

Natus® Keypoint® G4

User and Service Guide

Part Number: 269-653700 Rev 05 18/SEPTEMBER/2024

System Model Number: 9031A07XX



© 2016 - 2024 Natus Medical Incorporated or one of its subsidiaries. All rights reserved. Natus is a registered trademark of Natus Medical Incorporated. All product names appearing on this document are trademarks or registered trademarks owned, licensed to, promoted or distributed by Natus Medical Incorporated, its subsidiaries or affiliates. All other trademarks are the property of their respective owners.

Contact Information



Natus Manufacturing Limited

IDA Business Park
Gort, Co. Galway, Ireland
natus.com

Arazy Group Switzerland GmbH

Bruderholzallee 53
4059 Basel
Switzerland
Swiss.ar@arazygroup.com



Natus Nicolet UK Ltd

Baynards Green Trading Estate
Prospect House
Oxfordshire
Bicester
OX27 7SG
England, United Kingdom



Rx only



Technical Support / Customer Service

Domestic & International:

Natus Medical Incorporated
3150 Pleasant View Road
Middleton, WI USA 53562
Email: madison.helpdesk@natus.com
Phone: 1-800-356-0007
1-608-829-8500
Fax: 608.829.8589

Australia & New Zealand:

Email: service.ANZ@natus.com

Benelux:

Email: support.be@natus.com
Phone : +32 15 32 13 73

France:

Email: service.fr@natus.com
Phone: +33 5 56 08 54 76
Fax: +33 5 56 42 27 62

Germany:

Email: service.europe@natus.com
Phone: +49 89 83942 0
Fax: +49 898 394 2777

United Kingdom:

Email: neurosupportuk@natus.com
Phone : 020 3058 0850









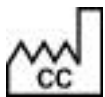
Copyright © 2016-2024 Natus Medical Incorporated. All Rights Reserved.






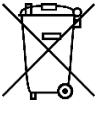



This manual contains proprietary information, which is protected by copyright laws and may not be copied in whole or in part except with the prior written permission of Natus Medical Incorporated. The copyright and the foregoing restrictions on the copyright use extend to all media in which this information is preserved.

This copy of the User Manual shall be used only in accordance with the conditions of sale of Natus Medical Incorporated or its distributors, including without limitation the Natus Software License Agreement. Natus Medical Incorporated makes no representations or warranties of any kind whatsoever with respect to this document. Natus Medical Incorporated disclaims all liabilities for loss or damage arising out of the possession, sale, or use of this document.

Glossary of Symbols

The following labels and symbols may be affixed to the Natus Keypoint G4 system:

Symbol	Standard Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	ISO 15223-1 Symbol 5.7.7	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Medical Device	This product is a medical device.
	Medical Device Directive 93/42/EEC or Medical Device Regulation 2017/745 as applicable	Council Directive 93/42/EEC Regulation (EU) 2017/745	CE Marking of Conformity	Signifies European technical conformity. Notified body number appears under symbol if applicable.
	UK MDR 2002	UKCA Mark	UKCA Mark	Signifies Great Britain (England, Wales, and Scotland) conformity. UK Approved Body number appears under symbol.
	Swiss Medical Device Ordinance (MedDO)	Swiss Authorized Representative	Swiss authorized representative	Indicates the Authorized representative in Switzerland.
Rx only	21 CFR 801.109(b)(1)	Labeling – Prescription Devices	Device is cleared for the US market as requiring a prescription	Indicates that the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	IEC 60601-1, Table D.2, Symbol 20 (ICE 60417-5333)	Part 1: General requirements for basic safety and essential performance.	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	ISO 15223-1 Symbol 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1 Symbol 5.1.5	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Batch code or Lot code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Symbol 5.1.6	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Symbol 5.1.11	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Country of Origin	Indicates the country of origin.

Symbol	Standard Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	ISO 15223-1 Symbol 5.1.1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Legal Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Symbol 5.1.3	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1 Symbol 5.3.7	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Temperature limit	Indicates the (storage) temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Symbol 5.3.8	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Humidity limit	Indicates the range of (storage) humidity to which the medical device can be safely exposed.
	ISO 15223-1 Symbol 5.3.9	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Directive 2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)	Disposal at end of operating life instructions	Indicates that electrical and electronic equipment waste should not be discarded together with unseparated waste but must be collected separately.
 natus.com	ISO 15223-1 Symbol 5.4.3 Annex A #A.15	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Consult Instruction for Use	Indicates an instruction to consult an electronic instruction for use
	ISO 15223-1 Symbol 5.4.4	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	IEC 60601-1 Table D.1 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		
	IEC 60601-1 Table D.2 #10	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Follow Instructions for Use	Refer to instruction manual/Booklet. NOTE on ME EQUIPMENT “Follow Instructions for use”.




Symbol	Standard Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	IEC 60601-1 Table D.2 #2	Medical electrical equipment — Part 1: General requirements for basic safety and Essential performance.	Warning	Indicates a hazard of potential personal injury to patient or operator.
	UL Listing	N/A	UL Classification Mark	Nationally Recognized Testing Laboratories (NRTL) certifications
	UL Listing	N/A	UL Recognized Component Mark	The optional C-UL-US Component Recognition Mark indicates compliance with both Canadian and U.S. requirements.
SWL	Safe Working Load	N/A	N/A	N/A

Table of Contents

<i>Contact Information</i>	2
<i>Glossary of Symbols</i>	3
<i>Table of Contents</i>	6
1. General Information	7
2. Safety, Warnings and Precautions	10
3. System Hardware	15
4. System Operation	31
5. Patient Information	34
6. Performing an Exam	38
7. Backup and Restore Data	49
8. Maintenance, Cleaning and Disposal	50
9. Electromagnetic Compatibility (EMC)	54
10. System Symbols	58
11. Technical Specifications	62

1. General Information

User Guide

This guide provides the basic information needed to setup, operate and maintain the Natus Keypoint G4 system.

A PDF copy of this user guide is available on the USB drive provided with the system. Copies of the user guide may also be accessed at natus.com in the Support section. Scroll to the EMG Product IFUs, select Natus Keypoint G4 and choose the version for your local language. The files can be printed, saved, or searched using Adobe Reader. A copy of Adobe Reader can be downloaded directly from Adobe Systems (www.adobe.com). A paper copy of the Instructions for Use in available languages can be obtained by contacting Natus Technical Support, or by contacting a Natus representative.

Some features and Part Numbers included in this User Guide may not be available in all markets.

Intended Use

Keypoint G4 is intended as an electrophysiological aid to assess diagnosis and prognosis, and to monitor diseases of the central and peripheral nervous system. It can also be used to study functional aspects of nerves and muscles in other fields such as rehabilitation (physical medicine), occupational medicine and sports medicine.

System Overview

Keypoint G4 system is designed for the acquisition, display, analysis, reporting, and management of electrophysiological information from the human nervous and muscular systems in adult and pediatric patients. Keypoint G4 provides the ability to conduct electrodiagnostic testing including nerve conduction studies (NCS), needle electromyography (EMG) testing, evoked potential (EP) testing and Autonomic studies. It is designed to address the testing requirements for medical professionals in hospitals and private practice. Optional software programs and accessories allow the user to customize the Keypoint G4 system to meet specific clinical requirements.

The Primary Operating functions of the Keypoint G4 system include:

- System startup with device check
- Test protocol selection, customization and execution
- Control of amplifier signals
- Control of electrical, visual and auditory stimuli
- User-controlled data review and analysis
- Reporting and test result summaries
- Storage and retrieval of recorded data

Clinical Performance

The Keypoint G4 allows the user to perform a wide range of Nerve Conduction Studies (NCS), Electromyography (EMG), Evoked Potential (EP) Studies and Autonomic Studies. Separate software programs and optional accessories allow the user to customize the Keypoint G4 to meet specific clinical needs.

Clinical Benefits

The Keypoint G4 system assists the physician in collecting measurements and waveforms of the nerves and muscles in the body to support the diagnosis of neuromuscular disease. Disease is indicated when measurements fall outside of expected or normative ranges. The Keypoint G4 system facilitates the diagnostic evaluation of diseases such as carpal tunnel, radiculopathy, nerve lesions, several types of dystrophy, and other diseases of the nervous and muscular system.

Medical Conditions

Neuromuscular disease is suspected when a patient complains of abnormal sensations such as tingling, numbness, pain, weakness and/or abnormal movements including tremor or spontaneous contractions. Electrodiagnostic testing and monitoring is performed on patients with suspected or confirmed neuromuscular diseases including muscular dystrophy, motor neuron disease (ALS), polio, myasthenia gravis, peripheral neuropathies, radiculopathies, myopathies, carpal tunnel syndrome, and multiple sclerosis. Intended Users

The Keypoint G4 is intended to be used by a qualified healthcare provider. Qualified healthcare providers include those with specialized training in the use of Electrodiagnostic (EDX) instrumentation for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular system.

Patient Population and Target Group

The Keypoint G4 assists the physician in the diagnosis of patients with neuromuscular diseases for pediatric and adult patients.

Residual Risks and Side Effects

There are no known residual risks or side effects for procedures performed with the Keypoint G4. Please note the Warnings and Cautions before applying power to and using the system.

Security Measures

Utilize best practice security measures in your clinical environment including the following:

General and Network Security Measures

General Security Policies

- Prevent physical access to the system from unauthorized persons.
- Make frequent backup of the system. Store the backup on a safely stored device.
- Protect the system with updated antivirus.
- Use the Microsoft Windows firewall at all times.
- Store all DCDs and flash drives provided with your system in a safe location.

Networked Environments

- Connect the system on secured networks only. Using the system on a wide-open network, including wi-fi, Bluetooth, etc. based networks is not recommended.
- Keep the network software updated with latest patches.
- Use encrypted data communication over "less safe" network segments (ipsec, VPN).
- Enforce that all resources within the network (shares, printers, other equipment) can be accessed by authenticated users only.
- All resources within the network can only be accessed by authenticated users.
- Avoid acquisition systems having contact with patient to act as network servers for different functionality.

Windows Systems Secure Access

- Users should require an account with suitable privileges to use the system (note no special elevated rights are required to use the EMG application).
- Policies should ensure passwords are complex, non-repeated and regularly changed.
- Enable auditing of system use including windows logins in the operating system.

Data Confidentiality

- The user should lock the system manually if they leave it unattended.
- Short inactivity timeouts are always active and lock the system when the timeout expires.
- The EMG application supports the use of windows screen saver, manual lock screen and automatic switch to the home page after a timeout on review stations to prevent showing confidential information on unattended systems.

Data Protection

- Do not install any 3rd party software which is not intended for use with the application. An unknown software can possess a potential security risk.
- Encrypt system drives which contain local databases and temporarily store data files/reports.
- Disable unnecessary windows services designed for not work-related features.

Protective and Equipment Classification

This system is intended for continuous operation and has an IEC 60601-1 protective classification of Class I, Type BF applied parts, ordinary equipment, not suitable for use in the presence of flammable anesthetics.

Accuracy of Controls

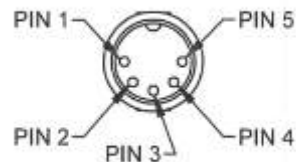
Stimulator values are determined by the operator based on the electrophysiological responses and the subjective reaction of the patient to the stimulus, therefore an accuracy of $\pm 30\%$ provides acceptable levels for safe use of this equipment in the intended applications.

Ancillary Accessories

To facilitate the acquisition of electrophysiological information using this system, there are ancillary accessories that must be used. These accessories include surface electrodes and needle electrodes that are not included with the system. To ensure proper use of the system; descriptions, recommendations and or specifications are provided for these ancillary accessories that are deemed compatible with the Keypoint G4 system.

Natus recommends using surface electrodes that have been cleared or approved for nerve conduction and/or evoked potential studies. Either disposable or reusable surface electrodes may be used. The size of the electrode should be appropriately selected for the test being conducted. Reusable surface electrodes are made of metal and are typically fabricated from platinum, gold or silver. Metallic reusable electrodes must be cleaned and or conditioned for reuse according to instructions provided by the manufacturer of those electrodes. All surface electrodes used should have a protective pin connector that complies with DIN 42 802 standard. This nonproprietary pin connector is an industry standard for EMG systems.

Disposable and reusable needle electrodes may be used. Needle electrodes are fabricated from a variety of materials. It is recommended that the needle electrodes selected are those that have been cleared or approved for electromyography applications. Use a length and gauge appropriate for the test being conducted. The connector is a circular 5 pin DIN connector. This nonproprietary pin connector is an industry standard for EMG systems. The pin configuration for this connector is as follows: **Pin 1** is active, **Pin 2** is reference, **Pin 3** and **Pin 4** are shield drivers and **Pin 5** is patient ground.



2. Safety, Warnings and Precautions

This chapter defines Safety, Warnings and Precautions applicable to the Natus Keypoint G4 system. Read all information in this chapter thoroughly prior to use of the Natus Keypoint G4 system.

Two labels identify potentially dangerous or destructive conditions and procedures:



Warning

A **WARNING** indicates that there is a risk of death or serious injury to the user or patient.



Caution










A **CAUTION** indicates that there is a risk of injury to the user or patient or risk of damage to the device.

Any serious incident that has occurred in relation to the Natus Keypoint G4 system be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Contraindications







There are no known contraindications under normal clinical use.






