Dantec® Keypoint™ Focus

Compact EMG/NCS/EP Workstation

Dantec Keypoint Focus workstation

The Dantec Keypoint Focus EMG system is based on nearly 50 years of experience in EMG system design. Quality, accuracy, and dependability – what you have come to expect from the Dantec brand.

Dantec Keypoint Focus is the next generation EMG system – delivering the quality and results you expect, at an economical price.

Its new compact design and intuitive, powerful functionality make the Dantec Keypoint Focus EMG system ideal for space conscious professionals in hospitals and private offices.

- All-in-One EMG/EP system with dedicated controls, integrated stimulators and high quality audio
- 3-, 4-, 6- or 8-channel amplifier options
- Advanced features for quantitative EMG, SF-EMG and tremor analysis
- On-line comparison to reference values

Dantec Keypoint Focus
portable notebook system

Digitally signed by Grabazei Alexandru
Date: 2021.09.30 15:02:33 EEST
Reason: MoldSign Signature
Location: Moldova

natus®

Dantec® Keypoint™ Focus

Handle difficult cases more quickly and efficiently

- Protocol-based testing
- Broad range of powerful analysis tools
- Automatic comparison with normative data
- The only system available with a complete MUP normative database
- Fast, automatic report generation

Design an EMG system that's perfect for you

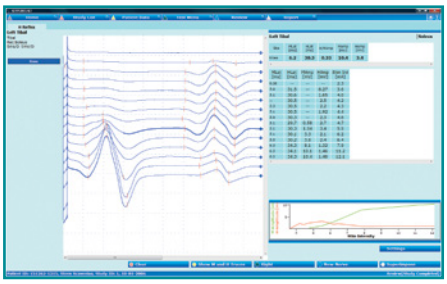
- Select the configuration that works for you - portable notebook systems to fully featured workstations
- Purchase only the applications you need
- Completely control all measurements, data tables/calculations and displays
- Create customized reports

IT-friendly features

- Microsoft® SQL database
- Automated study data back-up/archiving functionality
- Complete Active Directory Services
- GDT/HL7 connectivity

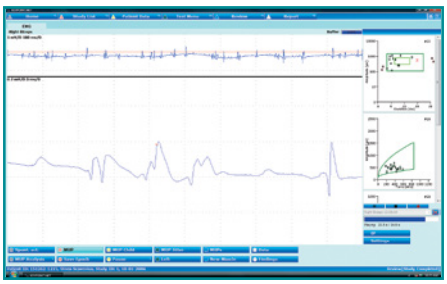
Versatile EMG/NCS/EP Software

Multimodality NCS with reference values

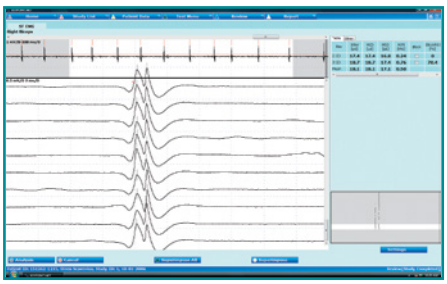


Advanced H Reflex

Advanced Decrement test



Multi-MUP with reference values



Peak-triggering SF-EMG

EP with reference values

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
- Replacement unit and spare part availability
- Extended warranty and service coverage programs
- Comprehensive, flexible customer training courses

Supplies

Convenient, complete, trusted

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

We also offer:

- Dedicated and knowledgeable customer service
- Streamlined order processing

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

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

Healthcare solutions with one thing in mind. You.

natus®

Natus Medical Incorporated

natus.com

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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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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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

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**
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'.

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
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.

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.

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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