Dantec™ KEYPOINT® G4

Model/Type reference: Keypoint 9031A070

Technical Notes
Manual Addendum for Brazil

At the time of printing / transfer to the CD-ROM, this manual correctly described the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more addenda to the manual. This manual including any such addenda must be thoroughly read, before using the device.

The following situations void any guarantee(s) and obligations for Natus Manufacturing Limited:

- The device is not used according to the enclosed manuals and other accompanying documentation.
- The device is installed or modified by persons other than Natus Manufacturing Limited service technicians

This system is CE marked in conformity with the requirements in the Medical Device Directive 93/42/EEC.

Natus Manufacturing Limited is a division of Natus Medical Incorporated.

Table of Contents

TECHNICAL DATA **4**

SPECIFICATIONS 4
DATA SAMPLING 7
Amplitude resolution. *7*
Stored sampling frequency *7*
Displayed sampling frequency *7*

MANUFACTURER'S DECLARATION **8**

ESSENTIAL PERFORMANCE 8
Maintaining *8*
EMC ACCEPTANCE CRITERIA 9
Deviations from collateral standard *10*
ELECTROMAGNETIC EMISSION 11
ELECTROMAGNETIC IMMUNITY 12

Technical Data

Specifications

Amplifiers	Input Impedance	Balanced: >200MOhm Common Mode: >1,000MOhm/25pF
	Noise Level typical (RMS)	0.4µV (2Hz-10kHz) shorted Input
	Isolation Mode Rejection	>160dB
	Common Mode Rejection Ratio	>124dB (EMG Amplifier) >112dB (EP Headbox)
	Sensitivity	0.5µV/D – 20mV/D (15 Steps)
	Display Sensitivity	0.05µV/D – 20mV/D (18 Steps)
	Filters	High Pass 0.01Hz - 3kHz (16 steps) Low Pass 20Hz – 13kHz (12 Steps)
	Connection Types	1.5mm Touch Proof / DIN socket
	Calibration Signal	With supplied test cable
	ADC Resolution	24 Bits (See section Data Sampling)
	Sampling Rate	48kHz per amplifier (See section Data Sampling)
Averager	Max. Averager per Channel	Min. 10,000 Sweeps/Averager
	Points per Channel	Up to 4800
Acquisition	Sweep Speeds	Program dependent 0.1ms/d - 16s/d
	Delay Line	NC+EP: -2,000ms –> +500ms
	EMG Epoch Recording	Max. 15 minutes per Epoch
	Gain Accuracy	± 3%
	Time Accuracy	± 2µs x 0.5/Sample Frequency (See section Data Sampling)
Display	Resolution	1680 x 1050 - at least
Stimulation	Repetition Rates	0.1– 200Hz
Size & Weight	Weight (typical system)	64kg
	Dimensions (HxWxD)	1136 x 610 x 630mm
Impedance test	Test signal	Sine Wave, 220Hz
	Current	≤ 0.1µA

<table>
<tr><td rowspan="11">Electrical Stimulator</td><td>Max. Output</td><td colspan="3">100mA Software controllable</td></tr>
<tr><td>Intensity Resolution</td><td colspan="3">0.1/0.02mA</td></tr>
<tr><td>Stimulus Duration</td><td colspan="3">20µs – 1ms</td></tr>
<tr><td>Safety Features</td><td colspan="3">Power Limitation, Power Up Test
Max. voltage: 400V+/-10%
Max. mean current: 2.5mA+/-10%</td></tr>
<tr><td>Max. DC Component</td><td colspan="3">Duration x Frequency x Current</td></tr>
<tr><td>Stimulus Polarity</td><td colspan="3">Positive, negative and biphasic stimulation.</td></tr>
<tr><td>Overload Safety</td><td colspan="3">The output voltage is limited by the mean current as show on the table below.</td></tr>
<tr><td rowspan="2">Mean current [mA]</td><td colspan="2">Output voltage U [Volt]</td><td>Power [W]</td></tr>
<tr><td>Min</td><td>Max</td><td>Max</td></tr>
<tr><td>0.1</td><td>360</td><td>440</td><td>0.044</td></tr>
<tr><td>1.0</td><td>320</td><td>400</td><td>0.4</td></tr>
<tr><td>1.4</td><td>210</td><td>330</td><td>0.46</td></tr>
<tr><td>1.8</td><td>160</td><td>240</td><td>0.43</td></tr>
<tr><td>2.2</td><td>60</td><td>140</td><td>0.31</td></tr>
<tr><td>2.6</td><td>0</td><td>80</td><td>0.26</td></tr>
<tr><td colspan="4">NOTE As it can be seen from this table, the mean output power is always below 0.5Watt.

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.