Warnings

	Do not use this PC-based equipment for anything else other than what it is intended for by the manufacturer –i.e. carrying out tests on patients and possibly subsequent report generation. Do not install any other software than authorized application software. Natus assumes no responsibility when the equipment is not used as described in this manual.
	The device is not intended for direct cardiac application.
	The device is not suitable for intensive care monitoring use.
	Possible explosion hazard, if used in the presence of flammable anesthetics.
	Any interruption of the protective earth conductor inside or outside of the device, or disconnection of the protective earth connector is likely to make the device dangerous. Intentional interruption is prohibited. The protective earth (ground) conductor should be checked regularly.
	Do not connect the "patient ground" to the protective earth connection on the rear panel of the Power Supply Unit/Isolating Transformer or to any other "ground" connections, as the electrode inputs are galvanically isolated.
	Electrical equipment for medical use requires special EMC precautions and needs to be installed and serviced according to the EMC documentation of device.
	When connecting the integrated LAN port to a network system, the NetBox Ref. 9031G046x must be properly connected into the LAN line between the LAN port and the network system. Do not make a direct connection between the PC LAN Port and the Network System! The NetBox Ref. 9031G046x provides electrical insulation to prevent dangerous electrical current from reaching the patient in the event that the network system becomes accidentally electrically shorted to a high voltage line. Failure to properly install the NetBox Ref. 9031G046x when making the LAN connection annuls this product's compliance certification with the IEC 60601-1 international safety standards for medical electrical equipment.
	The use of accessories, electrodes, and cables other than those specified by Natus may result in increased emissions, or decreased immunity of the equipment.

	When connecting other equipment, attention must be paid to standard IEC 60601-1– Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance. Failure to comply with this standard may result in safety risk.
	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
	Dangerous physiological effects! The current stimulator may give off dangerous currents and voltage.
	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.
	Electric shock hazard. Do not remove the cover. Refer servicing to qualified service personnel.
	This device is intended to be used by qualified medical personnel, knowledgeable in the field of neurophysiology and neurophysiological assessment, as well as in the use of the product / Keypoint equipment.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Keypoint system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	Portable and mobile RF communication equipment can affect electrical equipment for medical use.
	Dangerous physiological effects! The current stimulator may give off dangerous currents and voltage.
	Do not use cleaning detergents, or other cleaning agents based on alcohol, solvent, silicon-based, abrasive and/or flammable substances to clean the equipment.
	Avoid accidental contact between connected, but unapplied electrodes and other conductive parts - including those connected to protective earth.
	Always use shielded power line cables from Natus to avoid hum line interference, especially near the patient, or the amplifier.

Cautions

	Simultaneous connection of a patient to HF surgical equipment may result in burns at the site of the electrical stimulation or recording electrodes, and possible damage to the electrical stimulator or the electrode input amplifiers. Operation in close proximity (e.g., 1m) to short wave or microwave therapy equipment may produce instability in the electrical stimulator output.
	When connecting other equipment, qualified attention must be paid to the following excerpt from the medical safety standard to which this system complies.
	Use only optional devices specified by Natus in order to comply with IEC 60601-1.
	Use only the 6-outlets safety power supply / isolating transformer unit for all devices of the complete system in order to comply with the IEC 60601-1. See section Isolating Transformer for instructions for use.
	Avoid electrical stimulation for an extended period of time.
	It is strongly recommended to back up regularly. To back up the database, use the BackupSettings utility. To back up the directory containing archived studies, use the Windows Backup Tool.

	New reference values are required when changing the algorithm. If you use the reference value system, the values must reflect the algorithm you select.
	New settings require new reference values. If you use the reference value system, the values must reflect the settings you select.
	Due to risk of electric shock, the operator and / or patient must not directly or indirectly touch the metal shield on the LINK cable attached to the rear of the amplifier.
	Do not use additional multiple socket outlets or extension cord.
	Pay attention to the intensity indicator during the use of the program. See the section Stimulator Overload , and the section Stimulators for further information.

Safety Requirements

This device has been designed and tested in accordance with IEC 60601-1 Medical Electrical Equipment, cf. the text on IEC 60601-1 further below in this section.

The device has been designed for indoor use at temperatures between +10°C and +35°C (+50°F to +95°F).

The mains plug must only be inserted in a mains socket outlet provided with a protective earth contact.

- It is forbidden to use extension cords.
- It is forbidden to use multiple portable socket outlets (MPSO).

Adhere to the following recommendations for safe operation of the device:

- When connecting medical equipment being supplied from an outlet located in a non-medically used room, or when connecting non-medical electrical equipment to this device, please pay attention to the requirements of IEC 60601-1, Safety Requirements for medical electrical systems, cf. the text on IEC 60601-1, is found below in this section.
- When the device is connected to its mains supply, connectors may be live, and any opening of covers or removal of parts possible only with the aid of a tool is likely to expose live parts.
- The device must be disconnected from all voltage sources before being opened for any adjustment, replacement, maintenance or repair.
- Service must be referred to Natus authorized service personnel, except for such works described in this manual as being performed by the operator.
- Make sure that only fuses with the required rated current and of the specified type are used for replacement. The use of makeshift fuses and the short-circuiting of fuse holders are prohibited.
- Where more than one piece of equipment is connected to the patient, attention must be paid to the summation of patient leakage currents.
- Whenever it is likely that the protection has been impaired, the device shall be made inoperative and be secured against any unintended operation. Call qualified service personnel to conduct at least a functional test and a safety check that should include the following:
 - Insulation test
 - Ground continuity test
 - Leakage current test, according to IEC 60601-1
- The protection is likely to be impaired if, for example, the device:
 - Shows visible damage
 - Fails to perform the intended function(s)
 - Has been subject to severe transport stresses

Classification

Type of protection against electric shock: class I:

- Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Method(s) of cleaning recommended by the manufacturer:

- Please see [Maintenance and Cleaning](#).

Degree of protection against electric shock:

- Type BF: applied part providing a particular degree of protection against electric shock, particularly regarding:
- Allowable leakage current
- The applied part is electrically isolated (floating).
- Not intended for direct cardiac application.

Degree of protection against harmful ingress of water:

- IP20: ordinary equipment (enclosed equipment without protection against ingress of water).
- Note the Keypoint Triple Footswitch Ingress Protection: IPX1

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 such a mixture.

Mode of operation:

- Continuous operation.

Degree of patient vicinity:

- Whole equipment (system) is suitable for use in the patient environment.

Excerpt from the IEC 60601-1 Standard

Reference: IEC 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance. Chapter 16: Medical Electrical Systems.

When connecting to a medical appliance with an F-type applied part, or some additional equipment complying not with IEC 60601-1 but with the relevant safety standard for such equipment, the additional equipment:

1. must either be placed outside the patient environment --the patient environment is any area in which intentional, or unintentional contact can occur between patient and parts of the system (e.g., a printer, VEP Monitor) or as a result of some other person touching parts of the system;
or
2. if placed within the patient environment, must be:
 - a) provided with an additional protective earth connector;
or
 - b) supplied from a separating transformer, limiting the enclosure/touch leakage current to a value not exceeding: Normal Condition: 0.1 mA or Single Fault Condition 0.5 mA

Please refer to IEC 60601-1 for further details.

Source Voltage

The source voltage for the current stimulators is approx. 400 V. If the load impedance exceeds $400 \text{ V}/I_{s\text{kin}}$, where $I_{s\text{kin}}$ denotes the selected stimulating current, the stimulators will be unable to provide the selected currents. Furthermore, the stimulators will be unable to provide more than approximately 0.5 W. This may limit the output current for fast stimulations.

Stimulation Electrodes: Maximum Current Density

If the current density exceeds 2 mA rms/cm², it may require the special attention of the user (the risk of burning the skin). The maximum pulse current will depend on the frequency of the stimulation, pulse width and the area of the electrode. The current density may be calculated as follows:

$$J = \sqrt{(f \times Tp) \times \frac{I}{A}}$$

where f designates the frequency of stimulation, Tp pulse width, I pulse current and A the area of the electrode. In certain cases, however, e.g., nerve damage, it may be necessary to apply heavier currents.

Electrode Areas

$$9031E017 = 0.58 \text{ cm}^2$$

$$9013L036 = 0.39 \text{ cm}^2$$

An example: 9013L036 surface stimulation electrode, felt tips, stimulus frequency 2 Hz, pulse width 0.2 ms:

$$J = \sqrt{2 \times 0.0002} \times \frac{I}{0.39 \text{ cm}^2} < \frac{2 \text{ mA}}{\text{cm}^2}$$
$$I < 39 \text{ mA}$$

Stimulation Pulse Terminology

The term “pulse duration” or “pulse width” refers to the length of time from point A to point B. The “pulse amplitude” refers to the output level reference from points C and D with the rated load. See Figure 1.

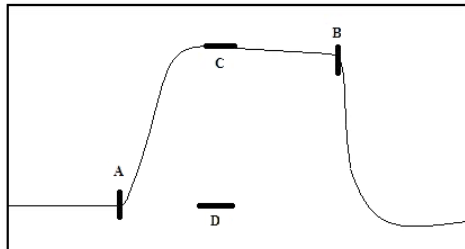


Figure 1

Accuracy of Controls

Stimulator values are determined by the operator based on the electrophysiological responses and the subjective reaction of the patient to the stimulus, therefore an accuracy of $\pm 30\%$ provides acceptable levels for safe use of this equipment in the intended applications.

3. System Hardware

This chapter describes the basic hardware used to operate the Natus Keypoint G4 system.

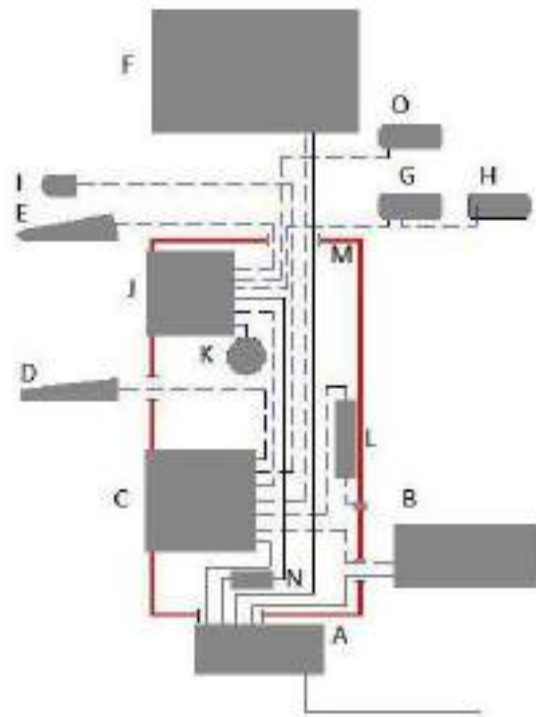
Workstation



1	Computer	9	Amplifier Box
2	Power Switch	10	Connection Panel
3	Monitor	11	Accessory Box Kit (optional)
4	Internal Speaker	12	Mouse
5	Control Panel	13	Printer (optional)
6	PC Keyboard	14	LAN Socket (optional)
7	Amplifier Arm (optional)	15	Cart
8	Current Stimulator	16	Power Supply / Isolating Transformer

NOTE All the positions of the devices shown on the picture are examples only.



Cable Connection Overview



A Power Supply / Isolating Transformer	F Screen	K Loudspeaker
B Printer (optional)	G Amplifier Box	L Network Isolator (optional)
C Computer	H Stimulator Box	M Cart Enclosure
D PC Keyboard	I Mouse	N DC power supply unit (used with Isolating Transformer)
E Control Panel	J Connection Panel	O 2nd Amplifier Box (optional)

Cable Connections

Before operating the device, the system parts should be connected.

1. Connect all the signal interface cables as depicted in the illustration (black thin).
2. Connect all the power interface cables as depicted in the illustration, except the power cord.
3. Check voltage:
 - a. On the Power Supply unit, make sure that the voltage selectors  are set to the proper voltage settings.
 - b. On the Isolating Transformer unit, make sure that the correct voltage type is used.
4. Connect the power cord to the wall outlet.
5. Press the Power on/off button  on the front panel of the computer for the system to turn on.

NOTE Unplugging the power line cable from the mains input on the power supply/Isolating Transformer disconnects the mains power of the complete system.

NOTE Make sure the device connected to the wall power outlet is positioned in such a way to allow easy disconnection from the mains, if needed.

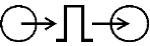





NOTE HS LINK – Multiple types of modules can be connected to HS LINK (see G, H, and O in the figure above). Certain types of module combinations are restricted due to HS LINK power limit. Module restrictions are software controlled.

Connection panel	3ch EMG amp	4ch EMG amp	6ch EMG amp	8ch EMG amp	6ch EP amp
No 2 nd acq box	x	x	x	x	x
3ch EMG amp	x	x			
4ch EMG amp	x				
6ch EMG amp					
8ch EMG amp					
6ch EP amp	x	x	x	x	

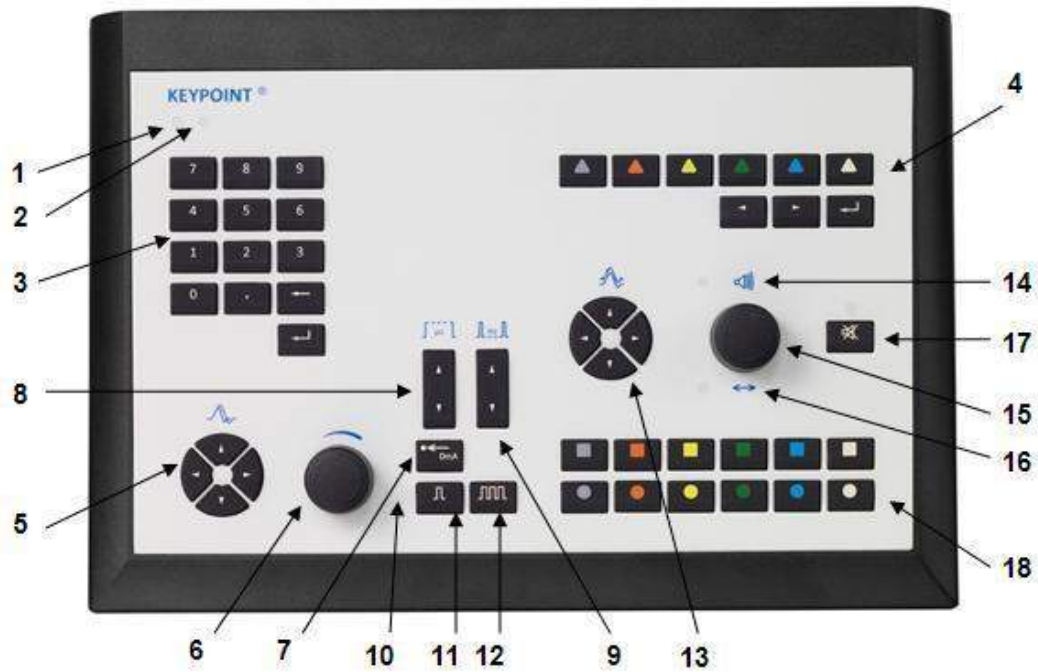
NOTE HS LINK – Modules (G, H, and O) connected to HS LINK may have certain limitations due to system power consumption conditions. Limitations are hardware related and can be avoided by using the DC Power Supply (N).

