System - WIN 10	21-Jul-2014	11467	Z121003
023667	Nicolet EEG - LTM System - WIN 10	21-Jul-2014	11467	Z121003
515-019000	NicoletOne V32 Amplifier	21-Jul-2014	11467	Z121003
515-019100	NicoletOne V32 Amplifier with Power Supply	21-Jul-2014	11467	Z121003
515-019200	ASSY/AMP v32 W/CABLE	21-Jul-2014	11467	Z121003
515-019300	NicoletOne V44 Amplifier	21-Jul-2021	11467	Z121003
515-019400	NicoletOne V44 Amplifier with Cable Kit and Power supply	21-Jul-2021	11467	Z121003
515-019500	NicoletOne V44 Amplifier with Cable Kit	21-Jul-2021	11467	Z121003
672-608400	Nicolet EEG Desktop Computer Windows 7	21-Jul-2021	11467	Z121003
688-627700	NicoletOne v5.94.1 Software Upgrade - Win7	21-Jul-2014	11467	Z121003
828-049700	Central Monitor Application Software Only	21-Jul-2021	11467	Z121003
842-683100	Nicolet V32 Amplifier (32 Channels)	21-Jul-2014	11467	Z121003
842-685900	Nicolet V44 Amplifier (44 Channels)	21-Jul-2021	11467	Z121003
842-695700	V32 AMP/8 CHAN CONFIGURATION	21-Jul-2021	11467	Z121003
842-695800	V32 AMP/16 CHAN CONFIGURATION	21-Jul-2021	11467	Z121003
982A0496	Nicolet EEG System	21-Jul-2021	11467	Z121003
982A0519	Nicolet EEG Computerless System	21-Jul-2021	11467	Z121003

Head Boxes

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
515-001501	ASSY/HEADBOX HB-3	14-Nov-2014	11467	Z121003
515-002002	HB3 HEADBOX FOR V SERIES AMPLIFIERS	14-Nov-2014	11467	Z121003
515-005800	HB4 HEADBOX FOR V SERIES AMPLIFIERS	14-Nov-2014	11467	Z121003
515-006200	HB5 HEADBOX FOR V SERIES AMPLIFIERS	14-Nov-2014	11467	Z121003
842-695900	HB-3 HEADBOX/8 CHAN CONFIG	14-Nov-2014	11467	Z121003
842-696000	HB-3 HEADBOX/16 CHAN CONFIG	14-Nov-2014	11467	Z121003

Natus Elite Software

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
828-069300	Natus Elite - Synergy Master Software	05-Nov-2020	47541	Z12100482
828-069400	Natus Elite - Viking Master Software	05-Nov-2020	47541	Z12100482
828-069500	Natus Elite - Synergy & Viking Combo Master Software	05-Nov-2020	47541	Z12100482
828-069700	EMG Reader Software	05-Nov-2020	47541	Z12100482
033418	Software Upgrade from v22 to Natus Elite Software	05-Nov-2020	47541	Z12100482
688-628500	EMG Software Upgrade to Newest Version	05-Nov-2020	47541	Z12100482
688-628600	Software Update to v22.3	05-Nov-2020	47541	Z12100482

Nicolet Isoboxes

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
515-014300	500VA ISOBOX 115V 8X 1X	21-Jul-2014	11467	Z121003
515-014400	500VA ISOBOX 230V 8X 1X	21-Jul-2014	11467	Z121003
842-670400	Nicolet 115V Isobox	21-Jul-2014	11467	Z121003
842-670500	Nicolet 220V Isobox	21-Jul-2014	11467	Z121003

Nicolet Monitor

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
023659	Nicolet EEG - Monitor Computerless System - WIN 10	21-Jul-2014	11467	Z121003
023673	Nicolet EEG - Monitor System - WIN 10	21-Jul-2014	11467	Z121003
022778	Nicolet ICU Monitor 21 Inch Panel PC Windows 10	21-Jul-2014	11467	Z121003
842-682600	NicoletOne Monitor Computerless Kit (Amplifier not included)	21-Jul-2014	11467	Z121003
842-682700	Nicolet EEG - Monitor Computerless System	21-Jul-2014	11467	Z121003

Nicolet LTM

Part #	Product Description	Shipment After Date	GMDN Code	EMDN Code
842-673100	Nicolet EEG - LTM Computerless System	21-Jul-2014	11467	Z121003
982A0378	Nicolet EEG - LTM System	21-Jul-2014	11467	Z121003