⚠ WARNING When stimulation is performed with set values that require a higher output voltage than available, the intensity field flashes in red.</td></tr>
<tr><td colspan="4">Example 1: Stimulation frequency 20Hz, pulse duration 1mSec, current setting 50mA: this gives a mean current 20*0.001*50mA= 1mA. This cause an output voltage of maximum U = 320V. This means that output current may be limited for R > 320V/50mA = 6.4kOhm.</td></tr>
<tr><td colspan="4">Example 2: Stimulation frequency 5Hz, pulse duration 0.2mSec, current setting <100mA: this gives a mean current less than 5*0.0002*100mA = 0.1mA. This cause an output voltage of maximum U = 360V. With a load resistance of <3.6kOhm the full 100mA can be delivered without limitation.</td></tr>
</table>

Auditory Stimulator	Stimulus Shape	Clicks, Tone, Burst, Pips, Half Sine, Full Sine
	Click	50 – 100µs
	Max. Intensity	Software dependent: 132dB peSPL (1.0dB Steps)
	Masking Level	15 to 99dB peSPL
Visual Stimulator	Pattern Type	Checkerboard, horizontal bars, vertical bars
	Sizes	3x4, 6x8, 12x16, 24x32, 48x64, 96x128
Patient Safety	Isolation between mains and patient-applied parts	> 4kV − Complies with IEC/EN 60601-1, type BF specifications.
Environmental Limits	Operating	Temperature: +10° to +35° Relative humidity: 20% to 80% (non-condensing) Altitude: -15m to 3,000m Pressure: 701 hPa to 1060 hPa
	Storage	Temperature: -40° to +65°C Relative humidity 20% to 80% (non-condensing) Altitude: -15m to 10,600m Pressure: 241 hPa to 1060 hPa
Isolating Transformer (9031D040x) (9031D041x)	See separate Hardware Manual for the Isolating Transformer.	

Data Sampling

Amplitude resolution.

All input sampling is performed with a resolution of 24 bits. Digital filtering (High and low pass) and Notch filtering is performed with this resolution to avoid clipping.
Raw input curves are stored and handled as 16 bit values with full scale as given below:

Program group	Full scale
EMG, Q-EMG, Macro EMG, SF, and StimSF	Input sensitivity * 12 divisions
All other	Input sensitivity * 20 divisions

Example: With EP and input sensitivity = 100 µV/D the resolution is
Resolution = 20 D * 100 µV/D / 65536 = 0.03 µV

Averager curves: Averaging calculations are made with 64 bit floating point numbers. This cause averaging to be precise with any practical number of averagings.

Averager Autostop: Autostop can be set to any value between 0 and 100000.

Stored sampling frequency

All hardware sampling is performed at 48 kHz. Depending on the selected test type, the signal is down sampled to a relevant sampling frequency as described in the table below. This downsampling is performed using phase linear FIR digital filters to avoid aliasing.

Program group	Recording length	Sampling frequency
EMG and Macro EMG		24 kHz
SF and StimSF		48 kHz (Resolution for calculations better than 1 MHz)
EMG Monitor and MER		User specified up to 48 kHz.
All other	10-100 ms	48 kHz
	200 ms	24 kHz
	300 ms	12 kHz
	500 and 800 ms	6 kHz
	1 s	3 kHz
	2 s	2 kHz
	3 s	1 kHz
	5 and 8 s	0.5 kHz
	10 s	0.3 kHz

Averager number of points can be calculated as ***RecordingLength / Sampling frequency.***
Example with recording length = 200 ms, number of points = 200 ms * 24 kHz = 4800.

Displayed sampling frequency

As the number of pixels horizontally may be lower than the number of samples stored, an algorithm is used to assure that all peaks are shown correctly.
For the single fiber program curves are restored at a sampling frequency of 196 kHz to avoid jitter due to sampling.

Manufacturer's Declaration

Essential Performance

The potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of a functioning the DIAGNOSTIC EQUIPMENT covered in RMF are:

- 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

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.

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:

- 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.
- 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.

It is not considered an unacceptable risk or effect on the ESSENTIAL PERFORMANCE if the DIAGNOSTIC EQUIPMENT covered in this RMF becomes completely non-functional, due to its intended use.

Maintaining

To maintain basic safety and essential performance with regard to electromagnetic disturbances for the expected service life follow guidance in system Instruction for Use 9031M1506 in relation to:

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

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 5µVpp. However, during Fast Transients und 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 0.1mAac
SFC 0.1mAdc 0.5mA ac
Maximum Patient Leakage current, mains on patient:
5 mA
Maximum Patient auxiliary current:
NC 0.01mAdc 0.1mAac
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 Work Station 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 Work Station 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 IEC60601-2-40 (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 Comminication 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 / Burts	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)

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 / Burts	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						
Fre-quency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maxi-mum 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
710 745 780	704 - 787	LTE Band 13, 17	Pulse 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse 18 Hz	2	0.3	28
1,720 1,845 1,970	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
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 5,500 5,785	5,100 – 5,800	WLAN 802.11 a/n	Pulse 217 Hz	0.2	0.3	9

Please consult www.natus.com for your local Sales & Service office.

Natus Medical Incorporated
www.natus.com

Importado e distribuído por:
VR Medical Importadora e Distribuidora de Produtos Médicos Ltda
Rua Batataes nº 391, cj 11, 13 e 8º andar – Jd. Paulista
CEP: 01423-010
São Paulo

CNPJ: 04.718.143/0001-94

Responsável Técnica: Cristiane Aparecida de Oliveira Aguirre – CRF/SP 121079

Registro ANVISA nº:

Natus Manufacturing Limited
IDA Business Park
Gort, Co. Galway, Ireland

CE 0086

9031M1262 rev. C – September 2018