Connection Panel



	Input / Output Connector Input / Output Magnetic Stimulation / tendon hammer, or synchronization of external trigger, or external stimulation acquisition.
	Footswitch Connector
	Pattern Stimulator Connector
	Auditory Stimulation Headset Connector
	Visual Goggles Stimulator Output Connector
	Power ON Indicator

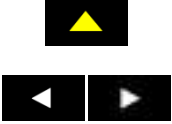
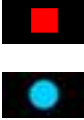
Control Panel




1	Standby Indicator	10	Stimulation Indicator
2	Power ON Indicator	11	Single Stimulation Key
3	Numeric Keypad	12	Repetitive Stimulation Key
4	Software Navigation Keys	13	Trace/Marker and Trigger Arrow Keys
5	Sweep Speed/Sensitivity Level Arrow Keys	14	Volume Indicator
6	Stimulation Intensity Control Knob	15	Volume/Cursor Control Knob
7	Reset Stimulation Intensity Key	16	Cursor Mode Indicator
8	Stimulation Duration Arrow Keys	17	Loudspeaker Mute Key / Indicator
9	Stimulation Repetition Rate Arrow Keys	18	Software Function Keys

Control Functions




Software Navigation / Software Functions

	<p>Software Navigation Keys – Color Coded</p> <p>The Software Navigation keys allows navigation through the application tabs.</p> <p>The 6 Software Navigation keys' colors and functions correspond to those of the Software Navigation buttons on the application.</p> <p>The Left and Right arrow keys allow test selection.</p>
	<p>Software Function Keys – Color Coded</p> <p>The Software Function keys allows of control the different software functions on the application.</p> <p>The 12 Software Function keys' colors and functions correspond to those of the Software Function buttons on the application.</p>



Display keys



	<p>The Right and Left control keys allow you to modify the sweep duration.</p> <p>The Right key decreases the sweep duration per division, which makes the trace wider.</p> <p>The Left key increases the sweep duration per division, which makes the trace narrower.</p> <p>The Up and Down control keys allow you to modify the sensitivity per division.</p> <ul style="list-style-type: none"> • The Up key decreases the sensitivity per division, which makes the trace larger. • The Down key increases the sensitivity per division, which makes the traces smaller.
---	---

Stimulation






	<p>Stimulation Indicator</p> <p>The Stimulation indicator green light (LED) blinks once for each Single Stimulation and Intermittently for Repetitive Stimulation.</p>
	<p>Single Stimulation Key</p> <p>When the Single Stimulation key is pressed, a single stimulus is released, and the indicator blinks once.</p> <p>The Single Stimulation key can also be used to stop Repetitive Stimulation.</p>
	<p>Repetitive Stimulation Key</p> <p>When the Repetitive Stimulation key is pressed, repetitive stimulus is released and the indicator blinks intermittently.</p> <p>To stop repetitive stimulation, press either the same Repetitive Stimulation key, or the Single Stimulation key.</p>

Stimulus Intensity / Duration / Repetition Rate

	<p>Stimulus Intensity Control Knob</p> <p>Use the Stimulus Intensity control knob to adjust the intensity of the stimulus released.</p> <p>Rotate the control knob to the right to increase the stimulus intensity.</p> <p>Rotate the control knob to the left to diminish the stimulus intensity.</p>
	<p>Reset Stimulus Intensity Key</p> <p>Press the Reset Stimulus Intensity key to reset the stimulus intensity to its base level.</p>

	<p>Stimulus Duration Control Keys</p> <p>Use the Stimulus Duration Up and Down control keys to increase / decrease the duration of the stimulus. The Up key Increases the stimulus duration. The Down key decreases the stimulus duration.</p>
	<p>Stimulus Repetition Rate Control Keys</p> <p>The Stimulus Repetition Rate Up and Down control keys increase and decrease the stimulus repetition rate. The Up key increases the stimulus repetition rate. The Down key decreases the stimulus repetition rate.</p>

Loudspeaker / Volume / Cursor Mode / Trace / Marker / Trigger

	<p>Loudspeaker Mute Key / Indicator</p> <p>Press the Loudspeaker Mute key to switch between the On and Off function.</p> <p>The yellow light (LED) indicates the loudspeaker is muted.</p> <p>To adjust the volume, see the Control knob function below.</p>
	<p>Volume Indicator</p> <p>The green light (LED) indicator is on when the volume function is enabled – see the Control knob function below.</p>
	<p>Volume / Cursor Control Knob</p> <p>Press the Control knob to switch between the Volume and the Cursor/Trigger Mode functions.</p> <p>When Volume is enabled, rotate the knob to adjust the volume level.</p> <p>When Cursor/Trigger Mode is enabled, rotate the knob to move the markers or the trigger cursor.</p>
	<p>Cursor Mode Indicator</p> <p>The green light (LED) indicator is on when the cursor mode is enabled.</p> <p>When enabled, it allows movement of the markers or the trigger cursor with the use of the control knob –see the control knob function above.</p>
	<p>Trace / Marker / Trigger Arrow Keys</p> <p>In NC; F-Wave; and H-Reflex Applications:</p> <p>The Up and Down arrow keys select the active trace.</p> <p>The Left and Right arrow keys select the active cursor.</p> <p>In EMG Application:</p> <p>The Up and Down arrow keys move the trigger cursor in small steps.</p> <p>The Left and right arrow keys move the trigger cursor to the left and to the right.</p>

Rear Panel





	<p>HS Link Input Connector - Connection Panel (internal)</p>
---	---

Amplifiers




EMG Amplifier Modules: 3, 4, 6, and 8 Channels



	<p>Power ON Indicator The green light (LED) indicates that the amplifier power is On.</p>	
	<p>Amplifier Input (isolated) All amplifier input connectors are electronically isolated. Electrostatic Sensitive Amplifier Input Connectors ⚠️WARNING Do not touch the Amplifier Input connectors as it may damage the amplifier or affect its performance.</p>	
	<p>Impedance Test Key / Indicator Press the Impedance Test key to start the impedance measurement. The green light (LED) indicates that the impedance test is in progress.</p>	
	<p>Loudspeaker Mute Key / Indicator Press the Loudspeaker key to switch between the On and Off function. The yellow light (LED) indicates that the loudspeaker is muted.</p>	
	<p>Active Electrode Indicator — Black The Active electrode corresponds to the black input connector. The green light (LED) indicates the results of the impedance test as described.</p>	
	<p>LED Status All LEDs Off Constantly lit LEDs</p>	<p>Result Impedance below threshold Impedance above threshold, high Impedance</p>
	<p>Reference Electrode Indicator — Red The Reference electrode corresponds to the red input connector. The green light (LED) indicates the results of the impedance test. See the LED Status and Results description under the Active Electrode Indicator.</p>	





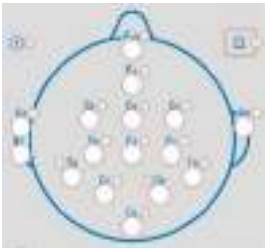
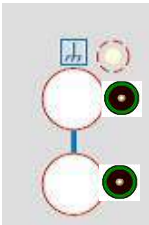
	<p>Amplifier Input Connectors (1-3) or (1-4)</p> <p>The amplifier input connectors 1-3 feature both a DIN-type socket and a pair of 1.5 mm touch-proof connectors. These amplifier input connectors can share the same reference pin.</p>
	<p>Amplifier Input Connectors (4-8)</p> <p>The amplifier input connectors 4-8 feature a pair of 1.5 mm touch-proof connectors. These amplifier input connectors can share the same reference pin.</p>
	<p>Patient Ground Connector / Indicator</p> <p>Connect the patient's ground electrode to the green connector.</p> <p>The green light (LED) indicates the results of the impedance test. –See the LED Status and Results description under the Active Electrode Indicator.</p>
	<p>Patient Ground Connector / Indicator</p> <p>Connect the patient's ground electrode to the green connector.</p> <p>The green light (LED) indicates the results of the impedance test. –See the LED Status and Results description under the Active Electrode Indicator.</p>

Rear Panel



	<p>HS Link Input Connector — Connection Panel (internal)</p>
	<p>HS Link Output Connector — Current Stimulator Connection</p>
	<p>HS Linkport</p> <p>HS Linkport allows an extra module connection (e.g. stimulator). To open the HS Linkport lid, use a tool (e.g. small screwdriver).</p>

EP Amplifier Module – 6 Channels



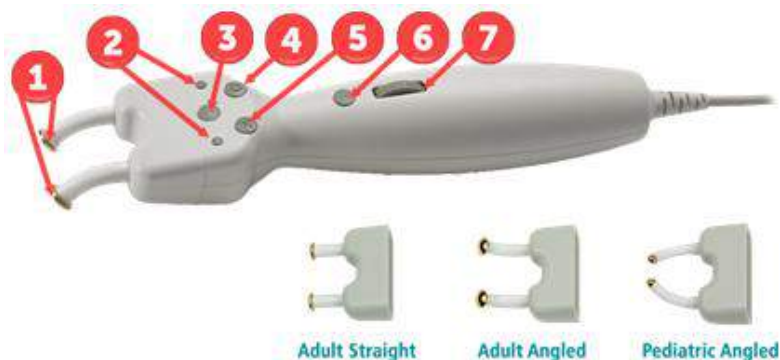
	<p>Power ON Indicator</p> <p>The green light (LED) indicates that the amplifier power is On.</p>						
	<p>Amplifier Input (isolated)</p> <p>All amplifier input connectors are electronically isolated</p>						
	<p>Impedance Test Key / Indicator</p> <p>Press the Impedance Test key to start the impedance measurement.</p>						
	<p>Amplifier Input Connectors – Common Array</p> <p>The green light (LED) indicates the results of the impedance test as described below.</p> <table border="1" data-bbox="518 1220 981 1294"> <thead> <tr> <th>LED Status</th> <th>Result</th> </tr> </thead> <tbody> <tr> <td>All LEDs Off</td> <td>Impedance below threshold</td> </tr> <tr> <td>Constantly lit LEDs</td> <td>Impedance above threshold, high Impedance</td> </tr> </tbody> </table>	LED Status	Result	All LEDs Off	Impedance below threshold	Constantly lit LEDs	Impedance above threshold, high Impedance
LED Status	Result						
All LEDs Off	Impedance below threshold						
Constantly lit LEDs	Impedance above threshold, high Impedance						
	<p>Amplifier Input Connectors – Head Array (Montage) The head array electrode connectors are labeled according to the International 10-20 System of Electrode Placement.</p> <p>The green light (LED) indicates the results of the impedance test. –See the LED Status and Results description under Amplifier Input Connectors – Common Array above.</p>						
	<p>Patient Ground Connector / Indicator</p> <p>Connect the patient's ground electrode to the green connector.</p> <p>The green light (LED) indicates the results of the impedance test. –See the LED Status and Results description under the Amplifier Input Connectors – Common Array above.</p>						

Rear Panel

	HS Link Input Connector — Amplifier Module/ Connection Panel (internal)
	HS Link Output Connector — Not Available For future use of extra module connection.

Stimulators

Natus Stimulus Probe (optional)



1	Output Electrode Pins For direct stimulus on the skin, see the description of the stimulus electrodes in this section.
2	Polarity and Stimulus Indicators The stimulus cathode is indicated by a constant green light (LED). During stimulus, the other LED indicator will flash yellow – once for single stimulus and intermittently for repetitive stimulus. Note that if the stimulator is not enabled, no LEDs will light.
3	Polarity Button Press the button to change polarity.
4	Button C Active in all tests, customizable per test type. Momentarily press the button on the handle.
5	Button A Active in all tests, customizable per test type. Momentarily press the button on the handle.
6	Single Stimulus Button Momentarily press the button on the handle. Repetitive Stimulus Button Press and hold down the button on the handle for at least 1 second. Stop To stop the repetitive stimulation, press the Repetitive Stimulation button again.
7	Stimulus Intensity Control Wheel To increase or decrease the current intensity, rotate the wheel. Alternatively, the mouse wheel or the Stimulus Intensity control knob on the control panel can be used. Reset To reset the intensity to its zero level, press the Reset Stimulation Intensity key on the control panel.

Constant Current Stimulators



Single CC Stimulator



Multi CC Stimulator

	<p>Power ON Indicator The green light (LED) indicates that the stimulator power is On.</p>
	<p>CC Stimulator Output (isolated) CC stimulator output connectors are electronically isolated.</p>
	<p>Stimulus Release Indicator Flashes for the stimulation pulse.</p>
	<p>CC Stimulator Output Socket (isolated) For connection of stimulation electrodes with DIN plugs. Support for the Natus Stimulus Probe.</p>
	<p>Touch-proof Output Connectors (isolated) For connection of stimulation electrodes with touch-proof connectors.</p>
	<p>Active Electrode Indicator The green lights (LEDs) indicate the active (cathode) stimulation electrodes.</p>

Rear Panel

	<p>HS Link Input Connector — Amplifier Module Connection.</p>
--	--

Stimulation Electrodes

The recommended stimulation electrodes to be used in ordinary investigations are:

Electrode Number	Type
9013S030	Digital Ring Electrode
9013L036	Miniature Hand-held Stimulation Electrode
9031E017	Advanced Stimulation Handgrip

When using the surface (cutaneous) electrodes, the following applies:

Before applying the 9013L035 felt tips, they should be soaked in saline to obtain good electrical contact with the skin. Each pair of felt tips is for use with one patient only.

Similarly, when using the electrode pins of the 9031E017, or other electrodes with metal contact provided without a conductive gel, the skin impedance can be reduced using electrode paste, or an equivalent.




When using the reusable surface electrodes, make sure to reprocess them in accordance with the manufacturer's instructions and in accordance with a validated infection control procedure.

Footswitch with 3 Pedals (Option)

A footswitch is available as a triple pedal model. Pedals may be programmed by selecting Test Options/Hardware Controls and inserting the desired function into each pedal designation.

Note Ingress Protection: IPX1.



Pedal	Default Function (User Programmable)
	Next
	Acquire
	Rollback

Temperature probe adaptor



The Temperature Probe Adaptor is a device which enables patient skin temperature measurements for the Keypoint G4 system. The temperature probe being used is a standard YSI-400 type skin temperature probe which connects to the device via a 1/4" mono Jack connector. The temperature probe contains an accurate NTC resistor which the device measures to get temperature reading. The adaptor connects to the USB port of the PC.

Ultrasound option

1. Use the Integration cable kit for InVisus Pro (crossed ethernet cable and Ethernet/USB adaptor) to connect the ultrasound tablet to the EMG computer.
2. On the Ultrasound communication unit, plug the ethernet cable into the rear of the communication unit located under the Ultrasound tablet.
3. On the EMG system side, connect the USB connector into the computer.



On the left, Ethernet connection at the back of the communication unit. On the right, USB connection to the computer.

Note: Always connect the USB cable into the same slot to ensure continuity of IP addresses. For more information on configuring InVisus Pro with Natus Elite, refer to 047753 Installation Guide for InVisus Pro with Natus Elite.

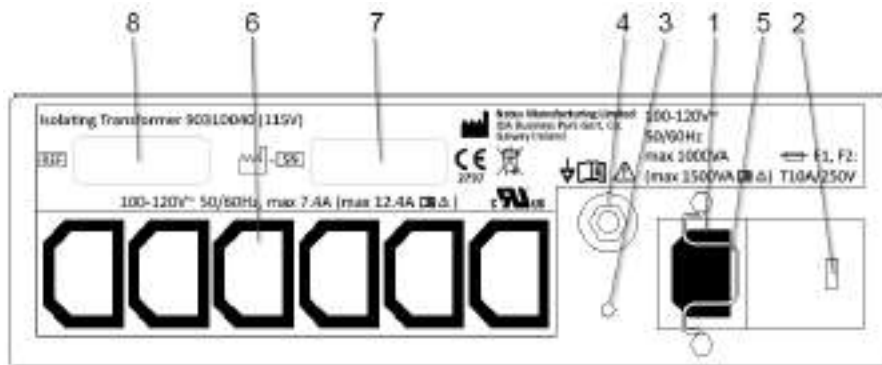
Isolation Transformer



The Isolation Transformer is intended for applications where medical devices require improved electrical isolation and/or reduced leakage current to comply with existing safety standards.

This device has been designed and tested in accordance with IEC 60601-1 Medical Electrical Equipment standard.

To ensure a safe operation and to maintain the device in a safe condition, follow the instructions in this manual and pay attention to all warnings and cautions.

Models: 9031D040x / 9031D041x



Function	Description
1	<p>Mains Input</p> <p>Plug the shielded mains power cord supplied with the system into this socket.</p> <p>NOTE Only use a shielded power cord from Natus.</p> <p>Rating Frequency: 50/60Hz.</p> <ul style="list-style-type: none"> - Continuous Operation: max. 1000VA - Momentary Operation: max 1500VA <p>9031D040x: 100/120V~ 9031D041x: 200/240V~</p>
2	<p>Fuse </p> <p>F1 and F2 Mains</p> <p>9031D040x: 110V/120V: T10AH / 250V~ 9031D041x: 200/240V: T6.3AH / 250V~</p> <p>Highest branch circuit short circuit current is less than 1000A.</p>
3	<p>M4 Thread for Electrical Enclosure Contact and Additional Protective Earth.</p>
4	<p>Potential equalization </p> <p>Where potential equalization is necessary or desirable, a potential equalization conductor may be connected to this connector as per DIN 42 801.</p>
5	<p>Spring Retaining Clamp for Power Cord</p> <p>Place the spring retaining clamp around the power cord to ensure a safe connection.</p>
6	<p>Auxiliary Outlet — 6 Outlets: 50/60Hz</p> <p>9031D040x: 100-120V~ total max. - Continuous Operation 7.4A - Momentary Operation 12.4A 7.4A equals 850VA, and 12.4A equals 1425VA at 115V~</p> <p>9031D041x: 200-240V~ total max. - Continuous Operation: 3.7A - Momentary Operation: 6.2A 3.7A equals 850VA and 6.2A equals 1425VA at 230V~</p>
7	<p>SN: Device Serial Number</p>
8	<p>REF: Device Reference Number</p>
<p>NOTE: Unplugging the power line cable from the mains input on the Isolating Transformer disconnects the mains power to all supplied devices.</p>	

Isolation Transformer Classification

Type of protection against electric shock:

- Class I: Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Method(s) of sterilization:

- Device is not intended to be sterilized.

Degree of patient vicinity:

- Device suitable for use in patient environment.

Degree of protection against electric shock:

- Enclosure protectively earthed (treated as applied part Type B).

Degree of protection against harmful ingress of water:

- IP20: Ordinary equipment (enclosed equipment without protection against ingress of water).

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 such a mixture.

Mode of operation:

- Continuous operation at normal load and Momentary operation at high load.
- Momentary operation at high load is used for short time printing with high power laser printers.
- Momentary operation at high load is possible for up to 60 sec per hour at elevated temperatures.

Operation at high load over prolonged time may cause thermal cut out. After cooling down (hours) internal thermal fuse will reset and normal operation can be resumed.

Additional Keypoint G4 Accessories and Software Options

The following accessories and software options are available for use with the Keypoint G4. Contact your sales representative or Technical Support representative for information.

Additional Accessories

9033C0731	Natus 3 channel Amplifier
9031C0732	3-ch. EMG/EP Amplifier
9031C0742	4-ch. EMG/EP Amplifier
9031C0762	6-ch. EMG/EP Amplifier
9031C0771	6-ch. EP Amplifier
9031C0782	8-ch. EMG/EP Amplifier
9031E0172	Natus Stimulus Probe
9031E0712	Single Electrical Stimulator
9031E0722	Multi Electrical Stimulator box/amp
9031E0258	Natus Unshielded Head Phones (DDR45)
9031E0277	Natus Tubal Insert Phones
9033B0332	P300 Reaction Time Switch
9031E0223	Natus LED Goggles with 5m cable
9031F1124	Natus Pattern Stimulator 22" TFT Display with Connection Kit
045724	Natus Temperature Probe Adaptor KIT
044704	Natus Temperature Probe (Adult)
045260	Natus Temperature Probe (Pediatric)
9031B0521	Amplifier Arm, Single
9031B0511	Amplifier Arm, Dual
9033B0761	Flex Arm with Clamp, 40cm

028623	Natus Stim Probe Holder
9031B0307	3-Key Foot Switch
047504	InVisus Pro Device Holder for Keypoint G4 Cart
047642	InVisus Pro Probe + Gel Bottle Holder for Keypoint G4 Cart
047744	Integration cable kit for InVisus Pro
9031E0402	Natus Reflex Hammer
9013L0241	Movement Sensor for Keypoint
9031G0703	Front End Box, Keypoint G4
9013S0164	EMG/NCS Accessories Kit
9031F0416	Laser Printer, Black & White, 115 V
9031F0405	Laser Printer, Black & White, 230V

Software Options

828-060900	NCS
828-060800	EMG
828-073300	Advanced NCS
828-060700	Reference Help
828-060200	CMAP Scan
828-073600	MUNIX
828-061200	Single Fiber EMG (SFEMG) / Macro EMG
018925	Interference Pattern Analysis (TA)
828-060600	Multi-MUP
828-061600	EP (3 Modality)
828-061500	Somatosensory EP (SEP)
828-061300	Auditory EP (AEP)
828-061400	Visual EP (VEP)
828-061700	P300 / CNV
828-061800	Ganzfeld Support (EOG/ERG)
828-069100	Basic EMG Transfer (One-button PDF)
828-062000	Tremor
828-060500	Automatic Stimulation
828-065800	Report Automatic Summary
031P047	Producer
828-061900	GDT
828-067200	Ultrasound/NMUS

4. System Operation


This chapter provides a detailed description of Natus Elite software operations.

Powering the Natus Keypoint G4 and Launching Natus Elite Software

1. Ensure that all the components are connected properly in accordance with directions provided in Chapter 3.
2. Connect the power cord into the wall outlet.
3. Boot the laptop or desktop computer.
4. The Windows login screen appears. Click the correct user icon and type in your password (if you have a password).

Installing Natus Elite Software

Follow these procedures to install and license your Natus Elite software if it has not been installed and licensed or if you are conducting a software upgrade.

1. Insert the Natus Elite Keypoint EMG thumb drive into the USB port, or the installation disk into the disk drive. The Setup program should start up automatically. If it does not start automatically, click the Setup.exe icon .
2. Select the EMG product to install: **Keypoint**.
3. If prompted **Do you want to allow this app from an unknown publisher to make changes to your device?** Click **Yes**.
4. The setup process begins, and a Welcome message is displayed. Click **Next**.
5. Check Accept license agreement and click **Next**.
6. For software upgrades, the Application Upgrade window is displayed. Click **Next**.
7. Select the Application Option, Acquisition System, and click **Next**.
8. If requested, enter the system serial number from the supplied licensing form and click **Next**.
9. For software upgrades, Database Installation, select the desired option and Click **Next**.
10. At the Start Installation window, click **Next**. The installation procedure begins. This will take about 3-6 minutes depending on the software licensing requirements.
11. Click **Finish** to complete the installation.
12. If prompted **Did this program work correctly?** Click **Yes, this program worked correctly**.

Basic System Operations

Software system operations are described below. Refer to Chapter 3 for Control Panel operations.

Controls	Operation
System Menu	Using the mouse, click the drop-down menus to display, select and enable functions
Function Keys	Using the mouse or the control panel keys, click the desired function key to enable the operation. To change the operation of the Function Key, right click the function key, select Configure, and select the new function for that key
Software Symbols/Icons	Hover the mouse over the software symbol to display the symbol's function. Click the symbol to enable the function. Refer to Chapter 10 for symbol functions
Trace Controls	Right click the data trace to display and select from multiple trace functions
Stimulus Intensity Status Panel	Click and drag the Status Panel indicator to the desired intensity. Right click to undock the Intensity Status Panel and move it to the desired location. Right click again to dock it to top or bottom of screen
Results Table	Right click to enter functions. Click the wrench symbol to enter Results Table Setup. Left click to enter Site/Segment Setup, text, values and comments
Reports	To display the Report, click the Report Icon
Window Sizing	Hover the mouse on the window border and at the arrow, drag the window to the desired position
Font Sizing	Right click the text area and select the desired percent change in font size

Screen Operations

The following are screen operations you can use during an exam. The graphics below are representational only. The actual appearance is determined by the test selected.

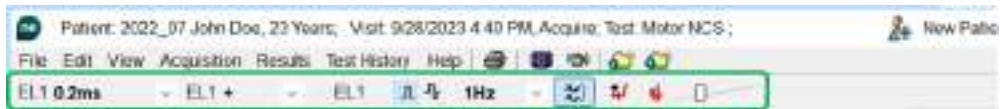
Header Bar: The Header Bar displays the patient's First and Last name, Age, and the visit Date and Time.



Menu Bar: The Menu Bar contains menus that, when clicked, displays a list of options from which you can choose to perform various operations.



Toolbar: The Toolbar contains several icons/settings fields, which are used to control the how data is displayed. The controls displayed on the Toolbar is determined by the Test/Study selected for use. Position the mouse pointer over an icon/field to see a brief description of its function.



Quick Access Bar: The Quick Access Bar is located above the Function Key Area. It allows you to quickly manage test workflow.

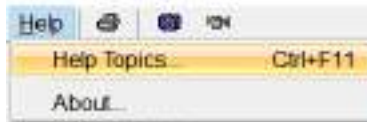


Function Keys: The Function Key area at the bottom of the Test window includes the options available in the current test mode.



Software Help

Access the Help function by clicking on Help and Help Topics in the Menu Bar. Detailed information of system function and operations is included in the Help section.



Shutting Down the Natus Keypoint System

Follow these procedures for a proper shutdown of your system to prevent damages to the unit.

1. From the Natus Elite Home page, click **File > Exit**. The application is closed, and the windows desktop is displayed.
2. Click the Microsoft Windows Power icon on the lower left corner of the computer screen.
3. Click **Start > Shutdown** on the lower left hand of the computer screen.
4. Disconnect the power cable from the wall outlet once the system is off.

Software Error Codes

In the Natus Elite Application, errors and other informational messages are designed to be self-explanatory. Additional descriptions are provided below:

Code ID	Cause(s)	Suggested Action
7	Hardware device connection failure. Usually preceded/accompanied by more specific error.	<ol style="list-style-type: none"> 1. Disconnect/Reconnect hardware. 2. Restart. 3. Reinstall. Contact Technical Support if persists.
100 101 375	Device communication error.	<ol style="list-style-type: none"> 1. Check cabling. 2. Reinstall. Contact Technical Support if persists.
139 - 144	Various text indicates a software failure has occurred	<ol style="list-style-type: none"> 1. Restart. 2. Reinstall. Contact Technical Support if persists.
145	Failed to activate a test, preceded by Parameter configuration failure messages.	<ol style="list-style-type: none"> 1. Reconfigure test for current connected hardware. 2. Restart. Contact Technical Support if persists.
318 319 320	Stimulator has detected an over current/voltage or other fault condition.	<ol style="list-style-type: none"> 1. Check stimulator connection to patient. 2. Check condition of stimulator cabling.
519	Could not select Impedance Check mode because Acquire is on	Turn Acquire off before starting an impedance check.
520	Cannot do impedance check when calibration signal is on.	Turn OFF calibration before running impedancecheck.
621 622	Limit reached, normal operation. Informs user that stimulator interval will no longer decrease or increase.	Not applicable.
628	Transducer calibration is inconsistent for current connected EP audio transducers.	Check and correct the transducer calibrations.
757 1953 1993	Driver or connection failure.	<ol style="list-style-type: none"> 1. Reconnect device. 2. Restart. Contact Technical Support if persists.
1003	Hardware (or software) watchdog has triggered.	<ol style="list-style-type: none"> 1. Disconnect/Reconnect hardware. 2. Restart. 3. Reinstall if persists. Contact Technical Support if persists.
1012 1014	Problem with registry, user rights or file system. Could not access the crash recovery folder.	<ol style="list-style-type: none"> 1. Check user rights, registry and/or file system 2. Reinstall if persists.
1200	Cannot open a connection to the databases.	<ol style="list-style-type: none"> 1. If networked, may be caused by network problems. Check network and retry. 2. May indicate corrupted database, if reoccurs use database recovery tools. 3. Check ODBC driver configuration.
1206, 1208, 1209, 1210, 1236	An exception was detected when accessing the database.	<ol style="list-style-type: none"> 1. If networked, may be caused by network problems. Check network and retry. 2. May indicate corrupted database. If reoccurs use database recovery tools.
1501	Attempting to run a hardware configuration that is not supported on the current hardware.	1. Use a configuration that is supported by the current hardware or edit the configuration to match the current hardware.
1807	Amplifier was not detected during start-up.	<ol style="list-style-type: none"> 1. Connect the amplifier before restarting. 2. Contact Technical Support if persists.




5. Patient Information

This chapter explains how to use the Patient Information feature used for working with patient exam files.

The Patient screen



Patient Information includes fields to enter specific data about the patient, such as the Patient ID, Gender, Birth Date, and Patient Name as well as physician information, impressions and conclusions.

Entering a new patient

1. Click **New Patient**  **New Patient** to prepare the system for the new patient. If there is any unsaved data, you will be asked to save or discard it. The patient demographic area is cleared.
2. Enter the patient demographic data and the visit information.
3. You must enter the required fields at a minimum. Once the required fields are entered, the full patient demographics will be available.
4. The highlighted field indicates the location on the screen where the text will be entered. Press **<Tab>** or **<Enter>** to advance to the next line in the form. Press **<Shift Tab>** to move the blinking cursor to the previous line. The patient data should be entered before beginning any test procedures.
5. If desired, to complete the remaining information fields, place the cursor in the desired field and type the information. Press **<Tab>** or **<Enter>** key to advance the cursor to the next field.
6. Click **OK** to save the patient data to the hard disc.
7. Software enters the **Select Test**  **Select Test** screen to start testing or to enter further visit details.
8. Visit information can be edited further in the **Test History**  **Test History** screen.

Selecting or Editing Patient Information

1. To find a patient:

- Click **Patients**  **Patients** to list all the patients in the Patient Database
- Type the patient's name into the **Search** bar 

2. Use the vertical scroll bar or up/down arrow keys to scroll down the fields to select a patient. Selected patient visits are displayed on the right side of the patient database. To load the patient data, either double-click the patient or highlight the patient and click **Open Patient**




. The current patient information appears on the left side of the screen.



The screenshot shows a 'Patient' form with the following fields and values:

Patient ID: 2022_06		
First Name: Susan	Last Name: Smith	
Date of Birth: 12/11/1998	Sex at Birth: Female	
Visit Date: 12/13/2022 11:33		
Age: 23 Years		
Height: 173 cm	Weight: 55 kg	BMI: 18.4
Technician:	Physician:	
Referring Physician:	Referring Department:	
Conclusion:		
Comments Memo 1 Memo 2 Memo 3 Test Comments		


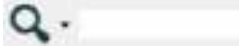

3. Click **Edit Patient**  to change patient information as needed. Any updates to patient information are applied to all reports.

4. To update information about a visit, click **Edit Visit** . Visit information is unique to each visit.




5. When finished with Visit Information, click **OK**. You will be prompted to save changes.
If only updating Current Patient Information, click **OK** when completed.

NOTE: Loading a patient replaces the current patient. You may be prompted to save the current patient before you can proceed.




Starting a new visit for an existing patient

- To find a patient:
 - Click **Patients**  to list all the patients in the Patient Database
 - Type the patient's name into the **Search** bar 
- Use the vertical scroll bar or up/down arrow keys to scroll down the fields to the patient. To load the patient, highlight the **patient** or double-click on the patient to open test history.
NOTE: Loading a patient replaces the current patient. Save the current patient before you can proceed.
- Click **New Visit** .




Recalling a patient for testing

- To find a patient:
 - Click **Patients**  to list all the patients in the Patient Database
 - Type the patient's name into the **Search** bar 
- Load the patient.
- If still in Patient screen, highlight the correct study on the right side of the patient screen.
- If in Test History, make any needed changes to the Visit Information.
- Click **Acquire Visit**  to add a new test to the existing visit.

Recalling an exam for review


- To find a patient, either:
 - Click **Patients**  to list all the patients in the Patient Database
 - Type the patient's name into the **Search** bar 
- Click on a patient to display that patient's visits and data.
- To correct data:
 - Click on the specific visit date to get list of studies. Double-click the waveform data name (Median APB, Ulnar FDI, etc.). Changes to the data can be made such as moving the markers.
 - Save changes by clicking **Exit Test**.
- Click **Report** to regenerate or recompile the report.
- Click **End Visit** to save changes and exit this patient profile. .
NOTE: A "+" or "-" sign appears before each section title. As in Windows, click the "+" to open a closed folder or section or click the "-" to close a section.


Deleting exams from a patient file

- To find a patient, either:
 - Click **Patients**  to list all the patients in the Patient Database
 - Type the patient's name into the **Search** bar 
- Double click on the patient to enter **Test History**.
- Find and click on the test type you want to delete. Click **Delete** . Confirm.
- To delete the entire visit, right-click on the visit and select **Delete Visit**. Confirm.

Deleting a patient profile

1. To find a patient, either:

a. Click Patients  Patients to list all the patients in the Patient Database

b. Type the patient's name into the Search bar 

2. Highlight the patient profile.

3. Either right-click the patient profile and select **Delete Patient** or press Delete on your computer's keyboard. Confirm your decision to delete the patient profile including all associated visits.

6. Performing an Exam

This chapter provides general instructions for performing a study or exam, using a Motor Nerve Conduction Study, a needle EMG study, and an Evoked Potential study as examples. You can apply these basic steps to perform most tests.

Setting up the System

Make sure the components are properly connected to your system.

For information about system components, please see *Chapter 3* in this guide. You will also need the appropriate application software installed on your system.

Getting started

When you switch on the main power, the system may display the Windows Logon screen.

After you log on to the system:

1. Double-click the Natus Elite - Keypoint icon on the desktop and log in.
2. Enter the patient's demographic information. Click **OK**.

Patient to report in seven steps

The normal procedure for performing an exam is as follows:

1. Click **New Patient** (or **End Visit** if prior patient's exam is not ended).
2. Enter the Patient Information.
3. Click **OK**.
4. Acquire the exams.
5. Look at Report.
6. Return to Test Menu/Study Menu.
7. Click **End Visit** prior to starting next patient.

Test Selection

There are two basic approaches to selecting exams for testing: **Test Menu** or **Study Menu**. Each is discussed in greater detail below.


Test menu

With Test Menu, exams are grouped by test type; motor, sensory, F-Waves, etc. For each test type, anatomies are sorted by body portions.



Study menu

In Study Menu, exam steps are grouped based on diagnosis, patient complaint, or some other custom setup. A study can contain motor, sensory, F-Wave, H-Reflex, needle EMG, etc. Exam steps are independent from exam type.

Test selection using Test menu

1. From **Select Test**, select the **Test Menu** view. 
2. select the specific **Side**, **Test Type** and **Anatomy**. Double click on the anatomy to start the recording.
3. Alternatively, one may double click on the exam type. In this instance, a test screen appears while a **Select protocol** dialog box appears. Choose the protocol and side to use for this exam and click **OK**.
4. Proceed with testing.
5. Click on **New** side (if performing the same test on the other side of the patient), **New Nerve** navigation key (if performing a nerve of the same type) or **Select Test** (if the nerve is from another folder).
6. Perform the exam.
7. Continue with testing until completed.

Test selection using Study menu

1. From **Select Test**, select the **Study Menu** view. 
2. Select Study side with the Left /Right icons . double-click on study title to enter test screen.
3. Perform the exam.
4. Press or click the **Next Study Exam** function key.
5. Continue with testing until completed.

Example: Motor Nerve Conduction Study

Position and secure the electrodes to the patient according to your conventions for the type of test you are performing.

Motor NCS electrode placement

- The active recording electrode is placed over the endplate zone of a muscle innervated by the tested nerve.
- The reference electrode is placed nearby in an electrically “quiet” area (tendon, bone).
- The ground electrode is usually placed between the stimulating and recording electrodes.
- Using electrolytic gel between the skin and recording electrode improves the “electrical contact” and reduces noise.
- Excessive noise may require abrading the skin to lower impedances.
- The nerve is stimulated using surface electrodes or stimulation probe at two or more sites where the nerve is located superficially. The stimulator is commonly oriented so that the cathode of the stimulator faces the active recording electrode.

Sensory NCS electrode placement

- Surface disk or ring electrodes are placed over the skin where the tested nerve is located superficially.
- The nerve is stimulated at sites where it is located superficially.
- The cathode of the stimulator is oriented towards the active recording electrode.

About the waveform screen



1	The toolbar indicates stimulator settings, filters, etc.
2	The trace labels and settings are indicated on the left side of the waveform.
3	The monitor trace displays the incoming signal to assess noise and interference.
4	The result table displays measured values from markers. The result table is automatically updated as markers are moved.
5	Function keys are associated to most useful features for the test and are linked to the function key with similar icon on the control panel.

Acquiring data

Data is acquired by the instrument, displayed on-screen, marked, and saved automatically. The waveforms and the measured values are then transferred to a Report.

1. Set the stimulus intensity to **0**.
2. Position the stimulator at the appropriate site.
3. Press the **Single Stimulus** key on the control panel (or footswitch or the **Acquire** button above the wheel on the stimulator probe) to stimulate and acquire responses.
4. Use the **Stimulus Intensity** control knob or the Intensity wheel on the stimulator probe to gradually increase the intensity of the electrical stimulus until reaching the supramaximal response.
5. If using continuous stimulation, press the **Repetitive** key on the Control Panel or press and hold briefly the **Acquire** button on the stimulator probe. When an acceptable response is observed, press either button again to stop stimulation.
6. To average, press the **Average** function key on the Control Panel. The averager is then enabled. Press the **Repetitive** key on the Control Panel to acquire the defined number of sweeps.
7. To advance to the next stimulus site, press the **Next** down arrow from the Function keys or the A button on the probe.
8. Follow the same procedure to obtain a response for each required site.
9. When testing is completed, the nerve and site labels can be changed. Left click the site to highlight it, then right-click and select **Edit Segment**.

Marking data

1. Markers are placed automatically as meaningful responses are acquired.
2. To adjust the markers with the mouse, click the desired marker and drag it to its new location.
3. Or press the Volume Control Cursor Knob to activate marker mode. Turn the knob to position the active marker (highlighted in red). Use the Trace selection Right/Left/Up/Down arrow keys to advance to other markers.
4. To manually add latency or amplitude markers, select the marker from the Cursor Panel below the waveform screen. From that panel, you can place individual markers, Fast Mark, and Clear, Clear All, Hide, Show markers. To remove a marker, click the undesired marker on the waveform, it turns red. Then select Clear from the Cursor Panel.
5. To repeat on additional traces, use the Up/down Cursor keys to activate the correct trace and repeat the previous steps.

Resetting the markers

If you have repositioned markers that have been placed automatically by the system, you can return those markers to their original positions by pressing Results > Reanalyze in the menu bar.

Erasing data

1. Click the waveform to highlight it.
2. Use the associated **Erase** function key, or Right-click the waveform.
3. Select **Erase**. Data is removed from the trace and results are cleared from the Results Table.
4. To undo the erase, right-click the waveform and select **Unerase**.

IMPORTANT: If unerasing data, it needs to be done immediately.

Deleting data

1. Click the waveform to highlight it.
2. Click the **Delete** function key.
3. The data, trace and site are deleted from the trace area and Results Table.

IMPORTANT: There is no undo once data has been deleted.

Superimposing traces

1. Click the **Superimpose** function key. All waveforms for a given channel are superimposed. The superimposed traces are displayed in the center of the screen.
2. Click the **Superimpose** function key again to return the traces to their original positions.

Calculating conduction velocity

1. Distances may be entered after each site has been acquired, or all distances may be entered after all sites have been acquired.
2. Enter distances in **mm** or **cm** to one decimal place (e.g., 235mm / 23.5cm)
3. The distance entered will be displayed in the Results Table in the corresponding **Distance** field.
4. Press **Enter** to accept the distance and to calculate the conduction velocity.


NOTE: Enter Default Distances using the protocol table. ConductionVelocities will be calculated automatically.

Graphs

Up to two graphs can be displayed on the test screen. Up to six graphs can be displayed in the full screen **Results** view.

Select **Results > Graph Options** to select the results to view.

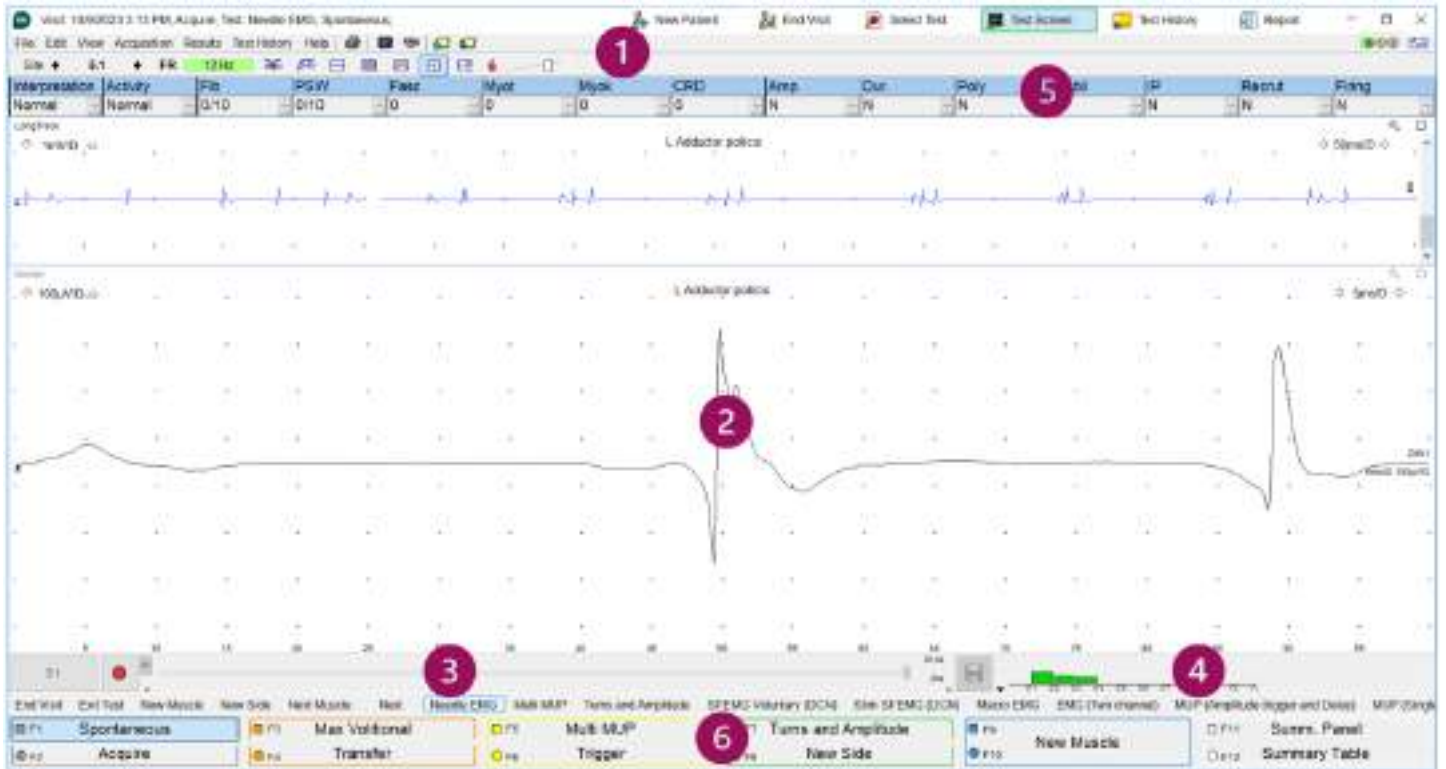
Test Menu and History

To display the patient Test History and Test Menu during a test, click on the Test Menu and History icon  on the top right corner of the test screen to show/hide the menu.

Otherwise, from the View drop down menu, select Test Menu and History.

Example EMG Study

About the EMG screen




1	The toolbar indicates settings, sound status, displays, filters, etc.
2	The anatomy and side are indicated on top of the waveform. Amplifier input is displayed on the right side of the waveform.
3	The EMG Liveplay continuously records the EMG signal and allows saving EMG sections for offline review/analysis.
4	The Quality Panel correlates to the distance of the needle to the endplate.
5	The Summary Panel allows the interpretation of the investigated muscle.
6	Function keys are associated to most useful features for the test (such as EMG stages) and are linked to the function key with similar icon on the control panel.

There are many EMG displays available on the software, from simple to complex views. Simple views display the EMG signal in one time base only. Complex views allow up to 4 different views and associated time bases.

As an example below, **Complex 1** displays LongTrace on upper screen, and Monitor trace with independent time base on the lower screen. **Complex 2** displays vertical splits.



Acquiring Data

1. To acquire free running EMG using the Test Menu, select **Needle EMG** with **side** and **Muscle** of your choice. Double click on the Muscle. The test screen appears.
2. The Monitor portion of the display begins displaying EMG. There is no sound initially. To enable sound, just unmute  the speakers or press the unmute button on the Control Panel.
3. When you are finished with the first muscle, move to a **New Muscle** from the function keys. The EMG Summary Selection dialog appears. Muscles with acquired data appear bold and red. Select your **muscle** and **side** and click **OK**.
4. EMG is displayed in the Monitor portion of the waveform screen. Again, unmute the speaker.
5. Continue with this process until all muscles have been tested.

In either case, press **Acquire** from the function keys to start and pause the needle EMG signal recording. If Acquire is used, the sound is activated automatically.

The Summary Table can be used to interpret the investigated muscles.

Storing data

Data is stored automatically as you advance to the next trace.

Scoring muscles

1. Single muscles may be scored from the **Summary Panel** displayed on the top of the EMG test screen. Select **Summary Panel** from the Function Keys and score the muscle using the Left/Right/Down/Up arrow keys from the keyboard.
2. If you prefer to score all muscles at once when needle EMG testing is completed, select **Summary Table** from the function keys. The EMG Summary Table is displayed showing all muscles that were tested.
3. By default, all muscles are scored as "N" or "None". In the lower half of this summary table, you can change the scoring by highlighting the muscle in question and then rescoring the various categories from the lower half of this dialog as appropriate.

Example Evoked Potential Study

Position and secure the electrodes to your patient according to your conventions for the type of test you are performing. The below example is based on Somatosensory Evoked Potentials.


About the waveform screen



1	The toolbar indicates stimulator settings, filters, etc.
2	The side, trace labels and settings are indicated to the left of the waveforms.
3	The monitor trace displays the incoming signal to assess noise and interference. Artefact rejection may be displayed, turned On/Off from the monitor trace
4	The replication panel manages the display and averaging of several recordings.
5	The result table displays measured values from markers. The result table is automatically updated as markers are moved.
6	Function keys are associated to most useful features for the test (such as EMG stages) and are linked to the function key with similar icon on the control panel.

Acquiring data

Data is acquired by the system, displayed on-screen, marked and saved automatically. The waveforms along with the measured values are then transferred to a report.

1. To acquire Evoked Potentials using the Test Menu, select the test type of your choice. Double click on the **Protocol**. The test screen appears.
2. After placing the electrodes, run the impedance test using the **Impedance** function key.
3. Position the stimulator at the appropriate site.
4. Set the stimulus intensity to **0** mA.
5. Start the repetitive stimulation with the repetitive button  from the control panel. Same button may be used for other stimulation type associated with auditory/visual stimulation.
6. Increase the intensity until a muscle twitch is observed. The intensity is shown on the Toolbar and the status panel as a sliding bar.
7. Click **Average** from the Function Keys. This will start data collection, averaging the potentials.

8. When signal averaging begins, the first 10 sweeps may be rejected automatically. The signal averager also excludes sweeps that have high amplitude potentials (i.e., noise) according to the set artefact rejection threshold.
9. After the first average is complete, press **Next Replicate** to record a second trial. It will assess the reproducibility of the potential. **Replicates** are shown on the Replication panel on the right side of the test screen.
10. If **Automatic Stimulation** is configured, the software starts a new replicate automatically after the first average is complete. After completing the second trial, the acquisition and stimulation stops.
11. Press **Other side** and follow the same procedure to obtain a response on the other side of the patient.

Marking data

1. Markers are placed automatically as the responses are acquired.
2. To adjust the markers with the mouse, click the desired marker and drag it to its new location.
3. Or press the Volume Control Cursor Knob to activate marker mode. Turn the knob to position the active marker (highlighted in red). Use the Trace selection Right/Left/Up/Down arrow keys to advance to other markers.
4. To manually add latency or amplitude markers, select the marker from the Cursor Panel below the waveform screen. From that panel, you can place individual markers, Fast Mark, and Clear, Clear All, Hide, Show markers. To remove a marker, click the undesired marker on the waveform, it turns red. Then select Clear from the Cursor Panel.
5. To repeat on additional traces, use the Up/down Cursor keys to activate the correct trace and repeat the previous steps.

Resetting the markers

If you have repositioned markers that have been placed automatically by the system, you can return those markers to their original positions by pressing **Results > Reanalyze** in the menu bar.

Erasing data

1. Click the waveform to highlight it.
2. Use the associated **Erase** function key, or Right-click the waveform.
3. Select **Erase**. Data is removed from the trace and results are cleared from the Results Table.
4. To undo the erase, right-click the waveform and select **Unerase**.

IMPORTANT: If unerasing data, it needs to be done immediately.

Deleting data


1. Right-Click on the waveform.
2. Select **Delete**.
3. The data, trace and site are deleted from the trace area and Results Table.

IMPORTANT: There is no undo once data has been deleted.

Superimposing Traces

1. Click the **Superimpose** function key. All waveforms for a given channel are superimposed. The superimposed traces are displayed in the center of the screen.
2. Click the Superimpose function key again to return the traces to their original positions.

Test Menu and History

To display the patient Test History and Test Menu during a test, click on the Test Menu and History icon  on the top right corner of the test screen to show/hide the menu.

Otherwise, from the View drop down menu, select Test Menu and History.

Reports

There are two locations to configure a report:

- From the Patient Screen: Select Edit/User Profile Setup/Report Setup, select the options for the desired report configuration. Three Report templates can be configured for overall report structure and content.
NOTE: Report 1 can be configured as an On-line Report allowing interactive changes between the data and the report. To select a report (Report 1, Report 2, or Report 3) options, from the Patient Screen, Test History menu, click the Add Report (Plus icon) drop down arrow.
- From the Test Screen: Select Edit/Test Report Setup and include the desired elements (table, comments, graphs, etc.) to be added to the report for that specific test.
To transfer traces to a report, from the test screen Results menu, select Transfer Traces to Report. To transfer specific traces, highlight the desired traces and select Transfer Selected Traces to Report.

To view the Report, click the Report icon. To print the report, click File/Print.

Example Ultrasound

About the screen display



1	The tool bar can be displayed to access all ultrasound features and options
2	Scanning window displays the NMUS scans, images, cines
3	A Zoom slider allows to zoom in/out and move around the image using the mouse
4	The Marker Panel allows for management of measurements
5	The result tables display the measurements placed on saved images
6	The function key area allows fast access to main operation from control panel and keyboard
7	Quick access to test menu and history

Select the exam

From the function keys or the Test/Study Menu, select the desired exam.

Select a protocol (only if using Test Menu)

- Select the tested side and protocol.
- Press **Enter** to accept the selection.

Acquire scans


Neuromuscular Ultrasound is displayed on-screen and may be saved (as an image or cine) and measured by the operator. The scans along with the measured values are then transferred to a report.

1. Check the recording site from the result table. The active site is highlighted.
2. Position the transducer on the appropriate position or move it in the direction of interest.
3. Click **Pause** from the Function Keys. The system saves the image and displays it on-screen.
4. Click **Next Scan** from the Function Keys to acquire an additional image on the same site. Click **Re-Scan** from the Function Keys to replace the current image on the same site.
5. Optional: Click **Get cine** from the Function Keys to save a video of a couple of seconds.
6. Click **Next Site** from the Function Keys to acquire scans on additional sites for comparison. Follow the same procedure for each required site.

Marking images

1. From the **Marker Panel**, select the appropriate measurement: it may be distance, ellipse, contour.
2. Click and drag the mouse to draw the measurement. Release the mouse to confirm measurement. Numerical data are displayed in the result table on the appropriate site.
3. To annotate anatomical structures, click on **label** in the Marker Panel. Click on the desired location of the annotation. In the pop-up screen, enter the text and confirm.
4. To remove a measurement or label, click the undesired marker/label on the image, it is highlighted in yellow. Then select Clear from the Marker Panel.
5. Additional functions are available on the Marker Panel: the following functions are available: Clear, Clear All, Hide, Show, Fast Mark or place individual markers.
6. Press The Up/down Cursor keys from the control panel or select the next site on the result table to activate the correct site and repeat the previous steps.

Test Menu and History

To display the patient Test History and Test Menu while in a test, Click on the History button on the top right corner of the test screen . Alternatively, one may access it from the View drop down menu: select **Test Menu and History**.

Storing data

Data is stored automatically when advancing to the next trace.

Saving test data

When selecting **Patients**  or **Select Test** , the data is saved automatically to the hard disk.


Creating / updating a report

Automatic

When advancing to Select Test, New Patient, or Patient List, the report is updated automatically.


Manual

To create / update a report manually on the hard disk without closing the Test screen:

Click the Report icon  .

Printing a standard data report





To print a standard data report for the exam just completed:

1. Click on the **Report** icon .
2. Click on the **File** tab.
3. Click on **Print** at the left side of the report.
4. Make your printing settings.
5. Click **Print** in the upper left section of the window.

Capturing screen display images and videos


Capturing a screen display image

To capture a copy of the current screen display at any time, use any of the following methods:

1. Click on the print screen icon  for a screen print.
2. Click on the **Camera** icon  to create a JPG file.
3. Click **File > Print Screen** for a printed hardcopy.
4. USB Control Panel: Press **Screen Copy**  for a printed hardcopy.
5. Viking Control Panel: Press **Screen Copy**  for a printed hardcopy.

Capturing a test screen video

To capture a video of the test screen display, use either of the following methods:

1. Click on the Capture Video icon . Repeat to stop recording.
2. Click on File > Producer > Capture Video. Repeat to stop recording.

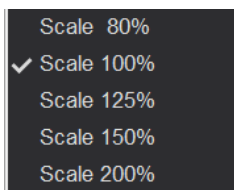
Reviewing a captured test screen video

1. Click on File > Producer > Producer Recordings.
2. Locate and open the desired video file (files are time stamped).

Modifying test screen font sizes

Font sizes may be configured to adapt to personal preferences. Changes may be applied to the Menu Bar, Quick Access Bar, Function Keys, Test View Captions and Marker Panel.

1. Right click on the panel of interest and select the sizing of choice. Options may differ depending on the panel



2. Save changes permanently by clicking on File>Save Test and Protocol Setup

7. Backup and Restore Data

This chapter provides instructions on backing up and restoring patient information and settings.

Backing Up Files

It is recommended that data be backed up monthly. Backing up data is easily done via the menu bar above the Patient Information screen. The data can be copied to the media of your choice: CD-R, DVD-R, flash drive, external hard drive, etc. Backed up data will appear as “.mps” files which can then also be restored to your patient database through the “Load Patient from File” function.

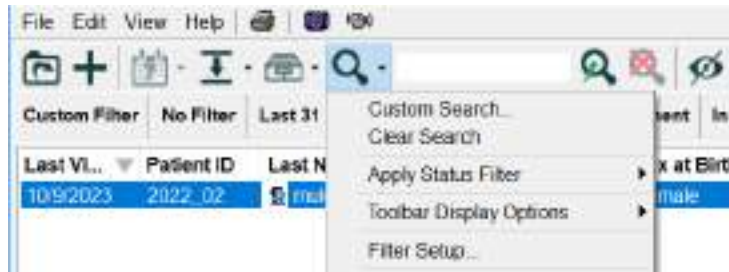
1. From the Home Page screen, click **Patient List** to display all patients on the right side of the screen.
2. Find the patient to be backed up and highlight the **name**. All visits for this patient are included in the backup.
3. From the menu bar at the top of the screen, click **File > Export Patient(s) to File**.
4. Find the backup device via the **Save In** cell at the top of this dialog. Name the file and click **Save**. A progress window appears while the data is copied to the media. When completed, confirmation of a successful backup is displayed.
5. The patient will then need to be deleted manually from the system if desired. With the Patient Name highlighted, click **File > Delete Patient**.


Restoring Files

Restoring patient data back to the local hard drive is like the back-up process.

1. Ensure the backup media is connected to the system.
2. From the Home Page screen, click **Patient List** to display all patients.
3. In the menu bar, click **File > Import Patient(s) from File**. A dialog appears where you can locate your back up device.
4. Once the back-up device has been located, search for the patients by looking for **.mps** files. It may be helpful to sort the files by **Type** to group all .mps files together to make it easier to find the patient(s) in question.
5. Highlight the patient’s file on the backup device and click **Open**. A confirmation dialog appears. If the information in this dialog is correct, click **Load**. The patient reappears in the Patient List.

Adding filters



Add custom filters with different criteria such as physician name, scheduled appointment, in-progress appointment to search relevant appointments/visits easily. The filters can be added by clicking dropdown menu on the search icon  and selecting **Filter Setup**.

8. Maintenance, Cleaning and Disposal

This chapter provides information on maintenance and cleaning of the Natus Keypoint G4 system. Natus Technical Support contact information is provided at the end of this chapter.

Maintenance

Follow a regular schedule of maintenance and safety checks to keep the Natus Keypoint G4 system in good working condition. Regular maintenance performed by the user does not involve access to the interior of the system or components. If issues arise, contact Natus Technical Support per contact information at the end of this chapter.

- Reboot the Natus Keypoint G4 laptop or desktop on a weekly basis to optimize computer operation.
- Restart the Natus Elite software application on a weekly basis. The Natus Keypoint G4 conducts internal checks of the system each time the application is restarted.
- Routinely check the system and accessories for exterior damage.
- Check all cables and cable connections for damage and wear monthly. Replace frayed or worn cables immediately.
- Clean the system monthly or sooner if the items are visibly soiled. Clean accessories between each patient use. Refer to the Cleaning instructions below.
- When using a cart, inspect the cart to ensure casters and caster locks are functioning and system components are properly placed, referring to the Keypoint G4 Cart IFU as needed.
- When moving the Keypoint G4 system, take care to not allow the system to hit objects during transport to prevent damage to the system and its components.
- The Keypoint G4 does not require routine preventive maintenance.

Safety Inspection Checks

The following safety inspection checks should be conducted after installation and at least once a year or per the facility's policies. References include the KPTest4 Manual, 9031M2403. This testing should be conducted only by qualified personnel:

1. Inspection for visible damage to device.
2. Inspection of mains cord and connecting cables.
3. Check of electrode cables and patient connections.
4. Conduct a ground continuity test.
5. Measurement of insulation resistance.
6. Measurement of leakage currents.
7. Measurement of resistance of protective earth conductor.
8. Measurement of resistance of protectively earthed enclosure and cart parts.
9. Check of current stimulator output in all ranges.
10. Check of Amplifier gain.

Troubleshooting Noisy Data

If the acquired data does not appear appropriate or appears noisy, the following troubleshooting steps are recommended.

✓	Ask the patient to relax, particularly the muscle area being tested.
✓	Make sure that there is a secure connection between the amplifier and the computer.
✓	Inspect and replace all system cables that are worn or damaged.
✓	Unplug any devices on the same circuit such as mechanical beds or other potential sources of interference.
✓	Turn off florescent lighting. Do not use dimmer switches.

✓	<p>Check the electrodes:</p> <p>Make sure that the patient electrodes are connected to the correct channel in the amplifier and fit securely.</p> <p>Do not use electrode cables that are broken, frayed or have kinks</p> <p>Use large surface ground electrodes</p>
✓	<p>Check the test Settings to insure they are appropriate for the test. If unsure, use the Natus default settings:</p> <p>Filter – Filters out unwanted signals (high and low frequencies).</p> <p>Notch filter – Minimizes 50/60Hz electrical interference.</p> <p>Sensitivity – Optimizes the signal at the amplifier.</p>
✓	<p>To improve NCS:</p> <p>Clean the skin surface and use electrode gel at the stimulation site</p> <p>Place ground between the stimulation and recording site</p> <p>Use data averaging to improve the signal-to-noise ratio</p> <p>Use bi-phasic stimulation</p>
✓	<p>Use the live monitor/scope window to detect unwanted noise or artifacts such as extraneous spikes or 50/60 Hz.</p>

Cleaning Instructions

Regular cleaning maintenance should be performed according to frequency of use of the device. Always observe your local hygiene authority's guidelines, and the following points below:

- Disconnect the mains power before cleaning the equipment.
- Clean with CaviWipe™ 2.0 disinfecting wipes or Sani-Cloth® germicidal wipes and allow to dry.
- Make sure that no liquids enter the device at push buttons and other openings in the enclosure.

To clean the probe:

Remove and dispose of the probe cover after use. Clean the probe according to your hospital protocol before storing it in the probe holder. For detailed cleaning instructions, see InVisus Pro Operation and Service Manual (P/N 045650-EN).

To clean the holders for probe and gel



1. Remove all coupling gel and other visible substances from the holders by wiping with a soft dry cloth. If necessary, the cloth can be moistened with lukewarm water to remove any debris dried to the surface.
2. Use CaviWipes™ 2.0 disinfecting wipes or Sani-Cloth® germicidal wipes to clean the exterior and interior surfaces of the holders of the probe and gel, paying attention to the inner holder surfaces.
3. The germicidal solution needs a dwell time of over 2 minutes to be effective.
4. Allow probe and gel holders to air dry before use.

Disposal at End of Operating Life Instructions

Natus is committed to meeting the requirements of the European Union WEEE (Waste Electrical and Electronic Equipment) Directive 2012. These regulations state that electrical and electronic waste must be separately collected for the proper treatment and recovery to ensure that WEEE is reused or recycled safely. In line with that commitment Natus may pass along the obligation for takeback and recycling to the end user unless other arrangements have been made. Please contact us for details on the collection and recovery systems available to you in your region at natus.com

Electrical and Electronic Equipment (EEE) contains materials, components and substances that may be hazardous and present a risk to human health and the environment when WEEE is not handled correctly. Therefore, end users also have a role to play in ensuring that WEEE is reused and recycled safely. Users of electrical and electronic equipment must not discard WEEE together with other wastes. Users must use the municipal collection schemes or the producer/ importers take-back obligation or licensed waste carriers to reduce adverse environmental impacts in connection with disposal of waste electrical and electronic equipment and to increase opportunities for reuse, recycling and recovery of waste electrical and electronic equipment.

Equipment marked with the below crossed-out wheeled bin is electrical and electronic equipment. The crossed-out wheeled bin symbol indicates that waste electrical and electronic equipment should not be discarded together with unseparated waste but must be collected separately.



Natus Technical Support Contact Information

For US, Canada and International Technical Support:

Email: madison.helpdesk@natus.com

Phone: 1-800-356-0007 or 608-829-8500

For Germany Technical Support:

Email: service.europe@natus.com

Phone: +49 89 83942 0

For France Technical Support:

Email: service.fr@natus.com

Phone: +33 5 56 08 54 76

Fax: +33 5 56 42 27 62

For Benelux Technical Support:

Email: support.be@natus.com

Phone: +32 15 32 13 73

For United Kingdom Technical Support:

Email: neurosupportuk@natus.com

Phone: 020 3058 0850

For Australia and New Zealand Technical Support:

Email: Service.ANZ@natus.com

Or contact your local Natus representative.

Please have the following information ready for your communication with Technical Support:

- Product name, system serial number and/or system component serial numbers
- Software version
- Detailed description of the problem
- The steps/procedures that occurred prior to when the problem occurred, and any error messages displayed on the system screen. Refer to Chapter 5 for error message descriptions
- Screen captures, Producer files, and/or reports exhibiting the problem

The Natus representative may ask for system Log Files or debugging information to gain more details. The Natus representative will guide you through this process.

9. Electromagnetic Compatibility (EMC)

This chapter provides EMC information for the Natus Keypoint G4 system.

Requirement	Description
Environment for use	The system is intended to be used in Hospitals and Private practice clinic except for near active HF surgical equipment and RF shielded room of system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
Essential performance	<p>The potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of a functioning the DIAGNOSTIC EQUIPMENT covered in this RMF are:</p> <ul style="list-style-type: none"> • Minimum noise on a waveform or artifacts or distortion in an image and any error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis • Free from the display of incorrect safety-related indications • Free from the production of excessive stimulation output level • Free from flames/ fire <p>Temporary disruption of the stimulators and waveform display has been assessed and determined to not adversely affect the patient. This type of degradation is not considered to affect essential performance or safety of the systems.</p> <ul style="list-style-type: none"> • In consideration of this, immunity to ESD and power interruptions while in operational mode, it is acceptable as it relates to the safety and essential performance of the systems that: <ul style="list-style-type: none"> a. Communication between the Base Unit, Amplifier and PC can be lost as long as a fail-safe mode is entered and the user can recover by re-powering the system and/or restarting the application software. b. In the case where communication is not disrupted, the waveforms may contain electrical artifacts which are distinguishable but must recover after test, with no mode or parameter changes. <p>It is not considered an unacceptable risk or affect on the ESSENTIAL PERFORMANCE if the DIAGNOSTIC EQUIPMENT covered in this RMF becomes completely non-functional, due to it's intended use.</p> <p>In case of temporary lost or degraded essential performance due to electromagnetic disturbances the system will be restored automatically or manual intervention is required to restart. This depends on degree of disturbance.</p>
Warnings, Cautions	Read all Warnings and Cautions prior to use of the Keypoint G4 system.
Note	NOTE: The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocation or re-orienting the equipment.

Maintaining

To maintain basic safety and essential performance with regard to electromagnetic disturbances for the expected service life follow guidance in system in this Instruction for Use in relation to:

- Attaching other equipment
- Maintenance
- List of accessories
- EMC related warnings and notes

The Keypoint G4 has been tested for EMC emissions and immunity as a standalone instrument. Do not use Keypoint G4 adjacent to or stacked with other electronic equipment (If adjacent, no closer than 30 cm to any part of the Keypoint Focus system). If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMC Acceptance Criteria

C1) Compliance for the CC-stimulator:

During immunity test Stimulation might be disturbed or switching to safe mode = 0mA and stopped pulsing. Before and after immunity test pulse max deviation should be 10%. During ESD test (CC mode) Stimulus Probe, LED goggles will be visually monitored and headphone will be audio monitored to ensure consistent functionality. The stimulators will continue to function throughout the immunity testing, except when fail safe condition occurs and the stimulation is stopped.

C2) Compliance for the EP Amplifier:

The amplifier curves can be disturbed during testing but must return to baseline after test completion. Before and after immunity test Amplifier curves disturbance should be max 5 μ Vpp. However, during Fast Transients and ESD, much higher disturbances are allowed and immunity level shall not be noted.

C3) Compliance for LEAKAGES currents after immunity test:

Maximum Patient Leakage current:

NC	0.01mAdc	0.1mA ac
SFC	0.1mAdc	0.5mA ac

Maximum Patient Leakage current, mains on patient:

5 mA

Maximum Patient auxiliary current:

NC	0.01mAdc	0.1mA ac
SFC	0.1mAdc	0.5mA ac

Maximum Earth leakage current:

NC	0.5 mA
SFC	1 mA

(NC = Normal Condition, SFC = Single Fault Condition)

C4) Compliance for the no damage:

Keypoint G4 power up test performs without errors.

C5) Compliance for the not losing stored patient data:

No change allowed. Check normal program start up before and after immunity tests.

Test proves safe storing of data.

C6) Compliance for the not burning:

No fire or smoke allowed. During all immunity tests observe that the system is not in fire or exposes smells from burned or overheated components.

C7) Compliance for intended operation:

Keypoint G4 shall remain safe and be restorable in case of cessation or interruption of any intended operation during immunity tests. Disturbance of display, reconnections of PC USB keyboard and USB mouse or loss of USB connection to Main Unit does not constitute noncompliance.

The Essential performance is verified after the tests.

Deviations from collateral standard

Acceptance criteria during immunity testing allowed per particular standard IEC 60601-2-40 (2nd. ed.) section 202.8.1.101 (A, B and C) are used.

Electromagnetic Emission

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Keypoint G4 uses RF energy only for its internal function. Therefore its RF emission is very low and is not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class A	Keypoint G4 is suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Enclosure Ports		
Phenomenon	Standard	Immunity test level
Electrostatic Discharges	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM Fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Proximity Fields from RF Wireless Communication Equipment	IEC 61000-4-3	See table “Enclosure Port to RF Wireless Communication Equipment” below
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m 50Hz or 60 Hz

Input A.C. Power Port		
Phenomenon	Standard	Immunity test level
Electrical Fast Transients / Bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Surge Line-to-line (Differential mode)	IEC 61000-4-5	±0.5 kV, ±1 kV
Surge Line-to-line (Common mode)	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted Disturbances Induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands (0.15 MHz to 80 MHz) 80% AM at 1 kHz
Voltage Dips	IEC 61000-4-11	100% dip; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip; 1 cycle And 30% dip; 25 cycles (50 Hz) Single phase 0°
Voltage Interruptions	IEC 61000-4-11	100% dip; 250 cycles (50 Hz) / 300 cycles (60 Hz)
Immunity to proximity magnetic fields	IEC 61000-4-39	30kHz:8A/m 134.2kHz:65A/m 13.56MHz:7.5A/m

Patient Coupling Port		
Phenomenon	Standard	Immunity test level
Electrostatic Discharges	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Conducted Disturbances Induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands (0.15 MHz to 80 MHz) 80% AM at 1 kHz


















Signal Input / Output Parts Port		
Phenomenon	Standard	Immunity test level
Electrostatic Discharges	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical Fast Transients / Bursts	IEC 61000-4-4	±1 kV 100 kHz repetition frequency
Surge Line-to-line (Common mode)	IEC 61000-4-5	±2 kV
Conducted Disturbances Induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands (0.15 MHz to 80 MHz) 80% AM at 1 kHz

Enclosure Port to RF Wireless Communication Equipment						
Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity level (V/m)
385	380 - 390	TETRA 400	Pulse 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM ±5 kHz 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse 18 Hz	2	0.3	28
870						
930						
1,720						
1,845	1,700 - 1,990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse 217 Hz	2	0.3	28
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse 217 Hz	2	0.3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse 217 Hz	0.2	0.3	9
5,500						
5,785						


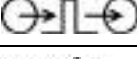


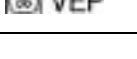
10. System Symbols













This chapter contains additional symbol descriptions which may appear on the Natus Keypoint system.

IEC 60417 Symbols

Symbol	Description
	Warnings associated with this device. A warning indicates that there is a risk of death or serious injury to the user or patient.
	Cautions associated with this device. A caution indicates that there is a risk of injury to the user or patient or risk of damage to the device.
	Standby
	Power On or Run
	Protective Earth (ground)
	Earth (ground)
	Input
	Output
	Frame or chassis
	Type BF equipment
	Attention, consult accompanying documents
	Stereophonic headphones
	Amplifier
	Electrostatic Sensitive
	USB Connector – Type B For computer interface.
	Consult instructions for use. Please read the instruction manual before using this device.
	Follow instructions for use.










Keypoint G4 System Symbols



























Symbol	Description
	Footswitch, Patient Response, Tendon Hammer Connector
	Trigger Input / Output Connector
	LED Goggles Transducer Connection
	Constant Current Stimulus
	Visual Transducer Connector








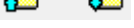


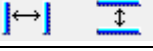




Symbol	Description
	Auditory Transducer Connection
	Dual USB Connectors – Type A
LINK	HS Link Output Connector
	Decrease Duration
	Increase Duration
	Start/Stop Stimulus (User definable)
	Speaker
	Speaker Mute
	Electrode Impedance check
	HS Link Output Connector Amplifier Connection
	3 and 4 Channel Amplifier: Active Electrode - Black The Active electrode corresponds to the black input connector.
	3 and 4 Channel Amplifier: Reference Electrode - Red The Reference electrode corresponds to the red input connector.
	4 Channel Amplifier: Run/Standby indicator

Natus Elite Software Symbols

NOTE: Hover the mouse over the software symbol to display the symbol's function. Click the symbol to enable the function.

Symbol	Description
	Edit Patient
	Edit Visit
	New Patient
	Patients
	Test Screen
	Report
	Help
	Visits
	Open Visit

Symbol	Description
	New Visit
	Visit Date Filter
	Acquire Visit / Acquire Test
	Search
	Refresh
	Hide Patient Names
	Save Settings
	Test History
	Add EMG Summary
	Add Report
	Order By
	Delete
	Reverse Side
	Study Menu
	Test Menu
	Level: Panel
	Single Sweep
	Repetitive Sweep
	Test Options Setup
	Right Trace Area On/Off
	Marker Bar On/Off
	Average
	Repeat Test
	Refilter
	Sum and Difference
	Notch Filter

Symbol	Description
	Display Replicates
	Match Sensitivity
	Smooth
	Reference Setup
	EMG Volume
	Capture Screen
	Capture Video
	Review: Previous and Next
	Print Screen
	Complex: 1 and 2
	Cursors: Vertical and Horizontal
	Trigger: Edge and Type
	EMG Display Options: Monitor, Cascade, Long Trace
	Motor Unit Stage
	EMG Filter

11. Technical Specifications

This chapter contains the technical specifications of the Natus Keypoint G4 system.

For technical specifications on the InVisus Ultrasound device, refer to 045650 Natus InVisus Pro Operation/Service Manual or 046370 Natus InVisus Reference Manual, available at natus.com

Keypoint G4 Specifications

Amplifiers	Input Impedance	Balanced: >200M Ω Common Mode: >1,000M Ω /25pF		
	Noise Level typical (RMS)	0.4 μ V (2Hz-10kHz) shorted Input		
	Isolation Mode Rejection	>160dB		
	Common Mode Rejection Ratio	>124dB (EMG Amplifier) >112dB (EP Headbox)		
	Connection Types	1.5mm Touch Proof / DIN socket		
	Calibration Signal	With supplied test cable		
	ADC Resolution	24 Bits		
	Sampling Rate	48kHz per amplifier		
	Points per Channel	Program dependent Up to 4800		
Averager	Types	Mean, Median, Exponential, Rectified, Weighted		
Acquisition	Filters	High Pass 0.2Hz - 5kHz (19 steps) Low Pass 30Hz – 20kHz (14 Steps)		
	Sweep Speed	Program dependent 0.1ms/d - 6s/d (27 steps)		
	Delay Line	\pm 99.9%		
	Sensitivity	10 nV/div – 100 mV/div (22 steps)		
	EMG LivePlay Recording	Max. 16 minutes per LivePlay recording		
Display	Resolution	1680 x 1050 - at least		
Stimulation	Repetition Rates	0.1 - 200Hz		
Size	Cart-based System	1136 x 610 x 630mm (W x D x H)		
Weight	Cart-based System	64kg		
Impedance Test	Test signal	Sine Wave, 220Hz		
	Current	\leq 0.1 μ A		
Electrical Stimulator	Max. Output	100mA Software controllable		
	Intensity Resolution	0.4/0.1mA		
	Stimulus Duration	50 μ s – 1ms		
	Safety Features	Power Limitation, Power Up Test Max. voltage: 400V \pm 10% Max. mean current: 2.5mA \pm 10%		
	Max. DC Component	Duration x Frequency x Current		
	Stimulus Polarity	Positive, negative and biphasic stimulation.		
	Stimulus Type	Single, Double, Dual Level, Train, Complex Train		
	Overload Safety	The output voltage is limited by the mean current as show on the table below.		
		Mean current [mA]	Output voltage U [Volt]	
			Min	Max
	0.1	360	440	
	1.0	320	400	
			Power [W]	
			Max	
			0.044	
			0.4	

	1.4	210	330	0.46
	1.8	160	240	0.43
	2.2	60	140	0.31
	2.6	0	80	0.26
	<p>NOTE As it can be seen from this table, the mean output power is always below 0.5 Watt. With a given output voltage U and a load resistance R the peak output current is limited to Max output current = U / R. The load resistance is the sum of the two electrode impedances.</p> <p>NOTE When stimulation is performed with set values that require a higher output voltage than available, the intensity field flashes in red.</p> <p>Example 1: Stimulation frequency 20Hz, pulse duration 1mSec, current setting 50mA: this gives a mean current $20 * 0.001 * 50\text{mA} = 1\text{mA}$. This cause an output voltage of maximum $U = 320\text{V}$. This means that output current may be limited for $R > 320\text{V}/50\text{mA} = 6.4\text{kOhm}$.</p> <p>Example 2: Stimulation frequency 5Hz, pulse duration 0.2mSec, current setting <100mA: this gives a mean current less than $5 * 0.0002 * 100\text{mA} = 0.1\text{mA}$. This cause an output voltage of maximum $U = 360\text{V}$. With a load resistance of <3.6kOhm the full 100mA can be delivered without limitation.</p>			
Auditory Stimulator	Stimulus Shape	Clicks, Tone, Burst, Pips, Half Sine, Full Sine		
	Presentation	Binaural, Ipsilateral, Contralateral		
	Click duration	50 – 100µs		
	Tone frequency	125 Hz to 20 kHz (30 steps)		
	Tone Envelope	Linear, Gaussian, Hanning, Blackman)		
	Pip Cycles	1-8000 cycles up to 1s duration (0.5 cycle steps) depending on frequency		
	Burst plateau	0- 2000 ms (0.02 ms steps) depending on frequency		
	Burst Rise/Fall	0-800 ms (0.02 ms steps) depending on frequency		
	Max. Intensity	Software dependent: 132dB peSPL and 139 dB pSPL(1.0dB Steps)		
	Masking Level	15 to 99dB peSPL or +10 to -50 dB pSPL relative to stimulus		
	Masking Type	White Noise, HP Noise, Notched Noise		
Visual Stimulator	Pattern Type	Checkerboard, horizontal bars, vertical bars		
	Pattern Field Screen Format	Full, Half, Quadrant		
	Stimulus Types	Onset/Offset, Reversal		
	Sizes	6x8, 12x16, 24x32, 48x64, 96x128		
	Target options	5 options		
	Goggles flash duration	1 ms		
	Stimulus rate	0.1 – 200 Hz		
Trigger In/Out	Trigger In duration	0.02 ms		
	Trigger In polarity	negative		
	Trigger Out duration	0.02 ms – 1 ms		
	Trigger Out polarity	negative		
	Trigger connection	Accessible via 9-pin D-SUB Trigger In/Out connector 1 - Synchro out 1 6 - Foot switch 1 2 - Synchro in 1 7 - +vcc 3 - Gnd 8 - Foot switch 2 4 - Foot switch 3 9 - Synchro out 2 5 - GND		
Temperature Probe Adaptor	Dimensions	(WxDxH): 100 mm x 62 mm x 26 mm		
Environmental Limits	Operating	Temperature: +10° to +40° Relative humidity: 20% to 80% (non-condensing) Altitude: -15m to 3,000m		

		Pressure: 700 hPa to 1060 hPa
	Storage/Transport	Temperature: -40° to +65°C Relative humidity: 10% to 100% (non-condensing) Altitude: -15m to 10,600m Pressure: 240 hPa to 1060 hPa
Isolating Transformer (9031D040X) (9031D041X) (Optional)	Rating Frequency	50/60Hz - Continuous Operation: max. 1000VA - Momentary Operation: max 1500VA 9031D040x: 100/120V~ 9031D041x: 200/240V~
	Fuse	F1 and F2 Mains 9031D040x: 110V/120V: T10AL / 250V~ 9031D041x: 200/240V: T6.3AL / 250V~ Highest branch circuit short circuit current is less than 1000A.
	Auxiliary Outlets	6 Outlets: 50/60Hz 9031D040x: 100-120V~ total max. - Continuous Operation 7.4A - Momentary Operation 12.4A 7.4A equals 850VA, and 12.4A equals 1425VA at 115V~ 9031D041x: 200-240V~ total max. - Continuous Operation: 3.7A - Momentary Operation: 6.2A 3.7A equals 850VA and 6.2A equals 1425VA at 230V~
	Weight and Dimensions	Weight: 10.9kg Dimension: 81x250x275mm (H x W x D)
	Operating	Temperature: +10°C to +35°C (+50°F to +95°F) Relative Humidity: 20% to 80% (non-condensing) Altitude: -15m to 3,000m Pressure: 700hPa to 1060 hPa